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Title 3—

The President

Proclamation 10551 of April 10, 2023

Black Maternal Health Week, 2023

By the President of the United States of America

A Proclamation

Black Maternal Health Week is a reminder that so many families experience pain, neglect, and loss during what should be one of the most joyous times of their lives. It is an urgent call for action. Black women in America are three times more likely to die from pregnancy-related complications than white women. This is on top of the fact that women in America are dying at a higher rate from pregnancy-related causes than in any other developed nation.

Tackling this crisis begins with understanding how institutional racism drives these high maternal mortality rates. Studies show that Black women are often dismissed or ignored in hospitals and other health care settings, even as they suffer from severe injuries and pregnancy complications and ask for help. Systemic inequities are also to blame. When mothers do not have access to safe and stable housing before and after childbirth, they are at greater risk of falling ill. When women face barriers traveling to the hospital for prenatal and postpartum checkups, they are less likely to remain healthy. Air pollution, water pollution, and lead pipes can have dangerous consequences for pregnant women and newborns. And when families cannot afford nutritious foods, they face worse health outcomes.

That is why my Administration wrote the Blueprint for Addressing the Maternal Health Crisis, which lays out specific actions that the Federal Government will take to improve maternal health, and secured funding from the Congress to help implement it. Vice President Kamala Harris has been a leader on the issue of maternal mortality for years and led the charge to improve maternal health outcomes, including by issuing a call to action to address disparities in maternal care. She continues to elevate the issue nationally, convening State legislators, medical professionals, and others so all mothers can access the care they need before, during, and after childbirth.

Additionally, my American Rescue Plan gave States the option to provide a full year of postpartum coverage to Medicaid beneficiaries—up from just 60 days of coverage. As a result, my Administration has approved requests from 30 States and Washington, D.C. to provide women with Medicaid coverage with a full year of postpartum coverage, and we have made this option permanent for every State that extends Medicaid postpartum coverage. My Administration has helped facilitate Medicaid expansion in four States since I took office, and I continue to call on the Congress to close the Medicaid coverage gap. We are also working to expand and diversify the maternal health workforce, helping health care providers hire and train diverse and culturally-competent physicians, certified nurse midwives, doulas, and community health workers to support women during pregnancy, delivery, and postpartum care. My American Rescue Plan included historic investments in our health workforce, and my Budget includes $471 million to reduce maternal mortality and morbidity rates—improving access to care in rural communities, expanding implicit bias training for health care providers, and further supporting the perinatal health workforce.

Because expecting mothers deserve to know where to find the best care, the Department of Health and Human Services created a new ''Birthing Friendly'' hospital designation, a public-facing recognition of the quality and safety of maternity care which will be publicly reported on the Care Compare website beginning this Fall. My Administration is committed to implementing the No Surprises Act, which helps ensure that women are protected from certain unexpected out-of-network medical bills that can come up during pregnancy, postpartum care, and delivery.

One in 5 women in America experience maternal mental health conditions like postpartum depression, anxiety, or substance use disorder, so we launched the Maternal Mental Health Hotline. By calling 1–833–9–HELP4MOMS—a confidential, 24-hour, toll-free number—new and expecting moms can now connect with professional counselors. We are also supporting and expanding maternal mental health screening programs, including for postpartum depression. My Administration is also partnering with community-based organizations to help pregnant people access addiction services and work with professionals trained in treating substance use disorder.

We are protecting the job security and workplace rights of pregnant and nursing mothers—including Black women, who are more likely to be fired, quit, or be forced to return to work after giving birth before it is healthy for them to do so. Over the past 2 years, I signed legislation to ensure employers make reasonable accommodations for pregnant workers and job applicants, expand the use of break time and access to private spaces for millions of nursing parents, and study the unique maternal health challenges facing veterans and help ensure they get the quality health care they deserve through the Department of Veterans Affairs.

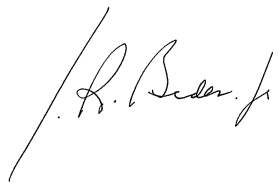
At the same time, my Administration is using the power of the Federal Government to address the long-standing disparities that Black communities continue to face—disparities that directly impact the health and well-being of Black mothers. During the height of the COVID–19 crisis, my Administration provided relief to hardworking families, cutting the rate of poverty for Black Americans by nearly a third.

We are also confronting racial discrimination in housing; expanding public transit to every neighborhood in the country; improving access to affordable and healthy food through our National Strategy on Hunger, Nutrition, and Health; and tackling dangerous environmental injustices that have hit communities of color the hardest.

This week, as we continue our work to make pregnancy and childbirth safe, dignified, and joyful for all, let us remember that health care should be a right and not a privilege. Let us give thanks to the extraordinary maternal health care workforce, which serves its patients and their families every day. And let us join in common cause to end the tragedy of maternal mortality once and for all.

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 April 11 through April 17, 2023, as Black Maternal Health Week. I call upon all Americans to raise awareness of the state of Black maternal health in the United States by understanding the consequences of institutional racism; recognizing the scope of this problem and the need for urgent solutions; amplifying the voices and experiences of Black women, families, and communities; and committing to building a world in which Black women do not have to fear for their safety, their well-being, their dignity, or their lives before, during, and after pregnancy.

IN WITNESS WHEREOF, I have hereunto set my hand this tenth day of April, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-seventh.



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Rules and Regulations

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1572; Project Identifier MCAI–2022–00350–T; Amendment 39–22388; AD 2023–06–02]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Bombardier, Inc., Model CL–600–1A11 (600), CL–600–2A12 (601), and CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes. This AD was prompted by a determination that, due to a lack of flightcrew awareness, smoke hoods with a certain part number installed throughout the airplane could be mistaken for protective breathing equipment (PBE). This AD requires an inspection or records review to determine if any smoke hood with a certain part number is installed in any location on the airplane and, depending on the results, removing the smoke hood and associated placards and installing new placards. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 18, 2023.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of May 18, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1572; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For service information identified in this final rule, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website: *bombardier.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2022–1572.

FOR FURTHER INFORMATION CONTACT: Chirayu Gupta, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Bombardier, Inc., Model CL–600–1A11 (600), CL–600–2A12 (601), and CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes. The NPRM published in the **Federal Register** on December 6, 2022 (87 FR 74535). The NPRM was prompted by AD CF–2022–10, dated March 10, 2022, (referred to after this as the MCAI) issued by Transport Canada, which is the aviation authority for Canada. The MCAI states that Bombardier, Inc., determined that, due to a lack of flightcrew awareness, smoke hoods with a certain part number installed throughout the airplane could be mistaken for PBE. The MCAI requires that operators verify if a smoke hood with a certain part number is installed in any location on the airplane and, depending on the results, removing the smoke hood and associated placards and installing new placards. The MCAI states that in a fire or smoke event the flightcrew might initially attempt to use the smoke hood believing it to be PBE, which could result in a delay in identifying the source of the smoke or fire.

In the NPRM, the FAA proposed to require an inspection or records review to determine if any smoke hood with a certain part number is installed in any location on the airplane and, depending on the results, removing the smoke hood and associated placards and installing new placards. The FAA is issuing this AD to address the unsafe condition on these products. You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–1572.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from one commenter, Boeing Executive Flight Operations. The following presents the comment received on the NPRM and the FAA's response to the comment.

Request To Update the Service Information to the Latest Revision

Boeing Executive Flight Operations requested that the FAA include Bombardier Service Bulletin 650–25–016, Revision 01, dated June 07, 2022, for Model CL–600–2B16 (604 Variants) Serial Number 6050 to 6099. The FAA infers that the commenter is requesting that the proposed AD be revised to refer to Bombardier Service Bulletin 650–25–016, Revision 01, dated June 07, 2022 (the proposed AD refers to Bombardier Service Bulletin 650–25–016, dated September 22, 2021, as the appropriate source of service information).

The FAA agrees to update this final rule to reference Bombardier Service Bulletin 650–25–016, Revision 01, dated June 07, 2022, which adds minor changes that do not affect the substantive requirements proposed in the NPRM. The FAA has revised paragraph (h)(5) of this AD to specify that required actions be done in accordance with Bombardier Service Bulletin 650–25–016, Revision 01, dated June 07, 2022; or Bombardier Service Bulletin 650–25–016, dated September 22, 2021.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed the following Bombardier, Inc. service information, which specifies procedures for verifying (via inspection or records review) if any smoke hood having part number MR–10008N is installed in the flight deck, forward wardrobe or any location on the airplane, removing any affected smoke hood and associated placards, and installing new placards. These documents are distinct since they apply to different airplane models and configurations.

- Bombardier Service Bulletin 600–0778, dated September 22, 2021.
- Bombardier Service Bulletin 601–1110, dated September 22, 2021.
- Bombardier Service Bulletin 604–25–004, dated September 22, 2021.
- Bombardier Service Bulletin 605–25–014, dated September 22, 2021.
- Bombardier Service Bulletin 650–25–016, dated September 22, 2021.
- Bombardier Service Bulletin 650–25–016, Revision 01, dated June 07, 2022.

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

Costs of Compliance

The FAA estimates that this AD affects 698 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hours × $85 per hour = $85	$0	$85	$59,330

The FAA estimates the following costs to do any necessary on-condition actions that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need these on-condition actions:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
1 work-hour × $85 per hour = $85	$9	$94

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2023–06–02 Inc: Amendment 39–22388; Docket No. FAA–2022–1572; Project Identifier MCAI–2022–00350–T.

(a) Effective Date

This airworthiness directive (AD) is effective May 18, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Bombardier, Inc., airplanes, certificated in any category, as identified in paragraphs (c)(1) through (3) of this AD.

(1) Model CL–600–1A11 (600) airplanes.
(2) Model CL–600–2A12 (601) airplanes.
(3) Model CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes.

(d) Subject

Air Transport Association (ATA) of America Code: 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by a determination that, due to a lack of flightcrew awareness, smoke hoods with a certain part number installed throughout the airplane could be mistaken for protective breathing equipment (PBE). The FAA is issuing this AD to address, in a fire or smoke event, that the flightcrew might initially attempt to use the smoke hood believing it to be PBE. The unsafe condition, if not addressed, could result in a delay in identifying the source of the smoke or fire.

(f) Compliance

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

(g) Inspection

Within 12 months after the effective date of this AD: Do an inspection to determine if any smoke hood having part number (P/N) MR–10008N is installed in the flight deck, forward wardrobe, or any other location in the airplane. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number of the smoke hood can be conclusively determined from that review.

(h) Corrective Action

If, during the inspection or records review required by paragraph (g) of this AD, any smoke hood having P/N MR–10008N is found on the airplane, within 12 months after the effective date of this AD, remove the smoke hood, including any associated placards, and install a new placard, in accordance with Section 2.B. of the Accomplishment Instructions of the applicable Bombardier service bulletin specified in paragraphs (h)(1) through (5) of this AD; or the method specified in paragraph (h)(6) of this AD; as applicable.

(1) For Model CL–600–1A11 (600) airplanes: Bombardier Service Bulletin 600–0778, dated September 22, 2021.

(2) For Model CL–600–2A12 (601) airplanes: Bombardier Service Bulletin 601–1110, dated September 22, 2021.

(3) For Model CL–600–2B16 airplanes (604 variant) with serial numbers 5301 through 5644 inclusive: Bombardier Service Bulletin 604–25–004, dated September 22, 2021.

(4) For Model CL–600–2B16 (604 variant) airplanes with serial numbers 5701 through 5988 inclusive: Bombardier Service Bulletin 605–25–014, dated September 22, 2021.

(5) For Model CL–600–2B16 airplanes (604 variant) with serial numbers 6050 through 6099 inclusive: Bombardier Service Bulletin 650–25–016, dated September 22, 2021; or Bombardier Service Bulletin 650–25–016, Revision 01, dated June 07, 2022.

(6) For Model CL–600–2B16 (601–3A and 601–3R Variants) airplanes: A method approved by the Manager, New York ACO Branch, FAA; or Transport Canada; or Bombardier, Inc.'s Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the New York ACO Branch, mail it to ATTN: Program Manager, Continuing Operational Safety, at the address identified in paragraph (j)(2) of this AD or email to: *9-avs-nyaco-cos@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada; or Bombardier, Inc.'s Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Additional Information

(1) Refer to Transport Canada AD CF–2022–10, dated March 10, 2022, for related information. This Transport Canada AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2022–1572.

(2) For more information about this AD, contact Chirayu Gupta, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) Bombardier Service Bulletin 600–0778, dated September 22, 2021.

(ii) Bombardier Service Bulletin 601–1110, dated September 22, 2021.

(iii) Bombardier Service Bulletin 604–25–004, dated September 22, 2021.

(iv) Bombardier Service Bulletin 605–25–014, dated September 22, 2021.

(v) Bombardier Service Bulletin 650–25–016, dated September 22, 2021.

(vi) Bombardier Service Bulletin 650–25–016, Revision 01, dated June 07, 2022.

(3) For service information identified in this AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com*; website: *bombardier.com.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

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

Issued on March 14, 2023.

Christina Underwood,

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

[FR Doc. 2023–07738 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–0019; Project Identifier MCAI–2022–01155–T; Amendment 39–22393; AD 2023–06–07]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus SAS Model A330–202, –203, –223, and –243 airplanes; Model A330–200 Freighter series airplanes; Model A330–300 series airplanes; Model A340–200 series airplanes; and Model A340–300 series airplanes. This AD was prompted by a report that damage was found to the firewall and fuselage skin in the auxiliary power unit (APU) compartment area on Model A330 airplanes. This AD requires replacing affected tee ducts with serviceable parts, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. This AD also prohibits the installation of affected parts. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 18, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 18, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–0019; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

• For material incorporated by reference in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*

• You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2023–0019.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3229; email *Vladimir.Ulyanov@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus SAS Model A330–202, A330–203, A330–223, A330–223F, A330–243, A330–243F, A330–301, A330–302, A330–303, A330–321, A330–322, A330–323, A330–341, A330–342, A330–343, A340–211, A340–212, A340–213, A340–311, A340–312, and A340–313 airplanes. The NPRM published in the **Federal Register** on January 20, 2023 (88 FR 3678). The NPRM was prompted by AD 2022–0175, dated August 23, 2022, issued by EASA, which is the Technical Agent for the Member States of the European Union (EASA AD 2022–0175) (also referred to as the MCAI). The MCAI states that damage was found to the firewall and fuselage skin in the APU compartment area on Model A330 airplanes. Subsequent investigation determined that cracks started because of high cycle fatigue in the tee duct, which led to a hot air leak. Due to the design similarity, this condition could also exist or develop on Model A340 airplanes. This condition, if not corrected, could lead to damage to the APU compartment firewall, possibly jeopardizing its capability to contain a fire.

In the NPRM, the FAA proposed to require replacing affected tee ducts with serviceable parts, as specified in EASA AD 2022–0175. The NPRM also proposed to prohibit the installation of affected parts. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–0019.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from Air Line Pilots Association, International (ALPA), who supported the NPRM without change.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comment received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0175 specifies procedures for replacement of affected tee ducts (Part Number (PN) 3884654–4 or PN 3884654–5) with serviceable parts (PN 3884654–6). EASA AD 2022–0175 also prohibits the installation of affected parts. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 123 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
4 work-hours × $85 per hour = $340	$35,931	$36,271	$4,461,333

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

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

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

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the

distribution of power and responsibilities among the various levels of government.

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2023–06–07 Airbus SAS: Amendment 39–22393; Docket No. FAA–2023–0019; Project Identifier MCAI–2022–01155–T.

(a) Effective Date

This airworthiness directive (AD) is effective May 18, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus SAS airplanes specified in paragraphs (c)(1) through (5) of this AD, certificated in any category.

(1) Model A330–202, –203, –223, and –243 airplanes.

(2) Model A330–223F and –243F airplanes.

(3) Model A330–301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes.

(4) Model A340–211, –212, and –213 airplanes.

(5) Model A340–311, –312, and –313 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 49, Airborne Auxiliary Power.

(e) Unsafe Condition

This AD was prompted by a report that damage was found to the firewall and fuselage skin in the auxiliary power unit (APU) compartment area on Model A330 airplanes. Subsequent investigation determined that cracks started because of high cycle fatigue in the tee duct, which led to a hot air leak. The FAA is issuing this AD to address cracks in the tee duct. This condition, if not corrected, could lead to a hot air leak from the tee duct and damage to the APU compartment firewall, possibly jeopardizing its capability to contain a fire.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022–0175, dated August 23, 2022 (EASA AD 2022–0175).

(h) Exceptions to EASA AD 2022–0175

(1) Where EASA AD 2022–0175 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2022–0175 does not apply to this AD.

(i) Additional AD Provisions

The following provisions also apply to this AD:

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

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

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

(j) Additional Information

For more information about this AD, contact Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3229; email *Vladimir.Ulyanov@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2022–0175, dated August 23, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0175, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

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

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

Issued on March 16, 2023.

Christina Underwood,

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

[FR Doc. 2023–07746 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0994; Project Identifier MCAI–2022–00052–T; Amendment 39–22395; AD 2023–06–09]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace LP (Type Certificate Previously Held by Israel Aircraft Industries, Ltd.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Gulfstream Aerospace LP Model Galaxy

airplanes and Model Gulfstream 200 airplanes. This AD was prompted by reports that wing flap fairing debonding and corrosion were discovered at certain areas of the lower skin on both wings. This AD requires an inspection for corrosion in certain areas of the wing skin fairings, additional inspections if necessary, resealing the fairings with new fillet seal, and applicable corrective actions, as specified in a Civil Aviation Authority of Israel (CAAI) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 18, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 18, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–0994; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For material incorporated by reference in this AD, contact CAAI, P.O. Box 1101, Golan Street, Airport City, 70100, Israel; telephone 972–3–9774665; fax 972–3–9774592; email *aip@mot.gov.il.* You may find this material on the CAAI website at *caa.gov.il.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2022–0994.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, FAA, 2200 South 216th Street, Des Moines, WA 98198; telephone 206–231–3225; email *dan.rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Gulfstream Aerospace LP Model Gulfstream G200 airplanes. The NPRM published in the **Federal Register** on August 17, 2022 (87 FR 50588). The NPRM was prompted by AD ISR I–57–2021–12–4, dated January 1, 2022 (CAAI AD ISR I–57–2021–12–4) (also referred to as the MCAI), issued by CAAI, which is the aviation authority for Israel. There were reports that wing flap fairing debonding and corrosion were discovered at the lower skin of rib 3 and rib 11 on both wings. The MCAI states that the reason for the AD is to prevent the possibility of flap fairing debonding, moisture intrusion and wing lower skin corrosion at rib 3 and rib 11.

In the NPRM, the FAA proposed to require an inspection for corrosion in certain areas of the wing skin fairings, additional inspections if necessary, resealing the fairings with new fillet seal, and applicable corrective actions, as specified in CAAI AD ISR I–57–2021–12–4.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–0994.

The FAA issued a supplemental notice of proposed rulemaking (SNPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Gulfstream Aerospace LP Model Galaxy airplanes and Model Gulfstream 200 airplanes. The SNPRM published in the **Federal Register** on December 13, 2022 (87 FR 76148). The SNPRM was prompted a determination that Model Galaxy airplanes must be added to the applicability. In the SNPRM, the FAA proposed to require an inspection for corrosion in certain areas of the wing skin fairings, additional inspections if necessary, resealing the fairings with new fillet seal, and applicable corrective actions. The FAA is issuing this AD to address flap fairing debonding and moisture intrusion that might lead to lower wing skin corrosion and cracking on both wings, and reduced structural integrity of the wings.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the SNPRM or on the determination of the cost to the public.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, this AD is adopted as proposed in the SNPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

CAAI AD ISR I–57–2021–12–4, dated January 1, 2022, describes procedures for an inspection for corrosion in the area of the wing skin (or doubler if installed) under the rib 3 and rib 11 fairings, a penetration or eddy current inspection for cracks if corrosion was found, a measurement of the thickness of remaining wing skin (or doubler) if no cracks were found, resealing of rib 3 and rib 11 fairings with new fillet seal, and applicable corrective actions. Corrective actions include cleaning and removing corrosion, crack repair, and repair of fairing installation locations with a certain thickness reduction.

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

Costs of Compliance

The FAA estimates that this AD affects 168 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
29 work-hours × $85 per hour = $2,465	Minimal	$2,465	$414,120

The FAA estimates the following costs to do any necessary on-condition action that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need these on-condition actions:

ESTIMATED COSTS OF ON-CONDITION ACTIONS [*]

Labor cost	Parts cost	Cost per product
Up to 10 work-hours × $85 per hour = $850	$0	Up to $850

* The FAA has received no definitive data on which to base the cost estimates for the on-condition repairs specified in this AD.

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2023–06–09 Gulfstream Aerospace LP (Type Certificate Previously Held by Israel Aircraft Industries, Ltd.): Amendment 39–22395; Docket No. FAA–2022–0994; Project Identifier MCAI–2022–00052–T.

(a) Effective Date

This airworthiness directive (AD) is effective May 18, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Gulfstream Aerospace LP Model Galaxy airplanes and Model Gulfstream 200 airplanes, certificated in any category, serial numbers 004 through 250 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

This AD was prompted by reports that wing flap fairing debonding and corrosion were discovered at the lower skin of rib 3 and rib 11 on both wings. The FAA is issuing this AD to address flap fairing debonding and moisture intrusion that might lead to lower wing skin corrosion and cracking on both wings, and reduced structural integrity of the wings.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Civil Aviation Authority of Israel (CAAI) AD ISR I–57–2021–12–4, dated January 1, 2022 (CAAI AD ISR I–57–2021–12–4).

(h) Exceptions to CAAI AD ISR I–57–2021–12–4

(1) Where CAAI AD ISR I–57–2021–12–4 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where the Compliance paragraph of CAAI AD ISR I–57–2021–12–4 requires compliance at a certain time, replace the text ''at the next suitable planned maintenance inspection within the next 24 months from the effective date of this AD'' with ''within 24 months after the effective date of this AD.''

(3) Where the Action paragraph of CAAI AD ISR I–57–2021–12–4 refers to certain service information, replace the text ''Gulfstream Service Bulletin No. 200–57–426, dated January 01, 2022, or later approved revision,'' with ''Gulfstream Service Bulletin No. 200–57–426, Revision 1, dated June 16, 2022, or later approved revision.''

(4) Where the service information specified in CAAI AD ISR I–57–2021–12–4 specifies to report to Gulfstream if ''cracks were discovered'' and ''for any fairing installation location with one or more grid squares with thickness reduction of greater than 10%,'' for this AD, cracks and fairing installation locations with one or more grid squares with thickness reduction of greater than 10% must be repaired before further flight using a method approved by the Manager, International Validation Branch, FAA; or CAAI; or CAAI's authorized Designee. If approved by the authorized Designee, the approval must include the Designee's authorized signature.

(i) No Reporting Requirement

Although the service information referenced in CAAI AD ISR I–57–2021–12–4 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Additional AD Provisions

The following provisions also apply to this AD:

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

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

(k) Additional Information

For more information about this AD, contact Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, FAA, 2200 South 216th Street, Des Moines, WA 98198; telephone 206–231–3225; email *dan.rodina@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) Civil Aviation Authority of Israel (CAAI) AD ISR I–57–2021–12–4, dated January 1, 2022.

(ii) [Reserved]

(3) For CAAI AD ISR I–57–2021–12–4, contact Civil Aviation Authority of Israel (CAAI), P.O. Box 1101, Golan Street, Airport City, 70100, Israel; telephone 972–3–9774665; fax 972–3–9774592; email *aip@mot.gov.il.* You may find this CAAI AD on the CAAI website at *caa.gov.il.*

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

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

Issued on March 17, 2023.

Christina Underwood,

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

[FR Doc. 2023–07739 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1654; Project Identifier MCAI–2022–01165–T; Amendment 39–22390; AD 2023–06–04]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Bombardier, Inc., Model CL–600–1A11 (600), CL–600–2A12 (601), and CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes. This AD was prompted by reports of some passenger oxygen mask dispensing units (MDUs) with lanyards that are too long to meet the proper length specifications of the airplane. This AD requires replacing the affected MDUs with units that meet the proper length specifications, replacing the placards, and re-identifying the assemblies. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 18, 2023.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of May 18, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1654; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For service information identified in this final rule, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2022–1654.

FOR FURTHER INFORMATION CONTACT: Elizabeth M. Dowling, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Bombardier, Inc., Model CL–600–1A11 (600), CL–600–2A12 (601), and CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes. The NPRM published in the **Federal Register** on December 27, 2022 (87 FR 79259). The NPRM was prompted by AD CF–2022–50, dated August 25, 2022, issued by Transport Canada, which is the aviation authority for Canada (referred to after this as the MCAI). The MCAI states that lanyards of passenger mask dispensing units installed in the affected airplanes are too long to meet the proper length specifications of the aircraft. This condition, if not corrected, could result in the inability to initiate the flow of oxygen to the mask when required in an emergency situation, with no indication to the passenger that they are not receiving oxygen.

In the NPRM, the FAA proposed to require replacing the affected MDUs with units that meet the proper length specifications, replacing the placards, and re-identifying the assemblies. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–1654.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA

reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed following Bombardier service information, which specifies procedures for identifying part numbers of the drop-down oxygen boxes, performing drop-down oxygen mask reach testing, marking failed seats as inoperative with placards, and replacing affected oxygen masks:

- Service Bulletin 600–0777, dated December 13, 2021.
- Service Bulletin 601–1109, Revision 01, dated May 6, 2022.
- Service Bulletin 604–35–007, Revision 01, dated May 6, 2022.

These documents are distinct since they apply to different airplane models. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 301 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85	$0	$85	$25,585

The FAA estimates the following costs to do any necessary on-condition actions that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need these on-condition actions:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
2 work-hours × $85 per hour = $170	$100	$270

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2023–06–04 Bombardier, Inc.: Amendment 39–22390; Docket No. FAA–2022–1654; Project Identifier MCAI–2022–01165–T.

(a) Effective Date

This airworthiness directive (AD) is effective May 18, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., airplanes, certificated in any category, with serial numbers as identified in the service information specified in paragraphs (c)(1) through (4) of this AD.

(1) Model CL–600–1A11 (600) airplanes: Bombardier Service Bulletin 600–0777, dated December 13, 2021.

(2) Model CL–600–2A12 (601) airplanes: Bombardier Service Bulletin 601–1109, Revision 01, dated May 6, 2022.

(3) Model CL–600–2B16 (601–3A, 601–3R) airplanes: Bombardier Service Bulletin 601–1109, Revision 01, dated May 6, 2022.

(4) Model CL–600–2B16 (604) airplanes: Bombardier Service Bulletin 604–35–007, Revision 01, dated May 6, 2022.

(d) Subject

Air Transport Association (ATA) of America Code 35, Oxygen System.

(e) Unsafe Condition

This AD was prompted by reports of passenger oxygen mask dispensing units installed in the affected airplanes with lanyards that are too long to meet the proper length specifications of the airplane. The FAA is issuing this AD to address the inability to initiate flow of oxygen to the mask. The unsafe condition, if not addressed, could result in no indication to the passenger that they are not receiving oxygen in an emergency situation.

(f) Compliance

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

(g) Inspection and Replacement

Within 5 years after the effective date of this AD, determine the part number of the drop-down oxygen box, in accordance with Section 2.B. of the Accomplishment Instructions of the applicable service information identified in paragraphs (c)(1) through (4) of this AD.

(1) If any drop-down oxygen box part number (P/N) installed on the airplane matches any P/N listed in Table 1 of Section 2.B. of the applicable service information: Before further flight, perform drop-down oxygen mask reach testing in accordance with Section 2.B.(2) of the Accomplishment Instructions of the applicable service information identified in paragraphs (c)(1) through (4) of this AD.

(i) If the test result is PASS: Before further flight, replace the drop-down oxygen box assembly in accordance with Section 2.C., and test the passenger oxygen supply system in accordance with Section 2.D.(2), of the applicable service information identified in paragraphs (c)(1) through (4) of this AD.

(ii) If the test result is FAIL for any individual seat: Before further flight, mark the failed seat as inoperative in accordance with Section 2.B.(3) of the applicable service information specified in paragraphs (c)(1) through (4) of this AD.

(2) If the part number of any drop-down oxygen box assembly installed on the airplane is not found in Table 1 of Section 2.B. of the applicable service information identified in paragraphs (c)(1) through (4) of this AD: Before further flight, do actions to correct the unsafe condition using a method approved in accordance with the procedures specified in paragraph (i)(1) of this AD.

(h) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Bombardier Service Bulletin 601–1109, dated December 13, 2021; or Bombardier Service Bulletin 604–35–007, dated December 13, 2021; as applicable.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the New York ACO Branch, mail it to ATTN: Program Manager, Continuing Operational Safety, at the address identified in paragraph (j)(2) of this AD or email to: *9-avs-nyaco-cos@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada; or Bombardier, Inc.'s Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Additional Information

(1) Refer to Transport Canada AD CF–2022–50, dated August 25, 2022, for related information. This Transport Canada AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2022–1654.

(2) For more information about this AD, contact Elizabeth M. Dowling, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (k)(3) and (4) of this AD.

(k) Material Incorporated by Reference

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

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

(i) Bombardier Service Bulletin 600–0777, dated December 13, 2021.

(ii) Bombardier Service Bulletin 601–1109, Revision 01, dated May 6, 2022.

(iii) Bombardier Service Bulletin 604–35–007, Revision 01, dated May 6, 2022.

(3) For service information identified in this AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*

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

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

Issued on March 14, 2023.

Christina Underwood,

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

[FR Doc. 2023–07741 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1482; Project Identifier MCAI–2022–00697–T; Amendment 39–22389; AD 2023–06–03]

RIN 2120–AA64

Airworthiness Directives; De Havilland Aircraft of Canada Limited (Type Certificate Previously Held by Bombardier, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain De Havilland Aircraft of Canada Limited Model DHC–8–401 and –402 airplanes. This AD was prompted by an investigation of incorrectly manufactured sleeves that were potentially installed in the main landing gear (MLG) forward door linkage assembly. This AD requires review of technical records and inspections to determine if a discrepant sleeve is installed, replacement of any discrepant sleeve and re-identification of the MLG forward door linkage assembly. This AD also prohibits the installation of affected parts. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 18, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 18, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at under Docket No. FAA–2022–1482; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket

Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For service information identified in this final rule, contact De Havilland Aircraft of Canada Limited, Dash 8 Series Customer Response Centre, 5800 Explorer Drive, Mississauga, Ontario, L4W 5K9, Canada; telephone North America (toll-free): 855–310–1013, Direct: 647–277–5820; email *thd@dehavilland.com;* website *dehavilland.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2022–1482.

FOR FURTHER INFORMATION CONTACT: Gabriel Kim, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain De Havilland Aircraft of Canada Limited Model DHC–8–401 and –402 airplanes. The NPRM published in the **Federal Register** on November 25, 2022 (87 FR 72424). The NPRM was prompted by AD CF–2022–29, dated May 27, 2022, issued by Transport Canada, which is the aviation authority for Canada (referred to after this as the MCAI). The MCAI states that some forward door linkage sleeves, part number (P/N) 46878–1, have been manufactured without lubrication grooves on the outer diameter. An investigation confirmed that incorrectly manufactured sleeves were potentially supplied from October 2019 to July 2021. A discrepant sleeve with missing lubrication grooves can result in the fatigue failure of the forward door linkage, leading to possible interference with the extension or retraction of the corresponding MLG. This condition, if not corrected and when combined with other failures, could result in an asymmetric MLG configuration at landing and a subsequent runway excursion.

In the NPRM, the FAA proposed to require review of technical records and inspections to determine if a discrepant sleeve is installed, replacement of any discrepant sleeve and re-identification of the MLG forward door linkage assembly. The FAA also proposed to prohibit the installation of affected parts. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–1482.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from The Air Line Pilots Association, International (ALPA), who supported the NPRM without change.

The FAA received an additional comment from Horizon Air. The following presents the comment received on the NPRM and the FAA's response to the comment.

Request To Refer to Latest Revision of Service Bulletin and Allow Credit for Required Actions Using Previous Service Bulletin

Horizon Air stated De Havilland Aircraft of Canada Limited Service Bulletin 84–32–169, Revision A, dated July 21, 2022, has been released. Horizon Air asked the FAA to revise the proposed AD to refer to De Havilland Aircraft of Canada Limited Service Bulletin 84–32–169, Revision A, dated July 21, 2022. Horizon Air also asked the FAA to allow credit for required actions done in accordance with De Havilland Aircraft of Canada Limited Service Bulletin 84–32–169, dated February 28, 2022, prior to the effective date of the AD.

The FAA agrees to use the updated service information. De Havilland Aircraft of Canada Limited Service Bulletin 84–32–169, Revision A, dated July 21, 2022, including Collins Aerospace Service Bulletin 46860–32–150, Revision 1, dated June 28, 2022, does not substantively affect the requirements proposed in the NPRM and only makes minor changes by adding references to an advisory document and the MCAI AD. The FAA has revised this final rule to refer to De Havilland Aircraft of Canada Limited Service Bulletin 84–32–169, Revision A, dated July 21, 2022, including Collins Aerospace Service Bulletin 46860–32–150, Revision 1, dated June 28, 2022. The FAA has also added paragraph (i) to this AD to provide credit for actions done in accordance with De Havilland Aircraft of Canada Limited Service Bulletin 84–32–169, dated February 28, 2022, including Collins Aerospace Service Bulletin 46860–32–150, dated February 1, 2022, prior to the effective date of this AD.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed De Havilland Aircraft of Canada Limited Service Bulletin 84–32–169, Revision A, dated July 21, 2022, including Collins Aerospace Service Bulletin 46860–32–150, Revision 1, dated June 28, 2022. This service information specifies procedures for review of the airplane records to determine the date of replacement, if any, of sleeve P/N 46878–1, a visual inspection of affected sleeves for the presence of lubrication grooves, and a visual inspection of the swivel link, clevis assembly, and swivel end assembly for discrepancies including signs of damage, deformation, erosion, and corrosion. Corrective actions include replacement of any sleeve that has missing lubrication grooves; repair or replacement of any discrepant swivel link, clevis assembly, and swivel end assembly; and re-identification of the forward door linkage. Assemble the forward door linkage, torque self-locking nuts, and re-install the forward door linkage assemblies.

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

Costs of Compliance

The FAA estimates that this AD affects 56 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
3 work-hours × $85 per hour = $255	$0	$255	$14,280

The FAA estimates the following costs to do any necessary on-condition actions that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need these on-condition actions:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
3 work-hours × $85 per hour = $255 to replace the sleeve	$1,284	$1,539

The FAA has received no definitive data on which to base the cost estimates for the on-condition repairs specified in this AD.

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2023–06–03 De Havilland Aircraft of Canada Limited (Type Certificate Previously Held by Bombardier, Inc.): Amendment 39–22389; Docket No. FAA–2022–1482; Project Identifier MCAI–2022–00697–T.

(a) Effective Date

This airworthiness directive (AD) is effective May 18, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to De Havilland Aircraft of Canada Limited (type certificate previously held by Bombardier, Inc.) Model DHC–8–401 and –402 airplanes, certificated in any category, serial numbers 4001, 4003 and subsequent.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing Gear.

(e) Unsafe Condition

This AD was prompted by an investigation of incorrectly manufactured sleeves that were potentially installed in the main landing gear (MLG) forward door linkages. The FAA is issuing this AD to address the discrepant sleeves with missing lubrication grooves, which can result in the fatigue failure of the forward door linkage, leading to possible interference with the extension or retraction of the corresponding MLG. The unsafe condition, if not corrected and when combined with other failures, could result in an asymmetric MLG configuration at landing and a subsequent runway excursion.

(f) Compliance

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

(g) Airplane Records Review

Within 30 days after the effective date of this AD, review the airplane records to determine whether any sleeve P/N 46878–1 was replaced after October 29, 2019, on any MLG forward door linkage assembly P/N 46860.

(1) For any sleeve P/N 46878–1 that was replaced after October 29, 2019, and for any sleeve for which its replacement date cannot be conclusively determined from the records: Within 1,500 flight cycles after the effective date of this AD, do the actions specified in paragraphs (g)(1)(i) and (ii) of this AD, in accordance with Section 3.B. of the Accomplishment Instructions of De Havilland Aircraft of Canada Limited Service Bulletin 84–32–169, Revision A, dated July 21, 2022, including Collins Aerospace Service Bulletin 46860–32–150, Revision 1, dated June 28, 2022.

(i) Do a general visual inspection of the sleeve for the presence of lubrication grooves, and before further flight replace any sleeve that does not have lubrication grooves.

(ii) Do a general visual inspection of the MLG forward door linkage assemblies (swivel

link, clevis assembly, and swivel end assembly) for damage, deformation, erosion, and corrosion, and before further flight repair or replace the discrepant parts.

(2) If the records confirm that no maintenance was performed on the MLG forward door linkage assembly P/N 46860 after October 29, 2019, no further action is required by this paragraph.

(h) Parts Installation Prohibition

As of the effective date of this AD, no person may install, on any airplane, a sleeve P/N 46878–1 with missing lubrication grooves.

(i) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD, using the service information identified in De Havilland Aircraft of Canada Limited Service Bulletin 84–32–169, dated February 28, 2022, including Collins Aerospace Service Bulletin 46860–32–150, dated February 1, 2022.

(j) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov* or send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada; or De Havilland Aircraft of Canada Limited's Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(k) Additional Information

(1) Refer to Transport Canada AD CF–2022–29, dated May 27, 2022, for related information. This Transport Canada AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2022–1482.

(2) For more information about this AD contact Gabriel Kim, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov*.

(l) Material Incorporated by Reference

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

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

(i) De Havilland Aircraft of Canada Limited Service Bulletin 84–32–169, Revision A, dated July 21, 2022, including Collins Aerospace Service Bulletin 46860–32–150, Revision 1, dated June 28, 2022.

Note 1 to paragraph (l)(2)(i): De Havilland issued De Havilland Service Bulletin 84–32–169, Revision A, dated July 21, 2022, with Collins Aerospace Service Bulletin 46860–32–150, Revision 1, dated June 28, 2022, attached as one ''merged'' file for the convenience of affected operators.

(ii) Reserved

(3) For service information identified in this AD, contact De Havilland Aircraft of Canada Limited, Dash 8 Series Customer Response Centre, 5800 Explorer Drive, Mississauga, Ontario, L4W 5K9, Canada; telephone North America (toll-free): 855–310–1013, Direct: 647–277–5820; email *thd@dehavilland.com;* website *dehavilland.com*.

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

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

Issued on March 14, 2023.

Christina Underwood,

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

[FR Doc. 2023–07737 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–0023; Project Identifier MCAI–2022–01030–T; Amendment 39–22398; AD 2023–06–12]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2021–08–08, which applied to all Airbus SAS Model A350–941 and –1041 airplanes. AD 2021–08–08 required replacing affected bleed duct assemblies and bleed gimbals at the wing-to-pylon interface, and prohibited the installation of affected parts. This AD was prompted by a report of a welding quality issue in the gimbal joint of the air bleed duct at each wing-to-pylon interface and the consequent deformation of the gimbal inner ring, and by new findings that affected bleed gimbals were found on certain airplanes that did not have any maintenance record of affected part replacement. This AD continues to require the actions in AD 2021–08–08 and, for certain airplanes, requires inspection of the bleed gimbals to determine the part number, and replacement if necessary, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 18, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 18, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–0023; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For material incorporated by reference in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2023–0023.

FOR FURTHER INFORMATION CONTACT: Dat Le, Aerospace Engineer, Large Aircraft Section, FAA, International Validation

Branch, 2200 South 216th Street, Des Moines, WA 98198; telephone 516–228–7317; email *dat.v.le@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2021–08–08, Amendment 39–21502 (86 FR 20453, April 20, 2021) (AD 2021–08–08). AD 2021–08–08 applied to all Airbus SAS Model A350–941 and –1041 airplanes. AD 2021–08–08 required replacing affected bleed duct assemblies and bleed gimbals at the wing-to-pylon interface with serviceable parts, and prohibited the installation of affected parts. The FAA issued AD 2021–08–08 to address a welding quality issue in the gimbal joint of the air bleed duct located at each wing-to-pylon interface; the inner ring of a gimbal had deformed to an oval shape, which could cause cracking by direct contact between metal parts, and could lead to hot bleed air leakage in the pylon area, and possibly result in loss of the pneumatic system and exposure of the wing structure to high temperatures, and lead to reduced structural integrity of the airplane.

The NPRM published in the **Federal Register** on January 24, 2023 (88 FR 4114). The NPRM was prompted by AD 2022–0156, dated August 2, 2022, issued by EASA, which is the Technical Agent for the Member States of the European Union (EASA AD 2022–0156) (also referred to as the MCAI). The MCAI states that a welding quality issue has been identified in the gimbal joint of the air bleed duct located at each wing-to-pylon interface; the inner ring of a gimbal had deformed to an oval shape, which could lead to cracking caused by direct contact between metal parts. The MCAI adds that affected bleed gimbals were found on certain airplanes that did not have any maintenance record of affected part replacement. The unsafe condition, if not addressed, could result in hot bleed air leakage in the pylon area, and possibly result in loss of the pneumatic system and exposure of the wing structure to high temperatures, and lead to reduced structural integrity of the airplane. You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–0023.

In the NPRM, the FAA proposed to continue to require the actions in AD 2021–08–08 and, for certain airplanes, requires inspection of the bleed gimbals to determine the part number and replacement if necessary, as specified in the EASA AD. The FAA is issuing this AD to address the unsafe condition on these products.

Discussion of Final Airworthiness Directive

Comments

The FAA received one comment from Air Line Pilots Association, International (ALPA), who supported the NPRM without change.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0156 specifies procedures, for certain airplanes, for replacing affected bleed duct assemblies and bleed gimbals at the wing-to-pylon interface with serviceable parts, and, for certain other airplanes, inspecting each bleed gimbal at the wing-to-pylon interface to determine if it is an affected part and replacing affected parts. EASA AD 2022–0156 also prohibits the installation of an affected part on any airplane.

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

Costs of Compliance

The FAA estimates that this AD affects 31 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions (Group 1 airplanes in the MCAI).	Up to 25 work-hours × $85 per hour = $2,125.	Up to $48,800	Up to $50,925	* $0
New actions (Group 2 airplanes in the MCAI)	2 work-hours × $85 per hour = $170	$0	$170	5,270

* The retained replacement from AD 2021–08–08 applies to Group 1 airplanes specified in the MCAI. There are no affected U.S. registered airplanes in Group 1.

The FAA estimates the following costs to do any necessary on-condition action that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
Up to 25 work-hours × $85 per hour = $2,125	Up to $48,800	Up to $50,925.

According to the manufacturer, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected

individuals. As a result, the FAA has included all known costs in the cost estimate.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2021–08–08, Amendment 39–21502 (86 FR 20453, April 20, 2021); and

■ b. Adding the following new Airworthiness Directive:

2023–06–12 Airbus SAS: Amendment 39–22398; Docket No. FAA–2023–0023; Project Identifier MCAI–2022–01030–T.

(a) Effective Date

This airworthiness directive (AD) is effective May 18, 2023.

(b) Affected ADs

This AD replaces AD 2021–08–08, Amendment 39–21502 (86 FR 20453, April 20, 2021) (AD 2021–08–08).

(c) Applicability

This AD applies to all Airbus SAS Model A350–941 and –1041 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code: 36, Pneumatic.

(e) Unsafe Condition

This AD was prompted by a report that a welding quality issue has been identified in the gimbal joint of the air bleed duct located at each wing-to-pylon interface; the inner ring of a gimbal had deformed to an oval shape, which could lead to cracking caused by direct contact between metal parts, and by new findings that affected bleed gimbals were found on certain airplanes that did not have any maintenance record of affected part replacement. The unsafe condition, if not addressed, could result in hot bleed air leakage in the pylon area, and possibly result in loss of the pneumatic system and exposure of the wing structure to high temperatures, and lead to reduced structural integrity of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022–0156, dated August 2, 2022 (EASA AD 2022–0156).

(h) Exceptions to EASA AD 2022–0156

(1) Where EASA AD 2022–0156 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph (6) of EASA AD 2022–0156 refers to August 26, 2020 (the effective date of EASA AD 2020–0169R1), this AD requires using May 25, 2021 (the effective date of AD 2021–08–08).

(3) Where the definition of ''Groups'' in EASA AD 2022–0156 specifies Group 1 airplanes are those manufacturer serial numbers (MSN) listed in certain service information, replace the text ''Airbus Service Bulletin (SB) A350–36–P021 and SB A350–36–P022'' with ''Airbus Service Bulletin A350–36–P021, dated January 17, 2020; and Airbus Service Bulletin A350–36–P022, dated January 17, 2020.''

(4) Where the definition of ''Groups'' in EASA AD 2022–0156 specifies Group 2 airplanes are those MSN listed in certain service information, replace the text ''Airbus SB A350–36–P029'' with ''Airbus Service Bulletin A350–36–P029, Revision 01, dated February 3, 2022.''

(5) This AD does not adopt the Remarks paragraph of EASA AD 2022–0156.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2022–0156 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Additional FAA AD Provisions

The following provisions also apply to this AD:

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

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

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

(k) Additional Information

For more information about this AD, contact Dat Le, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th Street, Des Moines, WA 98198; telephone 516–228–7317; email *dat.v.le@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2022–0156, dated August 2, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0156, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

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

Issued on March 21, 2023.

Christina Underwood,

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

[FR Doc. 2023–07740 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–0012; Project Identifier MCAI–2022–01317–T; Amendment 39–22387; AD 2023–06–01]

RIN 2120–AA64

Airworthiness Directives; ATR—GIE Avions de Transport Régional Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain ATR—GIE Avions de Transport Régional Model ATR42–500 and ATR72–212A airplanes. This AD was prompted by in-service experience that has shown that the lateral flight guidance of the flight director/auto pilot may not limit HI BANK turns in severe icing conditions. This AD requires the replacement of the affected new avionics suite (NAS), as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. This AD also prohibits the installation of the affected NAS on any airplane. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 18, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 18, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–0012; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For EASA material incorporated by reference in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2023–0012.

FOR FURTHER INFORMATION CONTACT: Shahram Daneshmandi, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3220; email *Shahram.Daneshmandi@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain ATR—GIE Avions de Transport Régional Model ATR42–500 and 72–212A airplanes. The NPRM published in the **Federal Register** on January 13, 2023 (88 FR 2295). The NPRM was prompted by AD 2022–0206, dated October 7, 2022, issued by EASA, which is the Technical Agent for the Member States of the European Union (EASA AD 2022–0206) (also referred to as the MCAI). The MCAI states that in-service experience has shown that the lateral flight guidance of the flight director/auto pilot may not limit HI BANK turns in severe icing conditions. The airplane is only protected during LO BANK turns. This condition, if not addressed, could result in loss of control of the airplane.

In the NPRM, the FAA proposed to require the replacement of the affected NAS, as specified in EASA AD 2022–0206. The NPRM also proposed to prohibit the installation of the affected NAS on any airplane. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–0012.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from the Air Line Pilots Association, International (ALPA) who supported the NPRM without change.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comment received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0206 specifies procedures for replacement of the affected NAS with NAS standard 2.2 or 3.1, or later-approved NAS standard. EASA AD 2022–0206 also prohibits the installation of the affected NAS on any airplane. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Costs of Compliance

The FAA estimates that this AD affects 20 airplanes of U.S. registry. The

FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85	*$0	$85	$1,700

*The FAA has received no definitive data on which to base the cost estimates for the parts specified in this AD.

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2023–06–01 ATR—GIE Avions de Transport Régional: Amendment 39–22387; Docket No. FAA–2023–0012; Project Identifier MCAI–2022–01317–T.

(a) Effective Date

This airworthiness directive (AD) is effective May 18, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to ATR—GIE Avions de Transport Régional Model ATR42–500 and ATR72–212A airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2022–0206, dated October 7, 2022 (EASA AD 2022–0206).

(d) Subject

Air Transport Association (ATA) of America Code 31, Instruments.

(e) Unsafe Condition

This AD was prompted by in-service experience that has shown that the lateral flight guidance of the flight director/auto pilot may not limit HI BANK turns in severe icing conditions. The FAA is issuing this AD to address the lateral flight guidance not limiting HI BANK turns in severe icing conditions. The unsafe condition, if not addressed, could result in loss of control of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2022–0206.

(h) Exceptions to EASA AD 2022–0206

(1) Where EASA AD 2022–0206 refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the ''Remarks'' section of EASA AD 2022–0206.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2022–0206 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Additional AD Provisions

The following provisions also apply to this AD:

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

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

(k) Additional Information

For more information about this AD, contact Shahram Daneshmandi, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3220; email *Shahram.Daneshmandi@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2022–0206, dated October 7, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0206, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

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

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

Issued on March 14, 2023.

Christina Underwood,

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

[FR Doc. 2023–07745 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1581; Project Identifier MCAI–2022–00803–T; Amendment 39–22394; AD 2023–06–08]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2019–18–07, which applied to certain Airbus SAS Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2019–18–07 required repetitive rototest inspections of the open tack holes and rivet holes at the cargo floor support fittings of the fuselage, including doing all applicable related investigative actions and repair if necessary. AD 2019–18–07 also adds actions (modification) for certain airplanes. Since the FAA issued AD 2019–18–07, it was determined that certain airplanes need to do additional work. This AD continues to require the actions in AD 2019–18–07 and requires additional work for certain airplanes, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 18, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 18, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1581; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For material incorporated by reference in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2022–1581.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3228; email *Todd.Thompson@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2019–18–07, Amendment 39–19734 (84 FR 50721, September 26, 2019) (AD 2019–18–07). AD 2019–18–07 applied to certain Airbus SAS Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2019–18–07 required repetitive rototest inspections of the open tack holes and rivet holes at the cargo floor support fittings of the fuselage, including all applicable related investigative actions, and repair if necessary. AD 2019–18–07 also added actions (modification) for certain airplanes. The FAA issued AD 2019–18–07 to address cracking in the open tack holes and rivet holes at the cargo floor support fittings of the fuselage. This condition, if not addressed, could affect the structural integrity of the airplane.

The NPRM published in the **Federal Register** on December 13, 2022 (87 FR 76155). The NPRM was prompted by AD 2022–0115, dated June 20, 2022 (EASA AD 2022–0115), issued by EASA, which is the Technical Agent for the Member States of the European Union (referred to after this as the MCAI). The MCAI states that new technical considerations identified the need to introduce additional work for certain airplanes previously modified as specified in AD 2019–18–07. The MCAI also states that cracking in the open tack holes and rivet holes at the cargo floor support fittings of the fuselage, if not addressed, could affect the structural integrity of the airplane.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–1581.

In the NPRM, the FAA proposed to continue to require the actions in AD 2019–18–07 and also proposed to require additional work for certain airplanes, as specified in EASA AD 2022–0115. The FAA is issuing this AD to address the unsafe condition on these products.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from The Air Line Pilots Association, International (ALPA), who supported the NPRM without change.

The FAA received additional comments from Delta Air Lines (DAL), United Airlines (UAL), and JetBlue Airlines (JBU). The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Allow Previous Alternative Methods of Compliance (AMOCs)

To address previously issued AMOCs that are also applicable to the proposed AD, DAL, UAL, and JBU requested that

the proposed AD be revised to allow AMOCs approved for FAA AD 2019–18–07 as acceptable AMOCs for the corresponding provisions of paragraph (g) of this AD. Otherwise, the operators would need to re-request previously approved AMOCs. DAL also requested that the proposed AD be revised to allow AMOCs approved for AD 2015–17–14, Amendment 39–18247 (80 FR 52182, August 28, 2015) (AD 2015–17–14) be approved as AMOCs for the corresponding provisions of this AD. DAL noted that AD 2019–18–07 allowed using AMOCs previously approved for AD 2015–17–14 for the corresponding provisions required by AD 2019–18–07.

The FAA agrees with the requested change by DAL, UAL, and JBU. The AMOCs for AD 2019–18–07 and AD 2015–17–14 are also approved as AMOCs for the corresponding provisions of EASA AD 2022–0115, dated June 20, 2022. The FAA has added paragraphs (i)(1)(i) through (iii) of this AD to include this information.

The FAA has received no definitive data that would enable the agency to provide cost estimates for the on-condition actions specified in this AD.

Authority for This Rulemaking

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

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

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0115 specifies procedures for repetitive inspections of the open tack holes and rivet holes of the fuselage frames below the cargo floor support fittings for cracking, including doing all applicable related investigative actions (inspections of the related frame layer (vertical web/horizontal flange) for cracking) and repair. EASA AD 2022–0115 also specifies procedures for modification of the fuselage (including replacing the shear webs and certain frame clips, adding additional support angles, and cold expanding one tack hole and one tooling home in each frame). EASA AD 2022–0115 also specifies procedures for additional work for certain Model A321 airplanes previously modified as specified in AD 2019–18–07. The additional work includes replacing affected fasteners on frames 62 and 63 after doing a rototest for cracking, cold working the fastener holes, and repair.

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

Costs of Compliance

The FAA estimates that this AD affects 1,267 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2019-18-07 ..	Up to 474 work-hours × $85 per hour = Up to $40,290.	$13,000	Up to $53,290	Up to $67,518,430.
New actions	28 work-hours × $85 per hour = $2,380	$50	$2,430	$2,430 per product.

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2019–18–07, Amendment 39–19734 (84 FR 50721, September 26, 2019); and

■ b. Adding the following new airworthiness directive:

2023–06–08 Airbus SAS: Amendment 39–22394; Docket No. FAA–2022–1581; Project Identifier MCAI–2022–00803–T.

(a) Effective Date

This airworthiness directive (AD) is effective May 18, 2023.

(b) Affected ADs

This AD replaces AD 2019–18–07, Amendment 39–19734 (84 FR 50721, September 26, 2019) (AD 2019–18–07).

(c) Applicability

This AD applies to Airbus SAS Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes; certificated in any category, as identified in European Aviation Safety Agency (EASA) AD 2022–0115, dated June 20, 2022 (EASA AD 2022–0115).

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by widespread fatigue damage (WFD) evaluations and full-scale fatigue testing that revealed several broken frames in certain areas of the cargo compartment, and by the determination that additional work is needed for certain airplanes. The FAA is issuing this AD to address cracking in the open tack holes and rivet holes at the cargo floor support fittings of the fuselage. The unsafe condition, if not addressed, could affect the structural integrity of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2022–0115.

(h) Exceptions to EASA AD 2022–0115

(1) Where EASA AD 2022–0115 refers to January 3, 2014 (the effective date of EASA AD 2013–0310), this AD requires using October 2, 2015 (the effective date of AD 2015–17–14, Amendment 39–18247 (80 FR 52182, August 28, 2015) (AD 2015–17–14)).

(2) Where EASA AD 2022–0115 refers to November 9, 2018 (the effective date of EASA AD 2018–0233 at original issue), this AD requires using October 31, 2019 (the effective date of AD 2019–18–07).

(3) Where EASA AD 2022–0115 refers to its effective date, this AD requires using the effective date of this AD.

(4) Where paragraph (2) of EASA AD 2022–0115 specifies ''contact Airbus for approved repair instructions and, within the compliance time identified therein, accomplish those instructions accordingly'' if a crack is detected, for this AD if any cracking is detected, the cracking must be repaired before further flight using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(5) The ''Remarks'' section of EASA AD 2022–0115 does not apply to this AD.

(i) Additional FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD.

(i) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(ii) AMOCs approved previously for AD 2019–18–07 are approved as AMOCs for the corresponding provisions of EASA AD 2022–0115 that are required by paragraph (g) of this AD.

(iii) AMOCs approved previously for AD 2015–17–14 are approved as AMOCs for the corresponding provisions of EASA AD 2022–0115 that are required by paragraph (g) of this AD.

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

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

(j) Additional Information

For more information about this AD, contact Todd Thompson, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3228; email *Todd.Thompson@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2022–0115, dated June 20, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0115, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

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

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

Issued on March 17, 2023.

Christina Underwood,

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

[FR Doc. 2023–07752 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–0013; Project Identifier MCAI–2022–01085–T; Amendment 39–22384; AD 2023–05–15]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2017–09–03 and AD 2018–20–07, which applied to all Dassault Aviation Model MYSTERE–FALCON 50 airplanes. AD 2017–09–03 and AD 2018–20–07 required revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. This AD continues to require the actions in AD 2018–20–07 and requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 18, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 18, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of November 7, 2018 (83 FR 49789, October 3, 2018).

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–0013; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For the EASA AD incorporated by reference in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- For Dassault Falcon 50/50EX service information incorporated by reference in this AD, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; website *dassaultfalcon.com.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2023–0013.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3226; email *tom.rodriguez@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2017–09–03, Amendment 39–18865 (82 FR 21467, May 9, 2017) (AD 2017–09–03) and AD 2018–20–07, Amendment 39–19441 (83 FR 49789, October 3, 2018) (AD 2018–20–07). AD 2017–09–03 and AD 2018–20–07 applied to all Dassault Aviation Model MYSTERE–FALCON 50 airplanes. AD 2017–09–03 and AD 2018–20–07 required revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA issued AD 2017–09–03 and AD 2018–20–07 to address reduced structural integrity of the airplane.

AD 2018–20–07 specifies that accomplishing the revision required by that AD terminates all requirements of AD 2017–09–03. AD 2018–20–07 also specifies that it terminates the requirements of AD 2010–26–05, Amendment 39–16544 (75 FR 79952, December 21, 2010) (AD 2010–26–05) and AD 2012–02–18, Amendment 39–16941 (77 FR 12175, February 29, 2012) (AD 2012–02–18) for certain Dassault Aviation Model MYSTERE–FALCON 50 airplanes. AD 2012–02–18 has since been removed (84 FR 11640, March 28, 2019). This AD therefore supersedes AD 2017–09–03 and terminates the requirements of AD 2010–26–05 for Dassault Aviation Model MYSTERE–FALCON 50 airplanes only.

The NPRM published in the **Federal Register** on January 13, 2023 (88 FR 2292). The NPRM was prompted by AD 2022–0166, dated August 11, 2022, issued by EASA, which is the Technical Agent for the Member States of the European Union (EASA AD 2022–0166) (also referred to as the MCAI). The MCAI states that new or more restrictive airworthiness limitations have been developed.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–0013.

In the NPRM, the FAA proposed to continue to require the actions in AD 2018–20–07 and to require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in EASA AD 2022–0166. The FAA is issuing this AD to address reduced structural integrity of the airplane.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed EASA AD 2022–0166. This service information specifies new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This AD also requires Chapter 5–40, Airworthiness Limitations, DGT 113872, Revision 24, dated July 2017, of the Dassault Falcon 50/50EX Maintenance Manual, which the Director of the Federal Register approved for incorporation by reference as of November 7, 2018 (83 FR 49789, October 3, 2018).

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

Costs of Compliance

The FAA estimates that this AD affects 239 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

The FAA estimates the total cost per operator for the retained actions from AD 2018–20–07 to be $7,650 (90 work-hours × $85 per work-hour).

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

The FAA estimates the total cost per operator for the new actions to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of

the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2017–09–03, Amendment 39–18865 (82 FR 21467, May 9, 2017) and AD 2018–20–07, Amendment 39–19441 (83 FR 49789, October 3, 2018); and

■ b. Adding the following new airworthiness directive:

2023–05–15 Dassault Aviation: Amendment 39–22384; Docket No. FAA–2023–0013; Project Identifier MCAI–2022–01085–T.

(a) Effective Date

This airworthiness directive (AD) is effective May 18, 2023.

(b) Affected ADs

(1) This AD replaces AD 2017–09–03, Amendment 39–18865 (82 FR 21467, May 9, 2017) (AD 2017–09–03) and AD 2018–20–07, Amendment 39–19441 (83 FR 49789, October 3, 2018) (AD 2018–20–07).

(2) This AD affects AD 2010–26–05, Amendment 39–16544 (75 FR 79952, December 21, 2010) (AD 2010–26–05);

(c) Applicability

This AD applies to all Dassault Aviation Model MYSTERE-FALCON 50 airplanes, certificated in any category.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address reduced structural integrity of the airplane.

(f) Compliance

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

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

This paragraph restates the requirements of paragraph (g) of AD 2018–20–07, with no changes. Within 90 days after November 7, 2018 (the effective date of AD 2018–20–07), revise the maintenance or inspection program, as applicable, to incorporate the information specified in Chapter 5–40, Airworthiness Limitations, DGT 113872, Revision 24, dated July 2017, of the Dassault Falcon 50/50EX Maintenance Manual. The initial compliance times for doing the tasks are at the time specified in Chapter 5–40, Airworthiness Limitations, DGT 113872, Revision 24, dated July 2017, of the Dassault Falcon 50/50EX Maintenance Manual, or within 90 days after November 7, 2018, whichever occurs later. Accomplishing the revision of the existing maintenance or inspection program required by paragraph (i) of this AD terminates the requirements of this paragraph.

(h) Retained Restrictions on Alternative Actions and Intervals With No Changes

This paragraph restates the requirements of paragraph (h) of AD 2018–20–07, with no changes. After the maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (m)(1) of this AD.

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

Except as specified in paragraph (j) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022–0166, dated August 11, 2022 (EASA AD 2022–0166). Accomplishing the maintenance or inspection program revision specified in EASA AD 2022–0166 as required by this paragraph terminates the requirements of paragraph (g) of this AD.

(j) Exceptions to EASA AD 2022–0166

(1) The requirements specified in paragraphs (1) and (2) of EASA AD 2022–0166 do not apply to this AD.

(2) Paragraph (3) of EASA AD 2022–0166 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2022–0166 is at the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2022–0166, or within 90 days after the effective date of this AD, whichever occurs later.

(4) The provisions specified in paragraphs (4) and (5) of EASA AD 2022–0166 do not apply to this AD.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2022–0166.

(k) New Provisions for Alternative Actions and Intervals

After the maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2022–0166.

(l) Terminating Actions for AD 2010–26–05

Accomplishing the actions required by paragraph (g) or (i) of this AD terminates the requirements of AD 2010–26–05 for Dassault Aviation Model MYSTERE–FALCON 50 airplanes only.

(m) Additional AD Provisions

The following provisions also apply to this AD:

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

your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(n) Additional Information

For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–231–3226; email *tom.rodriguez@faa.gov.*

(o) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on May 18, 2023.

(i) European Union Aviation Safety Agency (EASA) AD 2022–0166, dated August 11, 2022.

(ii) [Reserved]

(4) The following service information was approved for IBR on November 7, 2018 (83 FR 49789, October 3, 2018).

(i) Chapter 5–40, Airworthiness Limitations, DGT 113872, Revision 24, dated July 2017, of the Dassault Falcon 50/50EX Maintenance Manual.

(ii) [Reserved]

(5) For EASA AD 2022–0166, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(6) For Dassault Falcon 50/50EX service information, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; website *dassaultfalcon.com.*

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

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

Issued on March 9, 2023.

Christina Underwood,

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

[FR Doc. 2023–07751 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31478; Amdt. No. 4053]

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

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

DATES: This rule is effective April 13, 2023. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of April 13, 2023.

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

For Examination

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

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

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

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

Availability

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

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., STB Annex, Bldg 26, Room 217, Oklahoma City, OK 73099. Telephone (405) 954–1139.

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

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

Availability and Summary of Material Incorporated by Reference

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

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

The Rule

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

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

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

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

Lists of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on March 17, 2023.

Thomas J. Nichols,

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

Adoption of the Amendment

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

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

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

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

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

Effective 20 April 2023

Danbury, CT, KDXR, RNAV (GPS) RWY 26, Orig
Washington, DC, KDCA, RNAV (GPS) RWY 33, Amdt 1B, CANCELED
Washington, DC, KDCA, RNAV (GPS) RWY 33, Orig
St Petersburg, FL, KSPG, RNAV (GPS) RWY 7, Amdt 4
St Petersburg, FL, KSPG, RNAV (GPS) RWY 18, Amdt 1
St Petersburg, FL, KSPG, RNAV (GPS) RWY 36, Amdt 2
St Petersburg, FL, KSPG, Takeoff Minimums and Obstacle DP, Amdt 4
St Petersburg, FL, KSPG, VOR RWY 18, Amdt 10
Lihue, HI, PHLI, VOR OR TACAN RWY 21, Amdt 5
Ames, IA, KAMW, ILS OR LOC RWY 1, Amdt 4
Keokuk, IA, KEOK, ILS OR LOC RWY 26, Amdt 1
Keokuk, IA, KEOK, NDB RWY 14, Amdt 12B, CANCELED
Keokuk, IA, KEOK, RNAV (GPS) RWY 26, Amdt 1
South Bend, IN, KSBN, ILS OR LOC RWY 9R, Amdt 10C
South Bend, IN, KSBN, RNAV (GPS) RWY 9L, Amdt 1C
New Bedford, MA, KEWB, Takeoff Minimums and Obstacle DP, Amdt 8A
Festus, MO, KFES, RNAV (GPS)-A, Orig-A, CANCELED
Festus, MO, KFES, Takeoff Minimums and Obstacle DP, Amdt 4, CANCELED
Ardmore, OK, KADM, RNAV (GPS) RWY 31, Amdt 1F

[FR Doc. 2023–07634 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31479; Amdt. No. 4054]

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

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

DATES: This rule is effective April 13, 2023. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of April 13, 2023.

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

For Examination

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

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

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

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

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

Availability

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

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., STB Annex, Bldg 26, Room 217, Oklahoma City, OK 73099. Telephone: (405) 954–1139.

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

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section. The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for Part 97 of this final rule.

The Rule

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

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

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

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

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

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on March 17, 2023.

Thomas J. Nichols,

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

Adoption of the Amendment

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

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

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

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

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

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

** * * Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC Date	Subject
20–Apr–23	TX	Snyder	Winston Fld	2/8516	2/28/23	NDB RWY 35, Amdt 2C.
20–Apr–23	TX	Snyder	Winston Fld	2/8552	2/28/23	RNAV (GPS) RWY 35, Amdt 1B.
20–Apr–23	ME	Sanford	Sanford Seacoast Rgnl	3/0074	2/28/23	VOR RWY 25, Amdt 14D.
20–Apr–23	PA	State College	University Park	3/1756	3/2/23	RNAV (GPS) RWY 6, Amdt 2B.
20–Apr–23	PA	State College	University Park	3/2440	3/3/23	RNAV (GPS) RWY 24, Amdt 1B.
20–Apr–23	AL	Eufaula	Weedon Fld	3/3434	3/7/23	RNAV (GPS) RWY 18, Amdt 1C.
20–Apr–23	AL	Eufaula	Weedon Fld	3/3435	3/7/23	RNAV (GPS) RWY 36, Amdt 1C.

AIRAC date	State	City	Airport	FDC No.	FDC Date	Subject
20–Apr–23	MA	New Bedford	New Bedford Rgnl	3/5769	3/3/23	ILS OR LOC RWY 5, Amdt 26A.
20–Apr–23	MA	New Bedford	New Bedford Rgnl	3/5770	3/3/23	LOC BC RWY 23, Amdt 13.
20–Apr–23	MA	New Bedford	New Bedford Rgnl	3/5771	3/3/23	RNAV (GPS) RWY 23, Amdt 1.
20–Apr–23	MA	New Bedford	New Bedford Rgnl	3/5772	3/3/23	RNAV (GPS) RWY 5, Amdt 1C.
20–Apr–23	MA	New Bedford	New Bedford Rgnl	3/5773	3/3/23	RNAV (GPS) RWY 14, Orig-D.
20–Apr–23	WI	Chetek	Chetek Muni/Southworth	3/7769	2/22/23	Takeoff Minimums and Obstacle DP, Orig-A.
20–Apr–23	MI	Saginaw	Saginaw County/H W Browne.	3/7825	2/22/23	RNAV (GPS) RWY 10, Amdt 1A.
20–Apr–23	PA	State College	University Park	3/9474	2/27/23	ILS OR LOC RWY 24, Amdt 9D.

[FR Doc. 2023–07633 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2023–0180]

Safety Zone; Fireworks Display; Chesapeake Bay, Norfolk, VA

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

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for the Shore Thing Independence Day Celebration on June 30, 2023, in Virginia Beach, VA, to protect against hazards associated with a fireworks display and provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Fifth Coast Guard District identifies the regulated area for this event in Norfolk, VA. During the enforcement period, entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Virginia.

DATES: The regulations in 33 CFR 165.506 will be enforced for the location identified as Item 3 in table 3 to paragraph (h)(3) from 9:30 p.m. until 9:45 p.m. on June 30, 2023.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LCDR Ashley Holm, Chief, Waterways Management Division, Sector Virginia, U.S. Coast Guard; telephone 757–668–5580 email *Ashley.E.Holm@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone in 33 CFR 165.506 for Shore Thing Independence Day Celebration regulated area from 9:30 p.m. to 9:45 p.m. on June 30, 2023. This action is being taken to provide for the safety of life on navigable waterways during this event, which will feature live fireworks. Our regulation for marine events within the Fifth Coast Guard District, § 165.506, specifies the location of the regulated area for the Shore Thing Independence Day Celebration, which encompasses portions of the Chesapeake Bay located near Ocean View Fishing Pier. During the enforcement period, neither persons nor vessels may enter, remain in, or transit through the safety zone unless specifically authorized by the Captain of the Port Virginia.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts.

Dated: March 16, 2023.

Jennifer A. Stockwell,

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

[FR Doc. 2023–07749 Filed 4–12–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 160 and 164

Notice of Expiration of Certain Notifications of Enforcement Discretion Issued in Response to the COVID–19 Nationwide Public Health Emergency

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, HHS.

ACTION: Expiration of Notifications of Enforcement Discretion and transition period for telehealth.

SUMMARY: This document is to inform the public that four Notifications of Enforcement Discretion (''Notifications'') issued by the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR) regarding how the Privacy, Security, and Breach Notification Rules (''HIPAA Rules'') promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act will be applied to certain violations during the COVID–19 nationwide public health emergency (''COVID–19 PHE''), will expire upon expiration of the COVID–19 PHE, which is currently scheduled for 11:59 p.m. on May 11, 2023. Accordingly, upon expiration of the COVID–19 PHE, the Notifications will not provide a basis for OCR to exercise enforcement discretion with respect to imposing penalties for violations of the HIPAA Rules. OCR will continue to exercise enforcement discretion consistent with the Notifications for violations of the HIPAA Rules that occurred during the period that each Notification was in effect. In addition, OCR is affording covered health care providers a 90-calendar day transition period to come into compliance with the HIPAA Rules with respect to their provision of telehealth using non-public facing remote communication technologies.

DATES: The Notifications of Enforcement Discretion addressed in this document expire at 11:59 p.m. on May 11, 2023. The 90-calendar day transition period with respect to telehealth will expire at 11:59 p.m. on August 9, 2023.

FOR FURTHER INFORMATION CONTACT: Marissa Gordon-Nguyen at (202) 619–0403 or (800) 537–7697 (TDD).

SUPPLEMENTARY INFORMATION: In 2020 and 2021, OCR issued four Notifications of Enforcement Discretion (''Notifications'') regarding how the Privacy, Security, Breach Notification, and Enforcement Rules (''HIPAA Rules'') promulgated under the Health Insurance Portability and Accountability Act of 1996 [1] (HIPAA)

[1] Subtitle F of title II of HIPAA (Pub. L. 104–191, 100 Stat. 2548 (August 21, 1996)) added a new part C to title XI of the Social Security Act, Public Law 74–271, 49 Stat. 620 (August 14, 1935), (see sections 1171–1179 of the Social Security Act (codified at 42 U.S.C. 1320d–1320d–8)). Due to the public

and the HITECH Act [2] would be applied to certain violations during the COVID–19 PHE. OCR is informing the public that these Notifications, which were published in the **Federal Register** on April 7, 2020, April 21, 2020, May 18, 2020, and February 24, 2021, expire upon expiration of the COVID–19 PHE, which is currently scheduled for 11:59 p.m. on May 11, 2023. Accordingly, at that time, the Notifications will no longer provide a basis for the exercise of enforcement discretion in how OCR imposes penalties for violations of requirements under the HIPAA Rules. OCR will continue to exercise enforcement discretion consistent with the Notifications for violations of the HIPAA Rules that occurred during the period that each Notification was in effect. With respect to the Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID–19 PHE issued on April 21, 2020, with an effective beginning date of March 17, 2020, covered health care providers will be afforded a 90-calendar day transition period until 11:59 p.m. on August 9, 2023, to come into compliance with the HIPAA Rules in their provision of telehealth. During the transition period, OCR will continue to exercise its enforcement discretion and will not impose penalties on covered health care providers for noncompliance with the HIPAA Rules in connection with the good faith provision of telehealth.

I. Background

OCR is responsible for enforcing certain regulations issued under HIPAA and the HITECH Act to protect the privacy and security of protected health information (PHI), collectively known as the HIPAA Rules.

During the COVID–19 nationwide public health emergency that the HHS Secretary declared under section 319 of the Public Health Service Act,[3] OCR announced that it would exercise enforcement discretion to not impose penalties for violations of certain regulatory requirements under the HIPAA Rules by covered entities [4] and their business associates [5] (collectively, ''regulated entities''), to the extent specified in each of the four Notifications published in the **Federal Register** on April 7, 2020, April 21, 2020, May 18, 2020, and February 24, 2021. OCR's enforcement discretion applied to specific obligations under the HIPAA Rules and permitted regulated entities, as applicable, the flexibility to respond effectively to the public health emergency.

The Notifications stated that they would remain in effect until the Secretary of HHS declared that the COVID–19 PHE no longer existed or upon the expiration date of the declared COVID–19 PHE, including any extensions,[6] whichever occurred first. The HHS Secretary has announced that he does not plan to renew the COVID–19 PHE when it expires at 11:59 p.m. on May 11, 2023.[7] Thus, assuming the PHE ends on that date, the Notifications will no longer be in effect as of May 12, 2023.[8]

II. Notifications of Enforcement Discretion Effective and Ending Dates; Transition Period for Telehealth

The effective and ending dates of each Notification are provided below. OCR will continue to exercise enforcement discretion consistent with the Notifications for violations of the HIPAA Rules that occurred during the period that each Notification was in effect.

(1) *Enforcement Discretion Under HIPAA To Allow Uses and Disclosures of Protected Health Information by Business Associates for Public Health and Health Oversight Activities in Response to COVID–19.*[9] In this Notification, OCR announced that it would exercise its enforcement discretion to not impose penalties for violations of certain provisions of the HIPAA Privacy Rule by covered health care providers or their business associates for uses and disclosures of PHI by business associates for public health and health oversight activities. Specifically, the enforcement discretion covered Privacy Rule provisions 45 CFR 164.502(a)(3), 45 CFR 164.502(e)(2), 45 CFR 164.504(e)(1) and (5) if certain parameters were met.

This Notification has been in effect since April 7, 2020, and expires at 11:59 p.m. on May 11, 2023.

(2) *Enforcement Discretion Regarding COVID–19 Community-Based Testing Sites (CBTS) During the COVID–19 Nationwide Public Health Emergency.*[10] In this Notification, OCR announced that it would exercise its enforcement discretion to not impose penalties for noncompliance with the HIPAA Rules by covered health care providers, including some large pharmacy chains, and their business associates, in connection with the good faith participation in the operation of COVID–19 specimen collection and testing sites (''Community-Based Testing Sites'' or CBTS). For purposes of this Notification, a CBTS includes mobile, drive-through, or walk-up sites that only provide COVID–19 specimen collection or testing services to the public.

This Notification has been in effect since March 13, 2020, and expires at 11:59 p.m. on May 11, 2023.

(3) *Enforcement Discretion Regarding Online or Web-Based Scheduling Applications for the Scheduling of Individual Appointments for COVID–19 Vaccination During the COVID–19 Nationwide Public Health Emergency.*[11] In this Notification, OCR announced that it would exercise its enforcement discretion to not impose penalties for noncompliance with the HIPAA Rules by covered health care providers, including some large pharmacy chains and public health authorities,[12] or their business associates, in connection with the good faith use of online or web-

health emergency posed by COVID–19, the HHS Office for Civil Rights (OCR) exercised its enforcement discretion under the conditions outlined in the four Notifications of Enforcement Discretion. OCR believes that this guidance is a statement of agency policy not subject to the notice and comment requirements of the Administrative Procedure Act (APA). 5 U.S.C. 553(b)(3)(A). OCR additionally finds that, even if this guidance were subject to the public participation provisions of the APA, prior notice and comment for this guidance is impracticable, and there is good cause to issue this guidance without prior public comment and without a delayed effective date. 5 U.S.C. 553(b)(3)(B) and (d)(3).

[2] The HITECH Act was enacted as title XIII of division A and title IV of division B of the American Recovery and Reinvestment Act of 2009, Public Law 111–5, 123 Stat. 226 (February 17, 2009).

[3] *See* Renewal of Determination That a Public Health Emergency Exists by the HHS Secretary (February 9, 2023), *https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx.*

[4] *See* 45 CFR 160.103 (definition of ''Covered entity'').

[5] *See* 45 CFR 160.103 (definition of ''Business associate'').

[6] As determined by 42 U.S.C. 247d.

[7] See HHS, Fact Sheet: COVID–19 Public Health Emergency Transition Roadmap (Feb. 9, 2023), *https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html.*

[8] The public health emergency determination is currently expected to end at 11:59 p.m. on May 11, 2023. *See* Renewal of Determination That a Public Health Emergency Exists by the HHS Secretary, *supra* note 4.

[9] 85 FR 19392 (April 7, 2020).

[10] 85 FR 29637 (May 18, 2020).

[11] 86 FR 11139 (February 24, 2021).

[12] *See* 45 CFR 164.501 (definition of ''Public health authority''). The HIPAA Rules apply to a public health authority only if it is a HIPAA regulated entity. For example, a county health department that administers a health plan, or provides health care services for which it conducts standard electronic transactions (*e.g.,* checking eligibility for coverage, billing insurance), is a HIPAA covered entity. A public health authority that does not meet the definition of a regulated entity is not subject to the HIPAA Rules. *See also* HHS HIPAA FAQ # 358, ''Are state, county or local health departments required to comply with the HIPAA Privacy Rule?'' *https://www.hhs.gov/hipaa/for-professionals/faq/358/are-state-county-or-local-health-departments-required-to-comply-with-hipaa/index.html.*

based scheduling applications (collectively, WBSAs) for the limited purpose of scheduling individual appointments for COVID–19 vaccinations. For purposes of this Notification, a WBSA is a non-public facing online or web-based application that provides scheduling of individual appointments for services in connection with large-scale COVID–19 vaccination.

This Notification has been in effect since December 11, 2020, and expires at 11:59 p.m. on May 11, 2023.

(4) *Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID–19 Nationwide Public Health Emergency (''Telehealth Notification'').*[13] In this Notification, OCR announced that it would exercise its enforcement discretion and would not impose HIPAA penalties for noncompliance with the regulatory requirements under the HIPAA Rules in connection with the good faith provision of telehealth using a non-public facing remote communication technology. This exercise of discretion applied to telehealth provided for any reason, regardless of whether the telehealth service was related to the diagnosis and treatment of health conditions related to COVID–19.

The Telehealth Notification has been in effect since March 17, 2020, and expires at 11:59 p.m. on May 11, 2023; OCR is providing a 90-calendar day transition period for covered health care providers to come into compliance with the HIPAA Rules with respect to their provision of telehealth. The transition period will be in effect beginning on May 12, 2023, and will expire at 11:59 p.m. on August 9, 2023.

During the 90-calendar day transition period, OCR will continue to exercise its enforcement discretion and will not impose penalties on covered health care providers for noncompliance with the HIPAA Rules in connection with the good faith provision of telehealth. These regulatory requirements remain the same as they were before the COVID–19 PHE; however, OCR recognizes that regulated entities that began using remote communication technologies for telehealth for the first time during the COVID–19 PHE may need additional time to come into compliance. Therefore, covered health care providers may use this transition period, as necessary, to adjust their telehealth practices to come into compliance, such as by choosing a telehealth technology vendor that will enter into a business associate agreement and comply with applicable requirements of the HIPAA Rules. Covered entities may also review and update as necessary any policies and practices developed and implemented prior to the COVID–19 PHE for compliance with the HIPAA Rules. To assist covered entities, OCR has published FAQs and guidance on HIPAA and telehealth.[14] OCR will provide additional guidance on telehealth remote communications to help covered health care providers come into compliance during this transition period.

OCR will no longer use the Telehealth Notification as a basis to exercise its discretion in enforcing the HIPAA Rules, as they apply to the provision of telehealth, for noncompliance that occurs after 11:59 p.m. on August 9, 2023. Beginning on August 10, 2023, OCR will continue to exercise enforcement discretion consistent with the Telehealth Notification with respect to noncompliance that may occur during the 90-calendar day transition period (*i.e.,* noncompliance occurring from May 12, 2023, through August 9, 2023).

III. Collection of Information Requirements

This announcement of the expiration of the Notifications of Enforcement Discretion creates no legal obligations and no legal rights. Because this notice imposes no information collection requirements, it need not be reviewed by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: April 7, 2023.

Melanie Fontes Rainer,

Director, Office for Civil Rights, U.S. Department of Health and Human Services.

[FR Doc. 2023–07824 Filed 4–11–23; 8:45 am]

BILLING CODE 4153–01–P

[13] 85 FR 22024 (April 21, 2020).

[14] *See* HIPAA and Telehealth, U.S. Dep't of Health and Human Servs., *https://www.hhs.gov/hipaa/for-professionals/special-topics/telehealth/index.html.*

Proposed Rules

Federal Register
Vol. 88, No. 71
Thursday, April 13, 2023

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–0663; Project Identifier AD–2023–00020–E]

RIN 2120–AA64

Airworthiness Directives; General Electric Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain General Electric Company (GE) GEnx-1B and GEnx-2B model turbofan engines. This proposed AD was prompted by a manufacturer investigation that revealed that certain stages 6–10 compressor rotor spools and forward seals were manufactured from powder metal material suspected to contain iron inclusion. This proposed AD would require the replacement of the affected stages 6–10 compressor rotor spools and forward seals. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by May 30, 2023.

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

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

AD Docket: You may examine the AD docket at regulations.gov by searching for and locating Docket No. FAA–2023–0663; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For GE service information identified in this NPRM, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215; phone: (513) 552–3272; email: *aviation.fleetsupport@ge.com;* website: *ge.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

FOR FURTHER INFORMATION CONTACT: Alexei Marqueen, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7178; email: *Alexei.T.Marqueen@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–0663; Project Identifier AD–2023–00020–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Alexei Marqueen, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA was notified by the manufacturer of the detection of iron inclusion in a high-pressure turbine stage 2 disk manufactured from the same powder metal material used to manufacture certain stages 6–10 compressor rotor spools and forward seals for GEnx-1B64/P2, GEnx-1B67/P2, GEnx-1B70/75/P2, GEnx-1B70/P2, GEnx-1B70C/P2, GEnx-1B74/75/P2, GEnx-1B76/P2, GEnx-1B76A/P2, and GEnx-2B67/P model turbofan engines. A manufacturer investigation determined that the iron inclusion was introduced during the manufacturing process from raw material filtering screens that had degraded, and certain stages 6–10 compressor rotor spools and forward seals manufactured using the same process may have reduced material properties and a lower fatigue life capability due to the iron inclusion. Further investigation by the manufacturer identified additional degraded filtering screens which had the potential to increase the population of parts that were subjected to iron inclusion during manufacturing. As a result of its investigation, GE published service information that specifies procedures for the removal and replacement of certain stages 6–10 compressor rotor spools and forward seals. This condition, if not addressed, could result in uncontained debris

release, damage to the engine, and damage to the aircraft.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed GE GEnx-1B Service Bulletin 72–0515 R00, Initial Issue, dated January 31, 2023. The FAA also reviewed GE GEnx-2B Service Bulletin 72–0452 R00, Initial Issue, dated January 31, 2023. This service information specifies procedures for removal and replacement of the stages 6–10 compressor rotor spool and forward seal. These documents are distinct since they apply to different engine models. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Proposed AD Requirements in This NPRM

This proposed AD would require removal of the affected stages 6–10 compressor rotor spools and forward seals and replacement with a part eligible for installation.

Interim Action

The FAA considers that this proposed AD would be an interim action. If final action is later identified, the FAA might consider additional rulemaking.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 13 engines installed on airplanes of U.S. registry. The FAA estimates that nine of the 13 engines will require replacing the stages 6–10 compressor rotor spool and four of the 13 engines will require replacing the forward seal.

The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace stages 6–10 compressor rotor spool	8 work-hours × $85 per hour = $680	$841,088	$841,768	$7,575,912
Replace forward seal	8 work-hours × $85 per hour = $680	389,976	390,656	1,562,624

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

General Electric Company: Docket No. FAA–2023–0663; Project Identifier AD–2023–00020–E.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 30, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to General Electric Company (GE) GEnx-1B64/P2, GEnx-1B67/P2, GEnx-1B70/75/P2, GEnx-1B70/P2, GEnx-1B70C/P2, GEnx-1B74/75/P2, GEnx-1B76/P2, GEnx-1B76A/P2, and GEnx-2B67/P model turbofan engines with an installed:

(1) Stages 6–10 compressor rotor spool having a part number (P/N) and serial number (S/N) listed in paragraph 4, Appendix—A, Table 1 of GE GEnx-1B Service Bulletin 72–0515, Initial Issue, dated January 31, 2023 (GEnx-1B 72–0515); or

(2) Forward seal having a P/N and S/N listed in paragraph 4, Appendix—A, Table 2 of GEnx-1B 72–0515; or

(3) Stages 6–10 compressor rotor spool having a P/N and S/N listed in paragraph 4, Appendix—A, Table 1 of GE GEnx-2B Service Bulletin 72–0452, Initial Issue, dated January 31, 2023. (GEnx-2B 72–0452); or

(4) Forward seal having a P/N and S/N listed in paragraph 4, Appendix—A, Table 2 of GEnx-2B 72–0452.

(d) Subject

Joint Aircraft System Component (JASC) Code 7230, Turbine Engine Compressor Section; 7250, Turbine Section.

(e) Unsafe Condition

This AD was prompted by a manufacturer investigation that revealed certain stages 6–10 compressor rotor spools and forward seals were subject to iron inclusion introduced during the manufacturing process. The FAA is issuing this AD to prevent fracture and potential uncontained failure of certain stages 6–10 compressor rotor spools and forward seals. The unsafe condition, if not addressed, could result in uncontained debris release, damage to the engine, and damage to the aircraft.

(f) Compliance

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

(g) Required Actions

(1) For affected GEnx-1B model turbofan engines, at the next piece-part exposure after the effective date of this AD, or before the affected stages 6–10 compressor rotor spool reaches the cyclic removal threshold listed in paragraph 4., Appendix—A, Table 1 of GEnx-1B 72–0515, whichever occurs first, remove the affected stages 6–10 compressor rotor spool from service and replace with a part eligible for installation.

(2) For affected GEnx-1B model turbofan engines, at the next piece-part exposure after the effective date of this AD, or before the affected forward seal exceeds the cyclic removal threshold listed in paragraph 4., Appendix—A, Table 2 of GEnx-1B 72–0515, whichever occurs first, remove the affected forward seal from service and replace with a part eligible for installation.

(3) For affected GEnx-2B model turbofan engines, at the next piece-part exposure after the effective date of this AD, or before the affected stages 6–10 compressor rotor spool exceeds the cyclic removal threshold listed in paragraph 4., Appendix—A, Table 1 of GEnx-2B 72–0452, whichever occurs first, remove the affected stages 6–10 compressor rotor spool from service and replace with a part eligible for installation.

(4) For affected GEnx-2B model turbofan engines, at the next piece-part exposure after the effective date of this AD, or before the affected forward seal exceeds the cyclic removal threshold listed in paragraph 4., Appendix—A, Table 2 of GEnx-2B 72–0452, whichever occurs first, remove the affected forward seal from service and replace with a part eligible for installation.

(h) Definitions

(1) For the purpose of this AD, a ''part eligible for installation'' is any stages 6–10 compressor rotor spool or forward seal with a P/N and S/N not listed in paragraph 4, Appendix—A, Table 1 or paragraph 4, Appendix—A, Table 2 of GEnx-1B 72–0515 or GEnx-2B 72–0452.

(2) For the purpose of this AD, ''piece-part exposure'' is when the affected part is removed from the engine.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD and email to: *ANE-AD-AMOC@faa.gov.*

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

(j) Related Information

For more information about this AD, contact Alexei Marqueen, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7178; email: *Alexei.T.Marqueen@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) GE GEnx-1B Service Bulletin 72–0515, Initial Issue, dated January 31, 2023.

(ii) GE GEnx-2B Service Bulletin 72–0452, Initial Issue, dated January 31, 2023.

(3) For GE service information identified in this AD, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215; phone: (513) 552–3272; email: *aviation.fleetsupport@ge.com;* website: *ge.com.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

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

Issued on April 1, 2023.

Christina Underwood,

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

[FR Doc. 2023–07648 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–0583; Airspace Docket No. 22–ACE–20]

RIN 2120–AA66

Modification of Class E Airspace; Alliance Municipal Airport, Alliance, NE

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class E airspace extending upward from 700 feet above the surface to adequately contain all instrument flight rule (IFR) procedures at Alliance Municipal Airport, NE. This action will support the safety and management of IFR operations at the airport.

DATES: Comments must be received on or before May 30, 2023.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2023–0583 and Airspace Docket No. 22–ACE–20 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 7400.11G, 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 modify Class E airspace to support IFR operations at Alliance Municipal Airport, Alliance, NE.

Comments Invited

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

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

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

Availability of Rulemaking Documents

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

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

Incorporation by Reference

Class E5 airspace designations are published in paragraphs 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 7400.11G, dated August 19, 2022 and effective September 15, 2022. 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 7400.11G 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 modify the Class E airspace beginning at 700 feet above the surface at Alliance Municipal Airport, NE. The current class E airspace encircling the airport within a 7.2-mile radius is insufficient. The lateral protected area for aircraft descending from 1,500 feet above the surface for the Very High Frequency Omnidirectional Range (VOR) approaches, extends pass the current Class E lateral airspace. Class E airspace beginning at 700 feet above the surface should be expanded to a 7.6-mile radius, which would fully contain arriving IFR aircraft operating below 1,500 feet above the surface.

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''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), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

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

* * * * *

ACE NE E5 Alliance, NE [Amended]

Alliance Municipal Airport, NE
(Lat. 42°03′12″ N, long. 102°48′14″ W)

That airspace extending upward from 700 feet above the surface within a 7.6-mile radius of the airport

* * * * *

Issued in Des Moines, Washington, on April 6, 2023.

B.G. Chew,

Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2023–07703 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–0505; Airspace Docket No. 23–ASO–06]

RIN 2120–AA66

Amendment of Class D and Class E Airspace; Ormond Beach, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class D airspace, Class E airspace designated as an extension to a Class D surface area in Ormond Beach, FL, and Class E airspace extending upward from 700 feet above the surface in Daytona Beach, FL, as the result of a biennial airspace evaluation. This action would extend the Class E airspace extending upward from 700 feet above the surface surrounding Spruce Creek Airport. The FAA also proposes to update terminology in the Class D and Class E airspace designated as an extension to Class D for Ormond Beach, FL, in the legal descriptions, as well as the geographical coordinates for Daytona Beach International Airport in the legal description for the Class E airspace extending upward from 700 feet above the surface in Daytona Beach, FL.

DATES: Comments must be received on or before May 30, 2023.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2023–0505 and Airspace Docket No. 23–ASO–06 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 for 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* anytime. 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 for Federal holidays.

FAA Order JO 7400.11G, 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: Jennifer Ledford, Operations Support Group, Office of Policy, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone: (404) 305–5946.

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 controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

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 once 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 and 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 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 editing, 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 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 of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Ave., College Park, GA 30337.

Incorporation by Reference

Class D and Class E airspace designations are published in paragraphs 5000, 6004, and 6005 of FAA Order JO 7400.11, 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 7400.11G, dated August 19, 2022, and effective September 15, 2022. These updates will 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 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes to amend Class E airspace extending upward from 700 feet above the surface of Spruce Creek Airport by increasing the radius to 6.8

miles (previously 6.4 miles). The FAA also proposes to amend Class E airspace extending upward from 700 feet above the surface of Daytona Beach International Airport by updating the geographical coordinates to coincide with the FAA's database. In addition, this action would replace the outdated terms Airport/Facility Directory with the term Chart Supplement and Notice to Airmen with the term Notice to Air Missions in the Ormond Beach Class D airspace and Class E airspace designated as an extension to Class D descriptions.

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 per FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' before any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO FL D Ormond Beach, FL

Ormond Beach Municipal Airport, FL
(Lat 29°18′04″ N, long 81°06′50″ W)

That airspace extending upward from the surface, to but not including 1,200 feet MSL within a 3.2-mile radius of Ormond Beach Municipal Airport, excluding that airspace within the Daytona Beach, FL, Class C airspace area. This Class D airspace area is effective during the specific days and times established in advance by a Notice to Air Missions. The effective days and times will be continuously published in the Chart Supplement.

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

* * * * *

ASO FL E4 Ormond Beach, FL

Ormond Beach Municipal Airport, FL
(Lat 29°18′04″ N, long. 81°06′50″ W)
Ormond Beach VORTAC
(Lat 29°18′12″ N, long 81°06′46″ W)

That airspace extending upward from the surface within 2.4 miles on each side of the Ormond Beach VORTAC 342° radial, extending from the 3.2-mile radius to 6.9 miles northwest of the VORTAC. This Class E4 airspace area is effective during the specific days and times established in advance by a Notice to Air Missions. The effective days and times will thereafter be continuously published in the Chart Supplement.

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

* * * * *

ASO FL E5 Daytona Beach, FL

Daytona Beach International Airport, FL
(Lat 29°10′48″ N, long 81°03′29″ W)
Spruce Creek Airport
(Lat 29°04′49″ N, long 81°02′48″ W)
Ormond Beach Municipal Airport
(Lat 29°18′04″ N, long 81°06′50″ W)

That airspace extends upward from 700 feet or more above the earth's surface within a 10-mile radius of Daytona Beach International Airport, within a 6.8-mile radius of Spruce Creek Airport, and within a 7.3-mile radius of Ormond Beach Municipal Airport.

Issued in College Park, GA, on April 3, 2023.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2023–07637 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–368]

Definition of ''Cannabimimetic Agents'' and Assignment of an Administration Controlled Substances Code Number for All ''Cannabimimetic Agents''

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: On July 9, 2012, the President signed into law the Synthetic Drug Abuse Prevention Act of 2012. The Synthetic Drug Abuse Prevention Act of 2012 included a definition of ''cannabimimetic agents'' that are controlled under schedule I. The Drug Enforcement Administration is proposing this rule to address the broader definition of ''cannabimimetic agents,'' identify 18 additional substances that meet the definition, and consolidate most existing administration controlled substances code numbers (drug codes) into a single drug code number for substances that meet this definition. The listing for two schedule I ''cannabimimetic agents'' that are under international control, JWH-018 and AM2201, will be moved to the ''hallucinogens'' paragraph of schedule I in order to retain the existing drug codes for these two substances to facilitate quota and international reporting requirements. While the 18 additional substances are already controlled under schedule I because they meet the definition of ''cannabimimetic agents,'' this proposed rule establishes a single new drug code number for these and most other substances meeting this definition. This single drug code will simplify the registration and recordkeeping requirements for any ''cannabimimetic agents'' that the Drug Enforcement Administration may register persons to handle.

DATES: Comments must be submitted electronically or postmarked on or before May 15, 2023.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–368'' on all electronic and written correspondence, including any attachments.

• *Electronic comments:* DEA encourages commenters to submit all comments electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment

field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the on-line instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number. Submitted comments are not instantaneously available for public view on *regulations.gov.* If you have received a Comment Tracking Number, you have submitted your comment successfully and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

• *Paper comments:* Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA FR Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

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

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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

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

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

An electronic copy of this document is available at *https://www.regulations.gov* for easy reference.

Legal Authority

On July 9, 2012, the Synthetic Drug Abuse Prevention Act of 2012 (SDAPA), Public Law 112–144, Title XI, Subtitle D, became effective. SDAPA amended the CSA by legislatively placing ''cannabimimetic agents'' in schedule I. Public Law 112–144, Title XI, Subtitle D, Section 1152; 21 U.S.C. 812(d). On January 4, 2013, DEA published a final rule that added paragraph (g) to 21 CFR 1308.11 with the title ''cannabimimetic agents,'' and assigned unique administration controlled substances code numbers (drug codes) for 15 substances included in SDAPA that met this definition. 78 FR 664.

DEA is proposing this rule to make technical, organizational, and conforming amendments to paragraph (g). This rule would make no change in the current and continuing schedule I status for all of the substances discussed in this rule. This action proposes to:

• incorporate the structural and pharmacological definition of ''cannabimimetic agents'' found in 21 U.S.C. 812(d) into paragraph (g),

• list 18 additional substances that meet the structural and pharmacological definition of ''cannabimimetic agents'' in paragraph (g),

• consolidate 13 of the 15 existing drug codes previously assigned to ''cannabimimetic agents'' and establish a single drug code for most substances that meet this definition, and

• move two substances (JWH-018 and AM2201) from paragraph (g) to paragraph (d) and retain the existing drug codes (7118 and 7201, respectively) to facilitate quota and international reporting requirements.

DEA has collected data for 18 additional substances that meet the structural and pharmacological definition in accordance with SDAPA: AM-1220; AM-2233; EAM-2201; JWH-098; JWH-184; JWH-193; JWH-210; MAM-2201; JWH-007; JWH-022; JWH-147; JWH-302; JWH-307; JWH-412; WIN 55,212-2; CP-55,940; CP-47,497 C6 homolog; and CP-47,497 C9 homolog.

Two of the substances (JWH-018 and AM2201) that are currently listed in 21 CFR 1308.11(g) are also listed in Schedule II of the Convention on Psychotropic Substances of 1971 (1971 Convention).[1] In order to continue to establish aggregate production quota and grant individual manufacturing and procurement quota to DEA-registered manufacturers of JWH-018 and AM2201, and report these data as required under Article 16 the 1971 Convention, DEA proposes to move the listing for these two substances from 21 CFR 1308.11(g) to 21 CFR 1308.11(d). With the proposal to assign all substances in 21 CFR 1308.11(g) a single drug code, moving the listing of these two drugs will maintain their current drug codes (7118 and 7201, respectively) and allows DEA to continue collecting data reported to the International Narcotics Control Board (INCB) on Form P.[2]

Regulatory Analyses

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

This regulation has been drafted and reviewed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. This proposed rule is not a significant regulatory action under E.O. 12866. All of the substances listed in this proposed rule are already listed or defined as controlled substances in the United States under schedule I. In this proposed rule, DEA is proposing technical, organizational, and conforming amendments to its regulations to incorporate definitions found in 21 U.S.C. 812(d), list additional ''cannabimimetic agents'' that meet these definitions, and simplify drug codes assigned to ''cannabimimetic agents.'' These proposed changes only apply to substances that are already listed or defined as schedule I controlled substances. Creating listings for these substances and modifying drug

[1] On March 13, 2015, the Commission on Narcotic Drugs decided to include JWH-018 and AM2201 in Schedule II of the Convention on Psychotropic Substances of 1971.

[2] The current form can be downloaded from the INCB website: *www.incb.org,* under ''Psychotropic Substances'', Toolkit: ''Form P''.

codes will not alter the status of any of these substances as schedule I controlled substances. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988, Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Paperwork Reduction Act of 1995

This proposed action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), has reviewed this proposed rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA proposes technical, organizational, and conforming amendments to its regulations to incorporate definitions found in 21 U.S.C. 812(d), list additional ''cannabimimetic agents'' that meet these definitions, and simplify drug codes assigned to ''cannabimimetic agents.'' These proposed changes only apply to substances that are already listed or defined as schedule I controlled substances. If finalized, this action would not impose any new regulatory controls or new administrative, civil, and/or criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle ''cannabimimetic agents.''

Anyone currently handling ''cannabimimetic agents'' must already be registered with DEA and have all security and other handling processes in place, resulting in minimal impact to their operations. Therefore, DEA estimates the cost of this rule, in form of lost sales, if any, on small entities is minimal. DEA welcomes any public comment regarding this estimate.

Because of these facts, this proposed rule will not, if promulgated, result in a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the ''Regulatory Flexibility Act'' section above, DEA has determined pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.*) that this proposed action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 2. In § 1308.11:

■ a. Add paragraphs (d)(102) and (103); and

■ b. Revise paragraph (g).

The additions and revision read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(102) 1-pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	7118
(103) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201) 7201	7201

* * * * *

(g) *Cannabimimetic agents.* Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of cannabimimetic agents, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Cannabimimetic agents—7000.

(2) In this paragraph (g), the term *cannabimimetic agents* means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

(i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.

(ii) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.

(iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

(iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

(v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

(3) The definition in this paragraph (g) includes, but is not limited to, the following substances:

(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497);

(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog);

(iii) 1-butyl-3-(1-naphthoyl)indole (JWH-073);

(iv) 1-hexyl-3-(1-naphthoyl)indole (JWH-019);
(v) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);
(vi) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250);
(vii) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081);
(viii) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122);
(ix) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398);
(x) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);
(xi) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19 and RCS-4);
(xii) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8);
(xiii) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203);
(xiv) (1-((1-methylpiperidin-2-yl)methyl)-1*H*-indol-3-yl)(naphthalen-1-yl)methanone (AM-1220);
(xv) (2-iodophenyl)(1-((1-methylpiperidin-2-yl)methyl)-1*H*-indol-3-yl)methanone (AM-2233);
(xvi) (4-ethylnaphthalen-1-yl)(1-(5-fluoropentyl)-1*H*-indol-3-yl)methanone (EAM-2201);
(xvii) (4-methoxynaphthalen-1-yl)(2-methyl-1-pentyl-1*H*-indol-3-yl)methanone (JWH-098);
(xviii) 3-((4-methylnaphthalen-1-yl)methyl)-1-pentyl-1*H*-indole (JWH-184);
(xix) (4-methylnaphthalen-1-yl)(1-(2-morpholinoethyl)-1*H*-indol-3-yl)methanone (JWH-193);
(xx) (4-ethylnaphthalen-1-yl)(1-pentyl-1*H*-indol-3-yl)methanone (JWH-210);
(xxi) (1-(5-fluoropentyl)-1*H*-indol-3-yl)(4-methylnaphthalen-1-yl)methanone (MAM-2201);
(xxii) (2-methyl-1-pentyl-1*H*-indol-3-yl)(naphthalen-1-yl)methanone (JWH-007);
(xxiii) naphthalen-1-yl(1-(pent-4-en-1-yl)-1*H*-indol-3-yl)methanone (JWH-022);
(xxiv) (1-hexyl-5-phenyl-1*H*-pyrrol-3-yl)(naphthalen-1-yl)methanone (JWH-147);
(xxv) 2-(3-methoxyphenyl)-1-(1-pentyl-1*H*-indol-3-yl)ethan-1-one (JWH-302);
(xxvi) (5-(2-fluorophenyl)-1-pentyl-1*H*-pyrrol-3-yl)(naphthalen-1-yl)methanone (JWH-307);
(xxvii) (4-fluoronaphthalen-1-yl)(1-pentyl-1*H*-indol-3-yl)methanone (JWH-412);
(xxviii) (5-methyl-3-(morpholinomethyl)-2,3-dihydro-[1,4]oxazino[2,3,4-*hi*]indol-6-yl)(naphthalen-1-yl)methanone (WIN 55,212-2);
(xxix) 2-(5-hydroxy-2-(3-hydroxypropyl)cyclohexyl)-5-(2-methyloctan-2-yl)phenol (CP-55,940);
(xxx) 2-(3-hydroxycyclohexyl)-5-(2-methylheptan-2-yl)phenol (CP-47,497 C6 homolog); and
(xxxi) 2-(3-hydroxycyclohexyl)-5-(2-methyldecan-2-yl)phenol (CP-47,497 C9 homolog).

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on March 29, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–07578 Filed 4–12–23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1036]

Schedules of Controlled Substances: Placement of Nine Specific Fentanyl-Related Substances in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing nine substances, as identified in this proposed rule, in schedule I of the Controlled Substances Act. These nine substances fall within the definition of fentanyl-related substances set forth in the February 6, 2018, temporary scheduling order. Through the Temporary Reauthorization and Study of Emergency Scheduling of Fentanyl Analogues Act, which became law on February 6, 2020, Congress extended the temporary control of fentanyl-related substances until May 6, 2021. This temporary order was subsequently extended multiple times, most recently on December 29, 2022, through the Consolidated Appropriations Act, 2023, which extended the order until December 31, 2024. If finalized, this action would make permanent the existing regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle these nine specific controlled substances.

DATES: Comments must be submitted electronically or postmarked on or before May 15, 2023.

Interested persons may file a request for a hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.47 and/or 1316.49, as applicable. Requests for a hearing, and waivers of an opportunity for a hearing or to participate in a hearing, must be received on or before May 15, 2023.

ADDRESSES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). The electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period. To ensure proper handling of comments, please reference ''Docket No. DEA–1036'' on all electronic and written correspondence, including any attachments.

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

• *Hearing requests:* All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law asserted in the hearing, must be filed with the DEA Administrator, who will make the determination of whether a hearing will be needed to address such matters of fact and law in the rulemaking. Such requests must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. For informational purposes, a courtesy copy of requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

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

SUPPLEMENTARY INFORMATION: In this proposed rule, the Drug Enforcement Administration (DEA) proposes to permanently schedule the following nine controlled substances in schedule I of the Controlled Substances Act (CSA), including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

• *meta*-fluorofentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide),

• *meta*-fluoroisobutyryl fentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide),

• *para*-methoxyfuranyl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide),

• 3-furanyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylfuran-3-carboxamide),

• 2′,5′-dimethoxyfentanyl (*N*-(1-(2,5-dimethoxyphenethyl)piperidin-4-yl)-*N*-phenylpropionamide),

• isovaleryl fentanyl (3-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide),

• *ortho*-fluorofuranyl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide),

• *alpha*′-methyl butyryl fentanyl (2-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide),

• and *para*-methylcyclopropyl fentanyl (*N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide).

Posting of Public Comments

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

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

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

An electronic copy of this document and supplemental information to this proposed rule are available at *https://www.regulations.gov* for easy reference.

Request for Hearing or Appearance; Waiver

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. Interested persons, as defined in 21 CFR 1300.01(b), may file requests for a hearing in conformity with the requirements of 21 CFR 1308.44(a) and 1316.47(a), and such requests must:

(1) state with particularity the interest of the person in the proceeding;

(2) state with particularity the objections or issues concerning which the person desires to be heard; and

(3) state briefly the position of the person with regarding to the objections or issues.

Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(c), together with a written statement of position on the matters of fact and law involved in any hearing. 21 CFR 1316.49.

All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law involved in such hearing, must be sent to DEA using the address information provided above. The decision whether a hearing will be needed to address such matters of fact and law in the rulemaking will be made by the Administrator. If a hearing is needed, DEA will publish a notice of hearing on the proposed rulemaking in the **Federal Register**. 21 CFR 1308.44(b), 1316.53. Further, once the Administrator determines a hearing is needed to address such matters of fact and law in rulemaking, she will then designate an Administrative Law Judge (ALJ) to preside over the hearing. The ALJ's functions shall only commence upon designation, as provided in 21 CFR 1316.52.

In accordance with 21 U.S.C. 811 and 812, the purpose of a hearing would be to determine whether *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and/or *para*-methylcyclopropyl fentanyl meet the statutory criteria for placement in schedule I.

Legal Authority

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on his own motion.[1] This proposed action is supported by a

[1] 21 U.S.C. 811(a).

recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (Assistant Secretary for HHS or Assistant Secretary) and an evaluation of all other relevant data by DEA. If finalized, this action would make permanent the existing temporary regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle these nine substances.

Background

On February 6, 2018, pursuant to 21 U.S.C. 811(h)(1), DEA published an order in the **Federal Register** (83 FR 5188) temporarily placing fentanyl-related substances, as defined in that order, in schedule I of the CSA based upon a finding that these substances pose an imminent hazard to the public safety. As discussed below in Factor 3, the nine substances named in this proposed rule meet the existing definition of fentanyl-related substances as they are not otherwise controlled in any other schedule (*i.e.,* not included under another DEA Controlled Substance Code Number) and are structurally related to fentanyl by one or more of the five modifications listed under the definition. That temporary order was effective upon the date of publication. Pursuant to 21 U.S.C. 811(h)(2), the temporary control of fentanyl-related substances, a class of substances as defined in the order, as well as the nine specific substances already covered by that order, was set to expire on February 6, 2020. However, on February 6, 2020, as explained in DEA's April 10, 2020, correcting amendment (85 FR 20155), Congress extended that expiration date until May 6, 2021, by enacting the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (Pub. L. 116–114, sec. 2, 134 Stat. 103). This temporary order was subsequently extended multiple times, most recently on December 29, 2022, through the Consolidated Appropriations Act, 2023,[2] which extended the order until December 31, 2024. Consequently, the temporary control of these nine substances will remain in effect until December 31, 2024, unless DEA permanently places them in schedule I prior to that date.

Therefore, the Administrator, on her own motion pursuant to 21 U.S.C. 811(a), is initiating proceedings to permanently schedule *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl. DEA gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse for these substances. On October 12, 2021, in accordance with 21 U.S.C. 811(b), the Administrator submitted a request to the Assistant Secretary to provide DEA with a scientific and medical evaluation of available information and a scheduling recommendation for these nine substances.

On May 16, 2022, the Assistant Secretary submitted HHS's scientific and medical evaluation and scheduling recommendation for *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl and their salts to the Administrator. In accordance with 21 U.S.C. 811(c), upon receipt of the scientific and medical evaluation and scheduling recommendation from HHS, DEA reviewed the documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of these nine substances.

Proposed Determination To Permanently Schedule Nine Specific Fentanyl-Related Substances

As discussed in the background section, the Administrator is initiating proceedings, pursuant to 21 U.S.C. 811(a), to permanently add *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl to schedule I. DEA reviewed the scientific and medical evaluation, scheduling recommendation received from HHS, and all other relevant data and conducted its own eight-factor analysis of the abuse potential of these nine substances pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its proposed scheduling action. Please note that both DEA and HHS analyses are available in their entirety under ''Supporting Documents'' of the public docket for this proposed rule at *https://www.regulations.gov* under Docket Number ''DEA–1036.''

1. The Drug's Actual or Relative Potential for Abuse

The term ''abuse'' is not defined in the CSA. However, the legislative history of the CSA[3] suggests that DEA consider the following criteria when determining whether a particular drug or substance has a potential for abuse:

(a) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or

(b) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or

(c) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or

(d) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

The abuse potential of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl is associated with their pharmacological similarity to other schedule I and II mu-opioid receptor agonist substances which have a high potential for abuse. Similar to schedule II substances morphine and fentanyl and several schedule I opioid substances that are structurally related to fentanyl, these nine substances have been shown to bind and act as mu-opioid receptor agonists.

meta-Fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl

[2] Public Law 117–328, Division O, Title VI, Sec. 601.

[3] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 1 (1970); reprinted in 1970 U.S.C.C.A.N. 4566, 4603.

fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl have no approved medical use in the United States and have been encountered on the illicit drug market. Because these nine substances are not Food and Drug Administration (FDA)-approved drug products, a practitioner may not legally prescribe them and these substances cannot be dispensed to an individual. Accordingly, the use of these nine substances without medical advice leads to the conclusion that they are abused for their opioid-like properties. There are no legitimate channels for these nine substances to be marketed as FDA-approved drug products, but they are available for purchase from legitimate chemical companies to be used in scientific research. However, despite the limited legitimate use of these substances, reports from public health and law enforcement indicate that *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl are being abused and taken in amounts sufficient to create a hazard to an individual's health. Data from forensic databases can be used as an indicator of illicit activity with drugs and abuse [4] within the United States. According to drug seizure data from 2016 to 2021 from the National Forensic Laboratory Information System (NFLIS),[5] seven of the substances (*meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, and *alpha*′-methyl butyryl fentanyl) are being encountered in the United States. Two substances (2′,5′-dimethoxyfentanyl and *para*-methylcyclopropyl fentanyl) were not listed in the NFLIS database, however, reporting from NMS labs [6] in 2019 show that 2′,5′-dimethoxyfentanyl and *para*-methylcyclopropyl fentanyl have been positively identified in drugs seized by the Department of Homeland Security. Consequently, the positive identification of the nine substances in law enforcement encounters indicates that these substances are being abused, and thus pose safety hazards to the health of users.

2. Scientific Evidence of the Drug's Pharmacological Effects, if Known

meta-Fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl are pharmacologically similar to other schedule I and schedule II mu-opioid receptor agonist substances. Non-clinical and clinical studies conducted on abuse potential of mu-opioid receptor agonists such as morphine and fentanyl indicate that these substances share discriminative stimulus effects and have reinforcing properties. Similar to schedule I and II opioid analgesics, these nine substances bind to and activate the mu-opioid receptor. Additionally, behavioral studies in animals demonstrate that *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl produce analgesic effects similar to fentanyl and morphine. Further, pre-treatment with naltrexone, an opioid antagonist, attenuated analgesic effects of these nine substances as well as morphine. Thus, it is concluded from *in vitro* and *in vivo* pharmacological studies that the effects of these nine substances are similar to that of fentanyl and morphine and mediated by mu-opioid receptor agonism.

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

meta-Fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl are synthetic opioids in the 4-anilidopiperidine structural class which includes fentanyl. As defined in the February 6, 2018, temporary order, fentanyl-related substances include any substance not otherwise controlled in any schedule (*i.e.,* not included under any other Administration Controlled Substance Code Number) that is structurally related to fentanyl by one or more of the following modifications:

(A) Replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;

(B) substitution in or on the phenethyl group with alkyl, alkenyl, alkoxyl, hydroxyl, halo, haloalkyl, amino or nitro groups;

(C) substitution in or on the piperidine ring with alkyl, alkenyl, alkoxyl, ester, ether, hydroxyl, halo, haloalkyl, amino or nitro groups;

(D) replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle; and/or

(E) replacement of the *N*-propionyl group by another acyl group.

[4] While law enforcement data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332, Dec. 12, 2011.

[5] NFLIS is a DEA program and a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States. The NFLIS database also contains Federal data from U.S. Customs and Border Protection (CBP). NFLIS only includes drug chemistry results from completed analyses. NFLIS data were queried July 18, 2022. NFLIS is still reporting data from 2021 due to normal lag time in reporting.

[6] NMS Labs is an independent provider of professional laboratory testing services, specializing in clinical toxicology and forensic science.

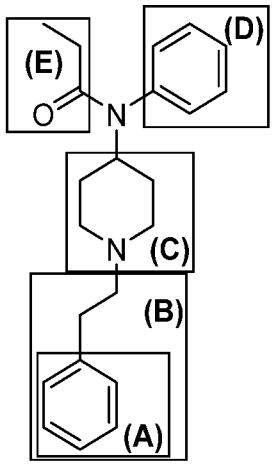


Figure 1: Regions of the chemical structure of fentanyl described in the definition of a fentanyl-related substance

According to the February 6, 2018, temporary scheduling order, the existence of a substance with any one, or any combination, of above-mentioned modifications (see Figure 1) would meet the structural requirements of the definition of fentanyl-related substances. The present nine substances fall within the definition of fentanyl-related substances by the following modifications:

1. *meta*-fluorofentanyl: substitution on the aniline ring (meets definition for modification D);
2. *meta*-fluoroisobutyryl fentanyl: substitution on the aniline ring and replacement of the *N*-propionyl group with another acyl group (meets definition for modifications D and E);
3. *para*-methoxyfuranyl fentanyl: substitution on the aniline ring and replacement of the *N*-propionyl group with another acyl group (meets definition for modifications D and E);
4. 3-furanyl fentanyl: replacement of the *N*-propionyl group with another acyl group (meets definition for modification E);
5. 2′,5′-dimethoxyfentanyl: substitution on the phenethyl group with alkoxyl groups (meets definition for modification B);
6. isovaleryl fentanyl: replacement of the *N*-propionyl group with another acyl group (meets definition for modification E);
7. *ortho*-fluorofuranyl fentanyl: substitution on the aniline ring and replacement of the *N*-propionyl group with another acyl group (meets definition for modifications D and E);
8. *alpha*′-methyl butyryl fentanyl: replacement of the *N*-propionyl group with another acyl group (meets definition for modification E);
9. *para*-methylcyclopropyl fentanyl: substitution on the aniline ring and replacement of the *N*-propionyl group with another acyl group (meets definition for modifications D and E);

No study has been undertaken to evaluate the efficacy, toxicology, and safety of the nine substances in humans. It can be inferred from data obtained from animal studies that these nine substances have sufficient distribution to the brain to produce depressant effects similar to that of mu opioid receptor agonists.

There are no FDA-approved marketing applications for drug products containing *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl for any therapeutic indication in the United States. Moreover, there are no clinical studies or petitioners which have claimed an accepted medical use in the United States for these substances.

4. Its History and Current Pattern of Abuse

Evidence suggests that the pattern of abuse of *meta*-Fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl parallels that of prescription opioid analgesics. Currently, the United States is in the midst of an illicit opioid abuse epidemic. There has been a marked increase in the encounters of synthetic opioids that are structurally related to fentanyl that parallels to an increase in deaths related to synthetic opioids. Thus, the recreational abuse of fentanyl-like substances continues to be a significant concern. These substances are distributed to users, often with unpredictable outcomes. According to HHS, the Centers for Disease Control and Prevention (CDC) reported there were over 68,000 deaths in 2020 associated with the use of opioids other than methadone, but including fentanyl and fentanyl-related substances (HHS, 2022).

Law enforcement encountered these nine substances in the United States. According to the NFLIS [7] database, 49 reports were registered containing seven of the substances (*meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, or *alpha*′-methyl butyryl fentanyl) from state or local forensic laboratories from 2016 to 2021. Two substances (2′,5′-dimethoxyfentanyl and *para*-methylcyclopropyl fentanyl) were not listed in the NFLIS database, however, reporting from NMS labs in 2019 show that 2′,5′-dimethoxyfentanyl and *para*-methylcyclopropyl fentanyl have been positively identified in seized drugs encountered by the Department of Homeland Security.

[7] NFLIS data were queried July 18, 2022. NFLIS data reporting is still pending for 2021 due to normal lag time.

5. The Scope, Duration, and Significance of Abuse

Similar to other substances structurally related to fentanyl, *meta*-Fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl are often used as recreational drugs. The recreational use of these nine substances and other fentanyl-related substances continues to be of significant concern in the United States. These substances are distributed to users often with unpredictable outcomes.

DEA notes that the data from pharmacological testing of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl are consistent with those of other opioids such as fentanyl and other related opioid agonists. Thus, it can be inferred the abuse potential of these substances is similar to mu opioid receptor agonists such as fentanyl and morphine.

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

The abuse of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl leads to the same qualitative public health risks as heroin, fentanyl, and other opioid analgesic substances. Further, abusers of these substances may not know the origin, identity, or purity of these substances. This unknown information poses significant adverse health risks when compared to abuse of pharmaceutical preparations of opioid analgesics, such as morphine and oxycodone. Taken together, evidence suggests that individuals experimenting with substances with unknown potency are at high risk of adverse health outcomes.

7. Its Psychic or Physiological Dependence Liability

There are no pre-clinical or clinical studies that have evaluated the psychic or physiologic dependence of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl. Several studies have shown that due to fentanyl's short duration of action, more frequent dosing is often required which can lead to a fast induction of tolerance, dependence, and opiate withdrawal syndrome. Opioid withdrawal includes nausea and vomiting, depression, agitation, anxiety, craving, sweats, hypertension, diarrhea, and fever. These nine substances act as agonists at the mu opioid receptors and exhibit a full and dose-dependent substitution for the discriminative stimulus effects produced by morphine. Thus, the pharmacological similarity and pattern of abuse of these nine substances to fentanyl are indicative of their potential to possess a psychic and physiological dependence liability similar to that of other mu opioid receptor agonist substances, such as heroin and fentanyl.

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

meta-Fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl are not immediate precursors of any controlled substance of the CSA as defined by 21 U.S.C. 802(23).

Conclusion: Based on consideration of the scientific and medical evaluation and accompanying recommendation of HHS, and on DEA's own eight-factor analysis, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl. As such, DEA proposes to permanently schedule these nine substances as controlled substances under the CSA.

Proposed Determination of Appropriate Schedule

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

(1) *meta*-Fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, alpha′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl have a high potential for abuse. According to HHS, these nine substances are mu-opioid receptor agonists. These substances have analgesic effects, and these effects are mediated by mu-opioid receptor agonism. HHS states that substances that produce mu-opioid receptor agonist effects in the central nervous system (*e.g.,* morphine and fentanyl) are considered as having a high potential for abuse. Data obtained from drug discrimination studies indicate that these nine substances fully substituted for the discriminative stimulus effects of morphine.

(2) FDA has not approved a marketing application for a drug product containing *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, alpha′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl for any therapeutic indication. In addition, DEA and HHS know of no clinical studies or petitioners claiming an accepted medical use in the United States. Therefore, these nine substances have no currently accepted medical use in the United States.[8]

(3) There is a lack of accepted safety for use of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl

[8] Although there is no evidence suggesting that *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl have a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated:

i. The drug's chemistry must be known and reproducible;

ii. there must be adequate safety studies;

iii. there must be adequate and well-controlled studies proving efficacy;

iv. the drug must be accepted by qualified experts; and

v. the scientific evidence must be widely available.

57 FR 10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994).

fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, alpha′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl under medical supervision. Because these nine substances have no FDA-approved medical use and have not been investigated as new drugs, their safety for use under medical supervision is has not been determined. Therefore, there is a lack of accepted safety for use of these nine substances under medical supervision.

Based on these findings, the Administrator of DEA concludes that *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, warrant continued control in schedule I of the CSA.[9]

Requirements for Handling *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl

As discussed above, these nine fentanyl-related substances are currently subject to a temporary scheduling order adding them to schedule I. If this rule is finalized as proposed, *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl would be subject, on a permanent basis, to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Security. meta*-Fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling these nine substances also must comply with the screening requirements of 21 CFR 1301.90–1301.93.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl must comply with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers are permitted to manufacture *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. *Inventory.* Any person registered with DEA to handle *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl must have an initial inventory of all stocks of controlled substances (including these substances) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl) on hand every two years pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, pursuant to 21 U.S.C. 827 and 832(a), and in accordance with 21 CFR 1301.74(b) and (c) and 1301.76(b) and parts 1304, 1312, and 1317.

7. *Order Forms.* Every DEA registrant who distributes *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl must comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. *Liability.* Any activity involving *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl not authorized by, or in violation of, the CSA or its implementing regulations is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 and 13563, Regulatory Planning and Review, and Improving Regulation and Regulatory Review

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is

[9] 21 U.S.C. 812(b)(1).

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

Executive Order 12988, Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. On February 6, 2018, DEA published an order to temporarily place fentanyl-related substances, as defined in the order, in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). However, as explained in DEA's April 10, 2020, correcting amendment (85 FR 20155), Congress extended that expiration date until May 6, 2021, by enacting the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (Pub. L. 116–114, sec. 2, 134 Stat. 103) (Feb. 6, 2020). This temporary order was subsequently extended multiple times, most recently on December 29, 2022, through the Consolidated Appropriations Act, 2023 (Pub. L. 117–328, Division O, Title VI, Sec. 601), which extended the order until December 31, 2024. DEA estimates that all entities handling or planning to handle *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl have already established and implemented systems and processes required to handle these substances which meet the definition of fentanyl-related substances.

There are currently 108 registrations authorized to specifically handle the fentanyl-related substances as a class, which include one or more of the following substances: *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. Some of these entities are likely to be large entities. However, since DEA does not have information of registrant size and the majority of DEA registrants are small entities, DEA estimates a maximum of 95 are small entities. Therefore, DEA conservatively estimates as many as 95 small entities are affected by this proposed rule.

A review of the 108 registrations indicates that all entities that currently handle *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl also handle other schedule I controlled substances and have established and implemented (or maintained) systems and processes required to handle these substances. Therefore, DEA anticipates this proposed rule will impose minimal or no economic impact on any affected entities; and thus, will not have a significant economic impact on any of the 95 affected small entities. Therefore, DEA has concluded that this proposed rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined and certifies that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 2. In § 1308.11:

■ a. Redesignate paragraphs (b)(73) through (92) as paragraphs (b)(82) through (101);

■ b. Redesignate paragraphs (b)(65) through (b)(72) as paragraphs (b)(72) through (79);

■ c. Redesignate paragraphs (b)(50) through (64) as paragraphs (b)(56) through (70);

■ d. Redesignate paragraphs (b)(47) through (49) as paragraphs (b)(51) through (53);

■ e. Redesignate paragraphs (b)(43) through (46) as paragraphs (b)(46) through (49);

■ f. Redesignate paragraphs (b)(33) through (42) as paragraphs (b)(35) through (44);

■ g. Redesignate paragraphs (b)(10) through (32) as paragraphs (b)(11) through (33); and

■ h. Add new paragraphs (b)(10), (34), (45), (50), (54), (55), (71), (80), and (81).

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(10) *alpha*′-Methyl butyryl fentanyl (2-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide) 9864

*	*	*	*	*
(34) 2′,5′-Dimethoxyfentanyl (*N*-(1-(2,5-dimethoxyphenethyl)piperidin-4-yl)-*N*-phenylpropionamide)				9861
*	*	*	*	*
(45) 3-Furanyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylfuran-3-carboxamide)				9860
*	*	*	*	*
(50) Isovaleryl fentanyl (3-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide)				9862
*	*	*	*	*
(54) *meta*-Fluorofentanyl *(N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide)				9857
(55) *meta*-Fluoroisobutyryl fentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide).				9858
*	*	*	*	*
(71) *ortho*-Fluorofuranyl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide)				9863
*	*	*	*	*
(80) *para*-Methoxyfuranyl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide				9859
(81) *para*-Methylcyclopropyl fentanyl (*N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide)				9865
*	*	*	*	*

Signing Authority

This document of the Drug Enforcement Administration was signed on April 3, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–07576 Filed 4–12–23; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 302

[EPA–HQ–OLEM–2022–0922; FRL–9064–01–OLEM]

RIN 2050–AH25

Addressing PFAS in the Environment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking (ANPRM).

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is seeking public input and data to assist in the consideration of potential development of future regulations pertaining to per- and polyfluoroalkyl substances (PFAS) under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund). The Agency is seeking input and data regarding potential future hazardous substance designation under CERCLA of: Seven PFAS, besides perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), and their salts and structural isomers, or some subset thereof; precursors (a precursor is a chemical that is transformed into another compound through the course of a degradation process) to PFOA, PFOS, and seven other PFAS; and/or categories of PFAS.

DATES: Comments must be received on or before June 12, 2023. Under the Paperwork Reduction Act, comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before May 15, 2023.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OLEM–2022–0922, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov (our preferred method).* Follow the online instructions for submitting comments.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, OLEM Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery or Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michelle Schutz, Office of Superfund Remediation and Technology Innovation (5201T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number 703–346–9536; email address: *schutz.michelle@epa.gov* or Linda Strauss, Office of Superfund Remediation and Technology Innovation (5201T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number 202–564–0797; email address: *strauss.linda@epa.gov.*

SUPPLEMENTARY INFORMATION:

Acronyms and abbreviations. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this ANPRM and for reference purposes, the EPA defines the following terms and acronyms here:

AFFF Aqueous film forming foam
ANPRM Advance Notice of Proposed Rulemaking
ATSDR Agency for Toxic Substances and Disease Registry
CASRN Chemical Abstracts Service Registry Numbers
CDC Centers for Disease Control and Prevention
CERCLA Comprehensive Environmental Response, Compensation, and Liability Act
DSSTox Distributed Structure-Searchable Toxicity
EPA Environmental Protection Agency
GenX Trade name for technology platform that uses HFPO–DA and its ammonium salt as a polymerization aid in the production of fluoropolymers
HFPO Hexafluoropropylene oxide
HFPO–DA Hexafluoropropylene oxide dimer acid
IRIS Integrated Risk Information System
LCPFAC Long-chain perfluoroalkyl carboxylate
NPL National Priorities List
NPRM Notice of Proposed Rulemaking
OMB Office of Management and Budget
PBI Proprietary Business Information
PFAS Per- and polyfluoroalkyl substances
PFBA Perfluorobutanoic acid
PFBS Perfluorobutanesulfonic acid
PFDA Perfluorodecanoic acid
PFHxA Perfluorohexanoic acid
PFHxS Perfluorohexanesulfonic acid
PFNA Perfluorononanoic acid

PFOA Perfluorooctanoic acid
PFOS Perfluorooctanesulfonic acid
SNUR Significant New Use Rule
TSCA Toxic Substances Control Act

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I. Public Participation

A. Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OLEM 2022–0922, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section of this document. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Proprietary Business Information (PBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about PBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.*

The EPA continues to monitor information carefully and continuously from the Centers for Disease Control and Prevention (CDC), local area health departments, and our federal partners so that we can respond rapidly as conditions change regarding COVID–19.

II. What action is the Agency taking?

The Agency is seeking input and data to assist in its consideration of the development of potential future regulations pertaining to designation as hazardous substances under CERCLA of:

(1) Seven PFAS, besides PFOA and PFOS, and their salts and structural isomers, or some subset thereof, which include:

- Perfluorobutanesulfonic acid (PFBS), CASRN 375–73–5
- Perfluorohexanesulfonic acid (PFHxS), CASRN 355–46–4
- Perfluorononanoic acid (PFNA), CASRN 375–95–1
- Hexafluoropropylene oxide dimer acid (HFPO–DA), CASRN 13252–13–6 (sometimes called GenX)
- Perfluorobutanoic acid (PFBA) CASRN 375–22–4
- Perfluorohexanoic acid (PFHxA) CASRN 307–24–4
- Perfluorodecanoic acid (PFDA) CASRN 335–76–2;

(2) Precursors to PFOA, PFOS, and other PFAS listed above; and

(3) Categories of PFAS.

III. General Information

A. Executive Summary

In October 2021, the EPA released the PFAS Strategic Roadmap that presents the EPA's whole-of-agency approach to addressing PFAS and sets timelines by which the Agency plans to take concrete actions to develop new policies to safeguard public health, protect the environment, and hold polluters accountable.[1] The actions described in the PFAS Roadmap, including the National PFAS Testing Strategy,[2] represent important steps to safeguard communities from PFAS contamination. Cumulatively, these actions will build upon one another and lead to more enduring and protective solutions.

The EPA's Office of Land and Emergency Management is responsible for three PFAS Roadmap actions, including:

- Designating PFOA and PFOS as CERCLA hazardous substances. EPA recently published a notice of proposed rulemaking (NPRM), 87 FR 54420, that, if finalized, is expected to increase transparency around PFOA/PFOS releases, offer additional tools that EPA and other government agencies could use to conduct faster cleanups at contaminated sites, and support other actions taken by EPA, other Federal agencies, states, Tribal Nations and international bodies that have set PFOA and PFOS benchmarks and standards and have undertaken PFOA- and PFOS-based regulatory activities and enforcement actions.
- Issuing updated guidance on destroying and disposing of certain PFAS and PFAS-containing materials. The 2020 National Defense Authorization Act required EPA to publish interim guidance on destroying and disposing of PFAS and certain identified non-consumer PFAS-containing materials. It also required EPA to revise that guidance at least every three years, as appropriate. EPA published the first interim guidance in December 2020. Since the publication of the interim guidance, EPA and other agencies have been conducting relevant research on destruction and disposal technologies. EPA anticipates that it will update the guidance no later than the statutory deadline of December 2023.
- Issuing this ANPRM regarding various PFAS under CERCLA. EPA has developed this ANPRM to seek public input regarding potential hazardous substance designation for: (1) Seven PFAS besides PFOA and PFOS; (2) precursors to PFOA, PFOS, and seven other PFAS; and (3) categories of PFAS.

B. What are PFAS?

PFAS are a class of manufactured chemicals that have been used in industry and consumer products since the 1940s because of their useful properties, including their resistance to water, grease, and stains. Several chemical definitions are used to describe PFAS in the scientific community, but it is generally recognized that there are potentially thousands of different PFAS, some of which have been more widely used and/or studied than others. Some PFAS, such as PFOA and PFOS, have been shown to be environmentally persistent, bioaccumulative, and harmful to human health and the environment at certain exposure levels.

PFAS can be present in water, soil, air, and food as well as materials found in homes and workplaces, including:

Drinking water—in public drinking water systems and private drinking water wells;

[1] U.S. EPA. (2021). PFAS Strategic Roadmap: EPA's Commitments to Section 2021–2024. U.S. Environmental Protection Agency. *https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.*

[2] U.S. EPA. National PFAS Testing Strategy. U.S. Environmental Protection Agency. *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/national-pfas-testing-strategy.*

Soil and water—at landfills, disposal sites, and sites and potential or existing CERCLA or RCRA facilities;

Fire extinguishing foam—aqueous film forming foam (AFFF) is used for fighting certain types of fires, including burning petroleum. Some of these foams contain multiple PFAS. PFAS can be found in groundwater and surface water at airports, military bases and other facilities where PFAS containing firefighting extinguishing foam was or is used for training and incident response;

Manufacturing and chemical production facilities that produce or use PFAS—for example at fluoropolymer production facilities, chrome plating, electronics, and certain textile and paper manufacturers;

Food—for example in fish caught from water contaminated with PFAS and dairy products derived from livestock exposed to PFAS;

Food packaging—for example in grease resistant papers, fast food containers and wrappers, microwave popcorn bags, pizza boxes, and candy wrappers;

Household products and dust—for example in stain and water-repellant treatments for carpets, upholstery, clothing, and other fabrics, cleaning products, non-stick cookware, paints, varnishes, and sealants; and

Personal care products—for example in some shampoos, dental floss, and cosmetics.

C. What is the purpose of this notice?

In this ANPRM, EPA is seeking input and data to assist in the potential development of future regulations pertaining to the designation of hazardous substances under section 102(a) of CERCLA, which authorizes the EPA Administrator to promulgate regulations designating as hazardous substances such elements, compounds, mixtures, solutions, and substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. Specifically, this ANPRM seeks public input regarding the possible designation of: (1) Seven PFAS besides PFOA and PFOS; (2) precursors to PFOA, PFOS, and certain other PFAS; and/or (3) categories of PFAS.

In EPA's NPRM designating PFOA and PFOS as hazardous substances, the Agency noted that evidence indicates that these chemicals may present substantial danger to public health or welfare or the environment when released into the environment, thereby warranting designation under section 102(a) of CERCLA. In reaching this determination, the EPA considered a number of criteria, including adverse human health effects and mobility, persistence, and prevalence, in addition to other factors. As mentioned in the NPRM, it is not necessary to have information on all of these criteria for EPA to designate a PFAS compound as a hazardous substance under CERCLA. EPA is requesting information on these factors in this ANPRM since it may be relevant and to guide public input.

In evaluating whether to designate additional PFAS as hazardous substances, different levels of information may exist for individual compounds or categories of PFAS with regards to adverse human health effects, mobility, persistence, prevalence, and other factors. Some of this information is presented on EPA's Comptox Dashboard.[3] EPA is seeking public input and additional information pertaining to these factors that the Agency could consider in evaluating whether these PFAS may present substantial danger to the public health or welfare or the environment.

EPA is not reopening for public comment or otherwise proposing to modify any proposed or existing regulatory actions through this ANPRM.

IV. Statutory Background

On September 6, 2022, the EPA published an NPRM designating PFOA and PFOS as hazardous substances pursuant to section 102(a) of CERCLA. In the ''Background'' section of the NPRM, 87 FR 54420, the Agency described the role and function of CERCLA and its authority to address the release or potential threat of a release of hazardous substances, pollutants, and/or contaminants. This ANPRM is soliciting public input to inform the EPA's consideration of the potential development of future regulations pertaining to additional PFAS, PFAS precursors, and/or categories of PFAS. Given the similarity of the issues of concern in this ANPRM and the NPRM the EPA encourages interested readers to refer to the NPRM's ''Background'' section for a detailed understanding of the statutory context for today's action.

Regarding CERCLA liability and enforcement, EPA is already separately developing a CERCLA PFAS enforcement discretion and settlement policy and seeking individual public input on CERCLA PFAS enforcement/liability concerns through two public listening sessions. The public input will be reviewed and considered by EPA in drafting the policy.

[3] U.S. EPA, Comptox Chemicals Dashboard, U.S. Environmental Protection Agency *https://comptox.epa.gov/dashboard/.*

V. What information is EPA seeking?

A. Request for Public Input Regarding Potential Future Hazardous Substance Designation of Seven Other PFAS

As previously discussed, EPA recently issued an NPRM, that, if finalized, would designate PFOA and PFOS and their salts and structural isomers as CERCLA hazardous substances. EPA is considering whether to initiate a future action that would potentially designate the following additional, seven PFAS and their salts and structural isomers or some subset thereof, as hazardous substances under CERCLA:

- Perfluorobutanesulfonic acid (PFBS), CASRN 375–73–5;
- Perfluorohexanesulfonic acid (PFHxS), CASRN 355–46–4;
- Perfluorononanoic acid (PFNA), CASRN 375–95–1;
- Hexafluoropropylene oxide dimer acid (HFPO–DA), CASRN 13252–13–6 (sometimes called GenX);
- Perfluorobutanoic acid (PFBA) CASRN 375–22–4;
- Perfluorohexanoic acid (PFHxA) CASRN 307–24–4; and
- Perfluorodecanoic acid (PFDA) CASRN 335–76–2.

EPA is soliciting information relevant to whether these compounds may present substantial danger to public health or welfare or the environment. For example, the Agency requests information concerning the characteristics of these compounds, such as mobility, persistence, prevalence, and other characteristics, that would supplement the existing toxicity data for these compounds. Although PFAS is a large class of chemical substances, these seven compounds were identified based on the availability of toxicity information previously reviewed by EPA and other Federal agencies. In April 2021 and 2022, EPA issued the final human health toxicity assessment for PFBS [*Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375–73–5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420–49–3)*],[4] Gen X chemicals *[Final Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and its Ammonium Salt, CASRN 13252–*

[4] U.S.EPA (2021). Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375–73–5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420–49–3). U.S. Environmental Protection Agency, Washington, DC. *https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=350888.*

12–6 and CSRN 62037–80–3],[5] and PFBA [IRIS Toxicological Review of Perfluorobutanoic Acid (PFBA) and Related Salts].[6] In May 2021, the Agency for Toxic Substances and Disease Registry (ATSDR) released the final *Toxicological Profile for Perfluoroalkyls,* which includes minimal risk levels for PFOA, PFOS, PFHxS and PFNA.[7] EPA's Integrated Risk Information System (IRIS) program is currently developing human health toxicity assessments of PFHxA, PFNA, PFDA, and PFHxS.[8]

To inform EPA's decision whether to potentially designate PFBS, PFHxS, PFNA, HFPO–DA, PFBA, PFHxA, and PFDA, or some subset thereof, as hazardous substances in a possible future action, EPA is soliciting responses to the following questions and requests for the PFAS listed above, and requests that commentors provide supporting information and specific scientific literature citations regarding applicable information where appropriate:

1. Please identify additional relevant information in published scientific literature or data regarding the environmental fate and transport (mobility, persistence, or other relevant chemical and physical properties) and environmental prevalence that would assist EPA in making determinations regarding potential designation as a hazardous substance.

2. Are there other PFAS EPA could consider designating as hazardous substances in a possible future rulemaking? If so, please provide references to any published, scientific information on the toxicity of these other PFAS in addition to the information requested in question one for those substances.

3. Please provide available information that EPA could consider in preparing an economic analysis of the potential direct and indirect costs and benefits, including impacts on small entities, associated with a potential rulemaking designating any of the above-mentioned compounds as hazardous substances. Although CERCLA section 102(a) precludes EPA from taking cost into account in the designation of a hazardous substance, the Agency is requesting this information to inform its understanding of the potential costs and benefits associated with any potential future regulatory action.

B. Request for Public Input Regarding Potential Future Hazardous Substance Designation of Precursors to PFOA, PFOS, and PFAS Listed in V.A.

EPA is also considering whether to initiate a future action that would potentially designate precursors to PFOA, PFOS, and possibly the seven PFAS and their salts and isomers, or some subset thereof, listed in Section V.A, of this **SUPPLEMENTARY INFORMATION** section. as hazardous substances. Thus, EPA is soliciting input regarding information that will assist the Agency in identifying compounds that degrade to these PFAS through environmental processes such as biodegradation, photolysis, and hydrolysis.

An example of how EPA has addressed precursors previously is the 2020 Significant New Use Rule (SNUR) for long-chain perfluoroalkyl carboxylate (LCPFAC) PFAS which included salts and precursors of these perfluorinated carboxylates. EPA explained, ''LCPFAC precursors may be simple derivatives of perfluorooctanoic acid (PFOA) and higher homologues or certain polymers that may degrade to PFOA or higher homologues,'' 85 FR 45109 (July 27, 2020).

To inform EPA's decision-making regarding the potential designation of precursors to PFOA, PFOS, and possibly the seven PFAS, or some subset thereof, listed in Section V.A as hazardous substances, EPA is soliciting responses to the following questions and requests on the topics described below and requests that commentors provide supporting information and specific scientific literature citations regarding applicable information where appropriate:

4. Please identify information in published scientific literature or data regarding the environmental degradation of substances to PFOA, PFOS, PFBS, PFHxS, PFNA, HFPO–DA, PFBA, PFHxA, and/or PFDA.

5. What factors, if any, regarding degradation time and environmental conditions (*e.g.,* aqueous vs. arid, anaerobic vs. aerobic, available nutrients) should be considered in identifying the appropriate precursor compounds?

6. Please provide relevant information or data in published scientific literature that characterizes the environmental prevalence of PFOA, PFOS, PFBS, PFHxS, PFNA, HFPO–DA, PFBA, PFHxA, and/or PFDA from the degradation of associated precursors

7. With respect to the preceding questions, please identify names and Chemical Abstracts Service Registry Numbers (CASRNs) or Distributed Structure-Searchable Toxicity (DSSTox) substance identifier for substances that EPA should consider as precursor compounds.

8. Available standard analytical methods, such as SW–846 Method 8327 or Method 533, may not include all precursors to PFOA, PFOS, PFBS, PFHxS, PFNA, HFPO–DA, PFBA, PFHxA, and/or PFDA. Furthermore, the development of additional methods may be limited by the availability of chemicals standards. Given these limitations, please provide information regarding how precursors could be measured in environmental samples. Additionally, please comment on whether and how EPA should consider the availability of analytical methods when determining whether to designate precursors as CERCLA hazardous substances.

9. Please provide available information that EPA could consider in preparing an economic analysis of the potential direct and indirect costs and benefits, including impacts on small entities, associated with a potential rulemaking designating these precursors as CERCLA hazardous substances. Although CERCLA section 102(a) precludes EPA from taking cost into account in the designation of a hazardous substance, the Agency is requesting this information to inform its understanding of the potential costs and benefits associated with any potential future regulatory action.

C. Request for Public Input Regarding Potential Future Designation, or Designations, of Categories of PFAS as Hazardous Substances

EPA is considering whether to initiate a future action that would potentially designate groups or categories of PFAS as hazardous substances. A group or category refers to a set of PFAS that share one or more similar characteristics. Characteristics of interest could include, but are not limited to, chemical structure (*e.g.,* carbon chain length, functional group), physical and chemical properties, mode

[5] U.S. EPA (2021). Human Health Toxicity Values for GenX Chemicals, Hexafluoropropylene Oxide (HFPO) Dimer Acid and its Ammonium Salt, (CASRN 13252–12–6 and CSRN 62037–80–3). U.S. Environmental Protection Agency, Washington, DC. *https://www.epa.gov/chemical-research/human-health-toxicity-assessments-genx-chemicals.*

[6] EPA (2022). IRIS Toxicological Review of Perfluorobutanoic Acid (PFBA) and Related Salts (Final Report). U.S. Environmental Protection Agency, Washington, DC. *https://www.epa.gov/chemical-research/iris-toxicological-review-perfluorobutanoic-acid-pfba-and-related-salts-final.*

[7] ATSDR (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237. 13See Office of Regulatory Enforcement.*

[8] U.S. EPA. IRIS Program Outlook. *https://www.epa.gov/iris/iris-program-outlook.*

of toxicological action, precursors or degradants, or co-occurrence.

EPA's 2020 SNUR for LCPFAC provides an example of a category based on chemical structure. In the SNUR, the LCPFAC category is defined as follows, where $5 < n < 21$ or $6 < m < 21$:

a. $CF_3(CF_2)_n$-COO–M where M = H^+ or any other group where a formal dissociation can be made;

b. $CF_3(CF_2)_n$-CH=CH_2;

c. $CF_3(CF_2)_n$-C(=O)-X where X is any chemical moiety;

d. $CF_3(CF_2)_m$-CH_2-X where X is any chemical moiety, and

e. $CF_3(CF_2)_m$-Y–X where Y = non-S, non-N heteroatom and where X is any chemical moiety.

In addition to the structures identified above, ''the category also includes the salts and precursors of these chemical substances. The precursors may be simple derivatives of PFOA and higher homologues or polymers that contain or may degrade to PFOA or higher homologues. These precursors include long-chain fluorotelomers.'' [80 FR 2885] [FRL–9915–63]. Thus, EPA's 2020 SNUR for LCPFAC included certain PFAS based on their chemical structure as well as other PFAS based on whether they degrade to the targeted LCPFACs.

To inform EPA's decision whether to designate certain groups or categories of PFAS as hazardous substances, EPA is soliciting responses to the following questions and requests, and requests that commentors provide supporting information and specific scientific literature citations regarding applicable information where appropriate:

10. Please identify published scientific literature that can inform whether categories of PFAS could or could not be designated as hazardous substances. This could include, for example, scientific data or information on the similarities or differences of a specific characteristic among PFAS. This could also include scientific data and information on the relationship between different characteristics, such as the relationship between chemical structure and specific chemical, physical, or toxicological properties.

11. Is there other information that EPA should consider when determining whether to designate one or more categories of PFAS as hazardous substances? Please provide comment on the extent to which EPA could include related PFAS in a given category (*e.g.,* structural isomers and/or salts).

12. Please provide available information that EPA could consider in preparing an economic analysis of the potential costs and benefits, including impacts on small entities, associated with a potential rulemaking designating categories of PFAS as hazardous substances. Although CERCLA section 102(a) precludes EPA from taking cost into account in the designation of a hazardous substance, the Agency is requesting this information to inform its understanding of the potential costs and benefits associated with any potential future regulatory action.

VI. Request for Comment and Additional Information

EPA is seeking comment on all questions and topics described in this ANPRM and requests that you submit any other information, which may not be specifically mentioned in this notice, that you believe is important for EPA to consider in connection with these questions and topics. At the same time, EPA does not plan to consider comments that are beyond the scope of the questions and topics described in this ANPRM. EPA requests that commenters making specific recommendations include supporting documentation where appropriate.

Instructions for providing written comments are provided under **ADDRESSES**, including how to submit any comments that contain PBI.

VII. What are the next steps EPA will take?

EPA intends to carefully review all comments and information received in response to this ANPRM. Once that review is completed, EPA would supplement the collected information, as appropriate, with information that the Agency has obtained independently, to determine whether a future rulemaking should address the designation of additional PFAS or precursors as CERCLA hazardous substances or whether one or more categories of PFAS can be designated as CERCLA hazardous substances.

VIII. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735; October 4, 1993) and Executive Order 13563 (76 FR 3821; January 21, 2011), this action was submitted to the OMB for review. Any changes made in response to OMB recommendations have been documented in the docket for this action. Because this action does not impose or propose any requirements, and instead seeks comments and suggestions for the Agency to consider in possibly developing a subsequent proposed rule, other statutory and Executive Order reviews that apply to rulemaking do not apply to this action. Should EPA subsequently determine to pursue a rulemaking, EPA will address the statutes and Executive Orders applicable to the rulemaking.

Nevertheless, the Agency welcomes comments and/or information that would help the Agency to assess any of the following: the potential impact of a possible future rule on small entities pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*); potential impacts on Federal, state, or local governments pursuant to the Unfunded Mandates Reform Act (2 U.S.C. 1531–1538); federalism implications pursuant to Executive Order 13132, entitled *Federalism* (64 FR 43255; November 2, 1999); availability of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995, Public Law 104–113; tribal implications pursuant to Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249; November 6, 2000); environmental health or safety effects on children pursuant to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885; April 23, 1997) and EPA's *2021 Policy on Children's Health;* energy effects pursuant to Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355; May 22, 2001); Paperwork burdens pursuant to the Paperwork Reduction Act (44 U.S.C. 3501); or human health or environmental effects on minority or low-income populations pursuant to Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629; February 16, 1994). The Agency will consider such comments during the development of any subsequent proposed rulemaking.

Michael S. Regan,

Administrator.

[FR Doc. 2023–07535 Filed 4–12–23; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 88, No. 71
Thursday, April 13, 2023

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

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2023–0009]

Notice of Request To Renew an Approved Information Collection: Laboratory Assessment Requests

AGENCY: Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and the Office of Management and Budget (OMB) regulations, FSIS is announcing its intention to request renewal of the approved information collection for non-FSIS laboratories (state, local, or private) that test food samples during illness outbreaks and recall investigations. There are no changes to the existing information collection. The approval for this information collection will expire on July 31, 2023.

DATES: Submit comments on or before June 12, 2023.

ADDRESSES: FSIS invites interested persons to submit comments on this **Federal Register** notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to *https://www.regulations.gov*. Follow the on-line instructions at that site for submitting comments.
- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250–3700.
- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350–E, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2023–0009. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *https://www.regulations.gov*.

Docket: For access to background documents or comments received, call (202) 937–4272 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; (202) 937–4272.

SUPPLEMENTARY INFORMATION:

Title: Laboratory Assessment Requests.

OMB Number: 0583–0183.

Expiration Date of Approval: July 31, 2023.

Type of Request: Renewal of an approved information collection.

Abstract: FSIS has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18 and 2.53), as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*). These statutes mandate that FSIS protect the public by verifying that meat, poultry, and egg products are safe, wholesome, and properly labeled and packaged.

FSIS is announcing its intention to renew the approved information collection for non-FSIS laboratories (state, local, or private) that test food samples during illness outbreak and recall investigations. There are no changes to the existing information collection. The approval for this information collection will expire on July 31, 2023.

As a public health regulatory agency, FSIS investigates reports of foodborne illness, contamination, and adulteration potentially associated with FSIS-regulated products. During these investigations, non-FSIS laboratories may test FSIS regulated product and share the results with FSIS. FSIS Office of Public Health Science (OPHS) Microbiological and Chemical Hazards Staff (MCHS) will review the results and associated documentation shared by the non-FSIS laboratory to determine whether FSIS will accept the results. If the MCHS lead investigator determines the non-FSIS laboratory result is acceptable, FSIS may use the result to inform regulatory action (*e.g.* request a recall or detain product).

As part of the process to determine if the non-FSIS laboratory result is acceptable, the MCHS lead investigator collects information from the non-FSIS laboratory and verifies that the non-FSIS laboratory can provide the appropriate certifications and documentation of accreditation, such as ISO17025, or another third-party accreditation entity covering the methods performed. The MCHS lead investigator also verifies that the laboratory has submitted to FSIS all the necessary information, including evidence of chain of custody, and the appropriate laboratory reports with sample identification, final results, and authorization by the responsible official for affirming results. Finally, the MCHS investigator collects and verifies laboratory methods and quality assurance records documentation from the accredited, non-FSIS laboratory.

FSIS has made the estimates below based upon an information collection assessment.

Estimate of Burden: FSIS estimates that it will take respondents an average of 7.5 hours each year to comply with the information request associated with this collection.

Respondents: Non-FSIS laboratories.

Estimated Number of Respondents: 3.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 22.5 hours.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record. Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; (202) 937–4272.

Comments are invited on: (a) whether the proposed collection of information

is necessary for the proper performance of FSIS' functions, including whether the information will have practical utility; (b) the accuracy of FSIS' estimate of the burden of the proposed collection of information, including the validity of the method and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20253.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: *https://www.fsis.usda.gov/federal-register.*

FSIS will also announce and provide a link to this **Federal Register** publication through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *https://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

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In accordance with Federal civil rights law and USDA civil rights regulations and policies, USDA, its Mission Areas, agencies, staff offices, employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (*e.g.,* Braille, large print, audiotape, American Sign Language) should contact the responsible Mission Area, agency, or staff office; the USDA TARGET Center at (202) 720–2600 (voice and TTY); or the Federal Relay Service at (800) 877–8339.

To file a program discrimination complaint, a complainant should complete a Form AD–3027, *USDA Program Discrimination Complaint Form,* which can be obtained online at *https://www.ocio.usda.gov/document/ad-3027,* from any USDA office, by calling (866) 632–9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights (ASCR) about the nature and date of an alleged civil rights violation. The completed AD–3027 form or letter must be submitted to USDA by:

(1) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410;

(2) *Fax:* (833) 256–1665 or (202) 690–7442; or

(3) *Email: program.intake@usda.gov.*

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Paul Kiecker,

Administrator.

[FR Doc. 2023–07762 Filed 4–12–23; 8:45 am]

BILLING CODE 3410–DM–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Texas Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that the Texas Advisory Committee (Committee) will hold a series of meetings via ZoomGov on the following dates and times listed below. These virtual business meetings are for the purpose of reviewing and editing their interim report.

DATES: These meetings will take place on:

- Thursday, April 27, 2023, from 12 p.m.–1 p.m. CT
- Wednesday, May 10, 2023, from 12 p.m.–1 p.m. CT

Zoom Link To Join

- Thursday, April 27th: *https://www.zoomgov.com/meeting/register/vJItfu-vqTIuHqhl4g6NNHdH-cyMH4iA4Sw.*
- Wednesday, May 10th: *https://www.zoomgov.com/meeting/register/vJItcuiorzMqHtrE2kJXykzAPNK0lOrhsSE.*

FOR FURTHER INFORMATION CONTACT: Brooke Peery, DFO, at *bpeery@usccr.gov* or (202) 701–1376.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the videoconference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Closed captions will be provided for individuals who are deaf or hard of hearing. To request additional accommodations, please email *bpeery@usccr.gov* at least 10 business days prior to the meeting.

Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be emailed to Brooke Peery (DFO) at *bpeery@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzkoAAA.*

Please click on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be

inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Roll Call
II. Approval of Minutes
III. Committee Discussion
IV. Public Comment
V. Adjournment

Dated: April 10, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–07841 Filed 4–12–23; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

URAL Airlines JSC, Utrenniy Lane 1-g, Yekaterinburg, Russia 620025; Order Renewing Temporary Denial of Export Privileges

Pursuant to section 766.24 of the Export Administration Regulations, 15 CFR parts 730–774 (2021) (''EAR'' or ''the Regulations''),[1] I hereby grant the request of the Office of Export Enforcement (''OEE'') to renew the temporary denial order (''TDO'') issued in this matter on October 13, 2022. I find that renewal of this order is necessary in the public interest to prevent an imminent violation of the Regulations.

I. Procedural History

On October 13, 2022, I signed an order denying URAL Airlines JSC (''URAL'') export privileges for a period of 180 days on the ground that issuance of the order was necessary in the public interest to prevent an imminent violation of the Regulations. The order was issued *ex parte* pursuant to section 766.24(a) of the Regulations and was effective upon issuance.[2]

On March 7, 2023, BIS, through OEE, submitted a written request for renewal of the TDO that issued on October 13, 2022. The written request was made more than 20 days before the TDO's scheduled expiration. A copy of the renewal request was sent to URAL in accordance with sections 766.5 and 766.24(d) of the Regulations. No opposition to the renewal of the TDO has been received.

II. Renewal of the TDO

A. Legal Standard

Pursuant to section 766.24, BIS may issue an order temporarily denying a respondent's export privileges upon a showing that the order is necessary in the public interest to prevent an ''imminent violation'' of the Regulations, or any order, license or authorization issued thereunder. 15 CFR 766.24(b)(1) and 766.24(d). ''A violation may be 'imminent' either in time or degree of likelihood.'' 15 CFR 766.24(b)(3). BIS may show ''either that a violation is about to occur, or that the general circumstances of the matter under investigation or case under criminal or administrative charges demonstrate a likelihood of future violations.'' *Id.* As to the likelihood of future violations, BIS may show that the violation under investigation or charge ''is significant, deliberate, covert and/or likely to occur again, rather than technical or negligent[.]'' *Id.* A ''lack of information establishing the precise time a violation may occur does not preclude a finding that a violation is imminent, so long as there is sufficient reason to believe the likelihood of a violation.'' *Id.*

B. The TDO and BIS's Request for Renewal

The U.S. Commerce Department, through BIS, responded to the Russian Federation's (''Russia's'') further invasion of Ukraine by implementing a sweeping series of stringent export controls that severely restrict Russia's access to technologies and other items that it needs to sustain its aggressive military capabilities. These controls primarily target Russia's defense, aerospace, and maritime sectors and are intended to cut off Russia's access to vital technological inputs, atrophy key sectors of its industrial base, and undercut Russia's strategic ambitions to exert influence on the world stage. Effective February 24, 2022, BIS imposed expansive controls on aviation-related (*e.g.,* Commerce Control List Categories 7 and 9) items to Russia, including a license requirement for the export, reexport or transfer (in-country) to Russia of any aircraft or aircraft parts specified in Export Control Classification Number (ECCN) 9A991 (section 746.8(a)(1) of the EAR).[3] BIS will review any export or reexport license applications for such items under a policy of denial. *See* section 746.8(b). Effective March 2, 2022, BIS excluded any aircraft registered in, owned, or controlled by, or under charter or lease by Russia or a national of Russia from being eligible for license exception Aircraft, Vessels, and Spacecraft (AVS) (section 740.15 of the EAR).[4] Accordingly, any U.S.-origin aircraft or foreign aircraft that includes more than 25% controlled U.S.-origin content, and that is registered in, owned, or controlled by, or under charter or lease by Russia or a national of Russia, is subject to a license requirement before it can travel to Russia.

OEE's request for renewal is based upon the facts underlying the issuance of the initial TDO and the evidence developed over the course of this investigation, which indicate a blatant disregard for U.S. export controls, as well as the TDO. Specifically, the initial TDO, issued on October 13, 2022, was based on evidence that URAL engaged in conduct prohibited by the Regulations by operating aircraft subject to the EAR and classified under ECCN 9A991 on flights into Russia after March 2, 2022 from destinations, including Bishkek, Kyrgyzstan; Dushanbe, Tajikistan; Khudzhand, Tajikistan; and Tamchy, Kyrgyzstan, without the required BIS authorization.[5] Further evidence submitted by BIS indicated that URAL was continuing to operate aircraft subject to the EAR domestically

[1] On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, 50 U.S.C. 4801–4852 (''ECRA''). While section 1766 of ECRA repeals the provisions of the Export Administration Act, 50 U.S.C. app. 2401 *et seq.* (''EAA'') (except for three sections which are inapplicable here), section 1768 of ECRA provides, in pertinent part, that all orders, rules, regulations, and other forms of administrative action that were made or issued under the EAA, including as continued in effect pursuant to the International Emergency Economic Powers Act, 50 U.S.C. 1701 *et seq.* (''IEEPA''), and were in effect as of ECRA's date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA. Moreover, section 1761(a)(5) of ECRA authorizes the issuance of temporary denial orders. 50 U.S.C. 4820(a)(5).

[2] The TDO was published in the **Federal Register** on October 19, 2022 (87 FR 63477).

[3] 87 FR 12226 (Mar. 3, 2022). Additionally, BIS published a final rule effective April 8, 2022, which imposed licensing requirements on items controlled on the Commerce Control List (''CCL'') under Categories 0–2 that are destined for Russia or Belarus. Accordingly, now all CCL items require export, reexport, and transfer (in-country) licenses if destined for or within Russia or Belarus. 87 FR 22130 (Apr. 14, 2022).

[4] 87 FR 13048 (Mar. 8, 2022).

[5] Publicly available flight tracking information shows multiple flights into Russia, including the following: on September 10, 2022, SN 5055 flew from Dushanbe, Tajikistan to Irkutsk, Russia, and on September 6, 2022, SN 5055 flew from Khudzhand, Tajikistan to Sochi, Russia. In addition, on October 6, 2022, serial number (SN) 5055 flew from Bishkek, Kyrgyzstan to Samara, Russia.

on flights within Russia, potentially in violation of section 736.2(b)(10) of the Regulations.

In its March 7, 2023 request for renewal of the TDO, BIS has submitted evidence that URAL continues to operate in violation of the October 13, 2022 TDO and/or the Regulations by operating aircraft subject to the EAR and classified under ECCN 9A991 on flights into and out of Russia, as well as domestically within Russia. Specifically, BIS's evidence and related investigation indicated that URAL has continued to operate aircraft subject to the EAR, including, but not limited to, on flights into and out of Russia from/to Bishkek, Kyrgyzstan, Dushanbe, Tajikistan, and Khujand, Tajikistan. Information about those flights includes, but is not limited to, the following:

Tail No.	Serial No.	Aircraft type	Departure/arrival cities	Dates
RA–73817	5055	A320–232	Dushanbe, TJ/Ufa, RU	March 20, 2023.
RA–73817	5055	A320–232	Osh, KG/Ufa, RU	March 19, 2023.
RA–73817	5055	A320–232	Osh, KG/Krasnoyarsk, RU	March 19, 2023.
RA–73817	5055	A320–232	Yekaterinburg, RU/Moscow, RU	March 16, 2023.
RA–73817	5055	A320–232	Irkutsk, RU/Moscow, RU	March 11, 2023.
RA–73817	5055	A320–232	Yekaterinburg, RU/Moscow, RU	March 7, 2023.
RA–73817	5055	A320–232	Moscow, RU/Yekaterinburg, RU	March 5, 2023.
RA–73817	5055	A320–232	Dushanbe, TJ/Chelyabinsk, RU	February 27, 2023.
RA–73817	5055	A320–232	Dushanbe, TJ/Novosibirsk, RU	February 25, 2023.
RA–73818	2376	A320–232	Bishkek, KG/Yekaterinburg, RU	March 19, 2023.
RA–73818	2376	A320–232	Moscow, RU/Yekaterinburg, RU	March 14, 2023.
RA–73818	2376	A320–232	Yekaterinburg, RU/Sochi, RU	March 11, 2023.
RA–73818	2376	A320–232	Kaliningrad, RU/Moscow, RU	March 7, 2023.
RA–73818	2376	A320–232	Moscow, RU/Kaliningrad, RU	March 7, 2023.
RA–73818	2376	A320–232	Dushanbe, TJ/Sochi, RU	March 2, 2023.
RA–73818	2376	A320–232	Dushanbe, TJ/Kazan, RU	February 24, 2023.
RA–73844	1941	A321–231	Dushanbe, TJ/Yekaterinburg, RU	March 21, 2023.
RA–73844	1941	A321–231	Osh, KG/Yekaterinburg, RU	March 20, 2023.
RA–73844	1941	A321–231	Dushanbe, TJ/Yekaterinburg, RU	March 19, 2023.
RA–73844	1941	A321–231	Sochi, RU/Yekaterinburg, RU	March 19, 2023.
RA–73844	1941	A321–231	Dushanbe, TJ/Yekaterinburg, RU	March 19, 2023.
RA–73844	1941	A321–231	Sochi, RU/Moscow, RU	March 16, 2023.
RA–73844	1941	A321–231	Kulob, TJ/Moscow, RU	March 15, 2023.
RA–73844	1941	A321–231	Sochi, RU/Yekaterinburg, RU	March 12, 2023.
RA–73844	1941	A321–231	Khujand, TJ/Yekaterinburg, RU	March 11, 2023.
RA–73844	1941	A321–231	Khujand, TJ/Yekaterinburg, RU	March 6, 2023.

III. Findings

Under the applicable standard set forth in section 766.24 of the Regulations and my review of the entire record, I find that the evidence presented by BIS convincingly demonstrates that URAL has acted in violation of the Regulations and the TDO; that such violations have been significant, deliberate and covert; and that given the foregoing and the nature of the matters under investigation, there is a likelihood of imminent violations. Therefore, renewal of the TDO is necessary in the public interest to prevent imminent violation of the Regulations and to give notice to companies and individuals in the United States and abroad that they should avoid dealing with URAL in connection with export and reexport transactions involving items subject to the Regulations and in connection with any other activity subject to the Regulations.

IV. Order

It is therefore ordered:

First, URAL Airlines JSC, Utrenniy Lane 1-g, Yekaterinburg, Russia, 620025, when acting for or on their behalf, any successors or assigns, agents, or employees may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR including, but not limited to:

A. Applying for, obtaining, or using any license (except directly related to safety of flight), license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations, or engaging in any other activity subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or from any other activity subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations.

Second, that no person may, directly or indirectly, do any of the following:

A. Export, reexport, or transfer (in-country) to or on behalf of URAL any item subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by URAL of the ownership, possession, or control of any item subject to the EAR that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby URAL acquires or attempts to acquire such ownership, possession or control except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from URAL of any item subject to the EAR that has been exported from the United States except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations;

D. Obtain from URAL in the United States any item subject to the EAR with knowledge or reason to know that the item will be, or is intended to be, exported from the United States except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations; or

E. Engage in any transaction to service any item subject to the EAR that has been or will be exported from the United States and which is owned, possessed or controlled by URAL, or service any item, of whatever origin, that is owned, possessed or controlled by URAL if such service involves the use of any item subject to the EAR that has been or will be exported from the United States except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations. For purposes of this paragraph, servicing means installation, maintenance, repair, modification, or testing.

Third, that, after notice and opportunity for comment as provided in section 766.23 of the EAR, any other person, firm, corporation, or business organization related to URAL by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order.

In accordance with the provisions of sections 766.24(e) of the EAR, URAL may, at any time, appeal this Order by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202–4022.

In accordance with the provisions of section 766.24(d) of the EAR, BIS may seek renewal of this Order by filing a written request not later than 20 days before the expiration date. A renewal request may be opposed by URAL as provided in section 766.24(d), by filing a written submission with the Assistant Secretary of Commerce for Export Enforcement, which must be received not later than seven days before the expiration date of the Order.

A copy of this Order shall be provided to URAL and shall be published in the **Federal Register**.

This Order is effective immediately and shall remain in effect for 180 days.

Matthew S. Axelrod,

Assistant Secretary of Commerce for Export Enforcement.

[FR Doc. 2023–07838 Filed 4–12–23; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Hydrometer Calibrations

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of workshop; request for comments.

SUMMARY: The National Institute of Standards and Technology (NIST), an agency of the United States Department of Commerce, is examining the economic impact and continued need for Hydrometer calibration services as provided to U.S. industry by the Fluid Metrology Group on NIST's campus in Gaithersburg, Maryland. NIST is also interested in whether there is a need for liquid density calibration services not presently offered by NIST. NIST publishes this notice to announce a workshop that will guide NIST planning for the future of its hydrometer calibration capabilities, and to request comments on government and industry interest in and needs for hydrometer calibrations. This is part of the effort to systematically review NIST's Measurement Services to assess gaps and ensure alignment with stakeholders' needs as discussed in the Government Accounting Office report GAO–18–445.

DATES:

For Comments: NIST will accept written responses to this request for information until 11:59 p.m. Eastern Time on May 2, 2023. Submissions received after that date may not be considered. Written comments in response to this notice should be submitted according to the instructions in the **ADDRESSES** section below.

For Workshop: A public workshop will be held on Tuesday May 2, 2023, from 1:00 p.m. to 3:00 p.m. Eastern Time, virtually by web conferencing. Interested parties must register to participate in the public workshop no later than 5:00 p.m. Eastern Time on Monday May 1, 2023, by sending an email to *sherry.sheckels@nist.gov.*

ADDRESSES:

For Comments: Comments should be submitted to Sherry Sheckels, Sensor Science Division, Physical Measurement Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8361, Gaithersburg, Maryland 20899, or by electronic mail to *sherry.sheckels@nist.gov.* Comments referencing studies, research, and other empirical data should include copies of the referenced materials. All comments, including attachments and other supporting materials, submitted in response to this document will become part of the public record and may be subject to public disclosure. Therefore, do not submit confidential business information or otherwise sensitive, protected, or personal information, such as account numbers, Social Security numbers, or names of other individuals.

For tours: Individuals or groups interested in touring the liquid density standard laboratories in person are welcome and can schedule tours by writing to the email address, *sherry.sheckels@nist.gov,* before or after the workshop.

FOR FURTHER INFORMATION CONTACT: *Mail:* Fluid Metrology Group, Attn: Sherry Sheckels, Hydrometer Calibrations, 100 Bureau Drive, Mail Stop 8361, Gaithersburg, Maryland 20899. Email: Sherry Sheckels at *sherry.sheckels@nist.gov.* Phone number: 301 975–5940.

SUPPLEMENTARY INFORMATION: NIST provides calibration services for reference hydrometers to measure liquid density. These reference standard hydrometers are generally used as laboratory standards to calibrate other hydrometers.

Reference hydrometers accepted for calibration include specific gravity, proof spirit for alcohol solutions, API degrees for petroleum measurements, degrees Baume heavy and degrees Baume light, and other arbitrary scales, all subject to discussion with the technical contacts. Specific gravity hydrometers cover the specific gravity range of 0.65 to 2.

NIST is seeking comments on the following topics; however, NIST does not intend to limit the responses to the topics listed below, provided that the responses address topics that would be useful in planning NIST offerings for liquid density calibrations service. When addressing the topics below, respondents may describe the practices of their organization or organizations with which they are familiar. Providing such information is optional and will not affect NIST's full consideration of the comment.

Topics of Interest:

1. Have you purchased hydrometer calibrations, if any, including:

a. If you have purchased calibrations from NIST, whether you purchased from NIST due to convenience, accuracy, cost, customer service, regulatory requirement, or some other reason;

b. If NIST was to terminate the hydrometer calibration service(s) you presently use, whether you have another source lined up that would meet your requirements; and

c. Whether it would pose a problem to your organization if the calibration service was not available at NIST.

2. How NIST calibration results are applied in your organization, including numerical examples of ''leverage'' to assess the economic impact of NIST hydrometer calibration services.

3. Whether hydrometer calibrations in your organization are traceable to NIST, including:

a. Whether you refer to NIST hydrometer publications or research to support your hydrometer measurements; and

b. If not directly traceable to NIST, whether you know how your hydrometer measurements compare to NIST hydrometer standards (for example by comparison against a hydrometer traceable to a NIST calibration).

4. Feedback on the cost, availability, turn-around time, business systems, and customer service provided by NIST hydrometer calibration services.

5. Whether you purchase hydrometer calibrations from another National Metrology Institute (NMI) or from another calibration laboratory, and your organization's experience with this approach.

6. Your opinions about the range, uncertainty, quality and cost of the NIST hydrometer calibration services.

7. Whether you manufacture and sell hydrometers or sell calibrations of such hydrometers; if so, whether your hydrometer calibration values are traceable to NIST; and, if not NIST, whether you use a secondary laboratory, another NMI, or have your own primary standard(s).

Authority: 15 U.S.C. 272(b) & (c).

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2023–07815 Filed 4–12–23; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Existence and Use of Large Datasets To Address Research Questions for Characterization and Autonomous Tuning of Semiconductor Quantum Dot Devices

AGENCY: National Institute of Standards and Technology, U.S. Department of Commerce.

ACTION: Notice of workshop; request for comments.

SUMMARY: The National Institute of Standards and Technology (NIST) is seeking input regarding needs and gaps in data-sharing approaches to accelerate innovations in using artificial intelligence and machine learning techniques to improve the experimental characterization and control of semiconductor quantum dot devices. As part of this effort, NIST hopes to identify the needs for quantum dot device tuning automation, including existing and future quantum dot related datasets that may be useful for research, means and methods currently deployed for tuning, barriers for advancing the current state of the art techniques to enable automation of large quantum dot arrays, and the meaningful measures of success for the various stages of characterization and control. NIST plans to hold a workshop on July 19–20, 2023, in conjunction with this notice. The information received in response to this notice and during the workshop will inform efforts and coordination needed to develop a reference database of experimental and simulated data. The reference database will ideally represent the various phases of tuning quantum dot devices, along with metrics for benchmarking the characterization and control methods for quantum dot devices.

DATES:

For Comments: Comments must be received by 5:00 p.m. Eastern Time on June 12, 2023. Written comments in response to this notice should be submitted according to the instructions in the **ADDRESSES** section below. Submissions received after that date may not be considered.

For Workshop: The in-person Workshop on Advances in Automation of Quantum Dot Devices Characterization and Control will be held on July 19–20, 2023, from 9:00 a.m. to 5:00 p.m. Eastern Time at the National Cybersecurity Center of Excellence (NCCoE), 9700 Great Seneca Highway, Rockville, MD 20850. Attendees must register at the workshop website by 5:00 p.m. Eastern Time on June 19, 2023.

ADDRESSES:

For Comments: Written comments may be submitted only by email to Dr. Justyna Zwolak at *aqd@nist.gov* in any of the following formats: ASCII; Word; RTF; or PDF. Please include your name, organization's name (if any), and cite ''Automation of Semiconductor Quantum Dot Devices'' in the subject line of all correspondence. Comments containing references, studies, research, and other empirical data that are not widely published should include copies of the referenced materials. All comments responding to this document will be a matter of public record. Relevant comments will generally be made publicly available at *https://www.nist.gov/news-events/events/2023/07/advances-automation-quantum-dot-devices-control* as submitted. NIST will not accept comments accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. Therefore, do not submit confidential business information or otherwise sensitive, protected, or personal information, such as account numbers, Social Security numbers, or names of other individuals.

For Workshop: The workshop will be held at NCCoE, 9700 Great Seneca Highway, Rockville, MD 20850. Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice. To register, go to: *https://www.nist.gov/news-events/events/2023/07/advances-automation-quantum-dot-devices-control.* Additional information about the workshop will be available at this web address as the workshop approaches.

FOR FURTHER INFORMATION CONTACT: For questions about this notice contact Justyna Zwolak or Jacob Taylor by email at *aqd@nist.gov* or Justyna Zwolak by phone at (301) 975–0527. Please direct media inquiries to NIST's Office of Public Affairs at (301) 975–2762.

SUPPLEMENTARY INFORMATION:

Background: Over the past five years, researchers working with semiconducting quantum dot devices have begun to take advantage of the data analysis tools provided by the field of artificial intelligence and, more specifically, supervised and unsupervised machine learning. When provided with proper training data, machine-learning-enhanced methods may have the flexibility of being applicable to various devices without any adjustments or retraining. Moreover, by learning the governing rules and dynamics directly from the data, machine learning algorithms may be less susceptible to programming errors. However, machine learning models typically require large, labeled datasets for training, validation, and benchmarking. They also often lack information about the reliability of the machine learning prediction. Moreover, since the application of machine learning to quantum dot tuning, characterization, and control is a relatively new field of research, it lacks standardized measures of success. The success rates reported in the various publications vary significantly in both the level and meaning of the reported performance statistics, making it hard (if

not impossible) to benchmark the proposed techniques against more traditional tuning approaches or against one another.

Through this notice, we seek public comment to identify existing large datasets that may be useful for research; identify best practices for creating new, large datasets that are valuable for research; understand the challenges and limitations that may impact data access; and current and future key metrics of performance for the tuning methods.

Request for Comments:

The following statements are not intended to limit the topics that may be addressed. Responses may include any topic believed to have implications for the development of auto-tuning methods for semiconductor quantum dot devices, regardless of whether the topic is included in this document. All relevant responses that comply with the requirements listed in the **DATES** and **ADDRESSES** sections of this notice will be considered.

NIST seeks input from stakeholders regarding the broadly defined needs for automation of quantum dot device characterization and tuning. A simple but crucial component of success for the field will be to solidify key metrics of performance as well as establish standard datasets that can be used to assess those metrics on the newly proposed methods and algorithms. Among the simple metrics that have been used to date are state identification accuracy (probability of a classifier identifying the right topology) and tuning success (probability of the navigation algorithm getting to the right region of parameter space). However, more such metrics, and associated datasets, will be necessary to leverage machine learning algorithms most effectively. So far, machine learning efforts for semiconductor quantum dots rely on datasets that either come from simulations (and thus may lack important features representing real-world noise and imperfections) or are labeled manually (and subject to qualitative and/or erroneous classification). Moreover, with a few exceptions, these datasets are not made publicly available. Yet, systematic benchmarking of tuning methods on standardized datasets, analogous to the MNIST or CIFAR datasets in the broad machine learning community, is a crucial next step on the path to developing reliable and scalable auto-tuners for quantum dot devices.

Through this notice, we seek public comment to initiate a community-wide effort to build an open-access data repository for benchmarking automated methods for quantum dot devices. To initiate such efforts, NIST has provided a starting point: an open dataset, *QFlow,* hosted at the NIST science data portal *www.data.nist.gov,* that includes a large number of simulated measurements as well as a small set of experimental scans. A standardized dataset that would enable systematic benchmarking of the already existing and new auto-tuning methods should represent data from different types of devices. This standardization work will take time and community engagement, based on experience from other machine learning disciplines. Once standardization is in place, more algorithmic exploration and improvement can be achieved.

We invite any member of the public, and specifically those who are aware of datasets relevant to auto-tuning quantum dot devices or interested in establishing a large open-access database of experimental data; those who have perspectives on the value of these datasets for research; and those who are aware of challenges and limitations to both access and use of large datasets to share their input on the following points in their comments:

(1) Identify public or restricted use datasets related to the various phases of tuning semiconductor quantum dot devices that are available for training and benchmarking new artificial intelligence models or to test hypotheses using data mining/machine learning methods. Describe the research needs that are not being met by the datasets that are currently available.

(2) Describe the work researchers need to do to access, and then explore the quality of, an existing dataset before conducting research with it. Identify what aspects of this work could be reduced or conducted just once so that future researchers can reduce the time needed to complete a research project.

(3) Describe promising approaches to testing and improving the validity of performance metrics within large datasets, especially those datasets that consist of experimental data that does not come with ground truth labels.

(4) Describe whether existing datasets, both simulated and acquired experimentally, contain data that are valuable for researchers and are of sufficient quality that research could be conducted with a high amount of rigor.

(5) Describe to what extent existing datasets capture enough information to address research related to all aspects of tuning quantum dot devices. Identify what additional data should be collected to address these research questions.

(6) Describe the best practices for creating new datasets or linking existing datasets and sharing them with researchers (open or restricted use) while adhering to local, State, and Federal laws. Identify barriers and limitations that currently exist.

(7) Describe what role NIST can play in developing infrastructure that supports the use of large-scale datasets for research on tuning quantum dot devices

Workshop:

The purpose of the workshop is to convene stakeholders from industry, academia, and the government interested in the research and development of semiconductor quantum computing technologies. Topics to be discussed include opportunities for research and development of tuning, characterization, and control methods for semiconductor quantum dot devices, the need for facilitating interaction and collaboration between the stakeholders to build a large open-access database of experimental and simulated data for benchmarking new machine learning algorithms, determining key performance metrics for the various aspects of the tuning, characterizing, and controlling of quantum dot devices, and identifying barriers to near-term and future applications of the auto-tuning methods. Furthermore, this workshop will provide a discussion place to consider methods of collaboration in a neutral setting and future roadmap development for methods for tuning large-scale devices.

This workshop will focus on addressing the key challenges described above under ''Request for Comments.'' It will include invited presentations by leading experts from academia, industry, and government; time for group discussion; and breakout sessions for discussing questions (1) through (7). No proprietary information will be accepted, presented or discussed as part of the workshop, and all information accepted, presented or discussed at the workshop will be in the public domain.

More information about the workshop can be found at *https://www.nist.gov/news-events/events/2023/07/advances-automation-quantum-dot-devices-control.* All participants must pre-register to be admitted. Also, please note that federal agencies, including NIST, can only accept a state-issued driver's license or identification card for access to federal facilities if such license or identification card is issued by a state that is compliant with the REAL ID Act of 2005 (Pub. L. 109–13), or by a state that has an extension for REAL ID compliance. NIST currently accepts other forms of federally-issued identification in lieu of a state-issued driver's license. For detailed information please contact Meliza Lane

at *elsie.lane@nist.gov* or by phone (303) 497–5356 or visit: *http://www.nist.gov/public_affairs/visitor/.*

Authority: 15 U.S.C. 272(b) & (c); 15 U.S.C. 278h–1.

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2023–07814 Filed 4–12–23; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XV192]

Space Weather Advisory Group Meeting

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Space Weather Advisory Group (SWAG) will meet for a full day on April 17, 2023.

DATES: The meeting is scheduled as follows: April 17, 2023 from 9 a.m.–5 p.m. Mountain Daylight Saving Time (MDT).

ADDRESSES: The public meeting will be a hybrid event with the SWAG and registered Space Weather Workshop attendees convening ''in person'' at the Embassy Suites Boulder, 2601 Canyon Blvd., Boulder, CO, and any additional public participants attending virtually via Webinar. For details on how to connect to the webinar or to submit comments, please visit *www.weather.gov/swag* or contact Jennifer Meehan, National Weather Service; telephone: 301–427–9798; email: *jennifer.meehan@noaa.gov*.

FOR FURTHER INFORMATION CONTACT: Jennifer Meehan, National Weather Service, NOAA, 1325 East West Highway, Silver Spring, Maryland, 20910; 301–427–9798 or *jennifer.meehan@noaa.gov*; or visit the SWAG website: *https://www.weather.gov/swag.*

SUPPLEMENTARY INFORMATION: Pursuant to the Promoting Research and Observations of Space Weather to Improve the Forecasting of Tomorrow (PROSWIFT) Act, 51 U.S.C. 60601 *et seq.,* the Administrator of NOAA and the National Science and Technology Council's Space Weather Operations, Research, and Mitigation (SWORM) Subcommittee established the Space Weather Advisory Group (SWAG) on April 21, 2021. The SWAG is the only Federal Advisory SWAG that advises and informs the interest and work of the SWORM. The SWAG is to receive advice from the academic community, the commercial space weather sector, and nongovernmental space weather end users to carry out the responsibilities of the SWAG set forth in the PROSWIFT Act, 51 U.S.C. 60601 *et seq.*

The SWAG is directed to advise the SWORM on the following: facilitating advances in the space weather enterprise of the United States; improving the ability of the United States to prepare for, mitigate, respond to, and recover from space weather phenomena; enabling the coordination and facilitation of research to operations and operations to research, as described in section 60604(d) of title 51, United States Code; and developing and implementing the integrated strategy under 51 U.S.C. 60601(c), including subsequent updates and reevaluations. The SWAG shall also conduct a comprehensive survey of the needs of users of space weather products to identify the space weather research, observations, forecasting, prediction, and modeling advances required to improve space weather products, as required by 51 U.S.C. 60601(d)(3).

Matters To Be Considered

The meeting will be open to the public. During the meeting, the SWAG will discuss the PROSWIFT Act, 51 U.S.C. 60601 *et seq.,* directed duties of the SWAG including the required 51 U.S.C. 60601(d)(3) user survey. The full agenda and meeting materials will be published on the SWAG website: *https://www.weather.gov/swag.*

Additional Information and Public Comments

The meeting will be held over one full day and will be conducted in a hybrid manner (for meeting details see **ADDRESSES**). Please register for the meeting through the website: *https://www.weather.gov/swag.*

This event is accessible to individuals with disabilities. For all other special accommodation requests, please contact *Jennifer.meehan@noaa.gov.* This webinar is a NOAA public meeting and will be recorded and transcribed. If you have a public comment, you acknowledge you will be recorded and are aware you can opt out of the meeting. Participation in the meeting constitutes consent to the recording. Both the meeting minutes and presentations will be posted to the SWAG website (*https://www.weather.gov/swag*). The agenda, speakers and times are subject to change. For updates, please check the SWAG website (*https://www.weather.gov/swag*).

Public comments directed to the SWAG members and SWAG related topics are encouraged. In particular, the SWAG would like to hear from all interested parties who would like to participate in the required 51 U.S.C. 60601(d)(3) user survey focus groups for Aviation, Power Grid, Space Situational Awareness, Human Space Flight, and Research sectors. If you are willing and able to participate, please indicate your interest in the Google form: *https://forms.gle/ATABkpKCybUcjLLk9.*

For other written public comments, please email *jennifer.meehan@noaa.gov* by April 17, 2023. Written comments received after this date will be distributed to the SWAG but may not be reviewed prior to the meeting date. As time allows, public comments will be read into the public record during the meeting. Advance comments will be collated and posted to the meeting website.

Michael Farrar,

Director, National Centers for Environmental Prediction, National Weather Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2023–07728 Filed 4–12–23; 8:45 am]

BILLING CODE 3510–KE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC757]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Pile Driving and Removal to Improve the Auke Bay East Ferry Terminal

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 Alaska Department of Transportation and Public Facilities (ADOT&PF) for authorization to take marine mammals incidental to pile driving to improve the Auke Bay East Ferry Terminal in Juneau, 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, as described in Request for Public Comments at the end of this notice. 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 May 15, 2023.

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.cockrell@noaa.gov.*

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, 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 *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: Craig Cockrell, Office of Protected Resources, NMFS, (301) 427–8401. 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 above.

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 mitigation, monitoring and reporting of the takings are set forth. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

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 NOAA Administrative Order 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.

We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the IHA request.

Summary of Request

On September 13, 2022, NMFS received a request from ADOT&PF for an IHA to take marine mammals incidental to vibratory and impact pile driving to improve the Auke Bay East Ferry Terminal. Following NMFS' review of the application, ADOT&PF submitted a revised version on January 11, 2023. The application was deemed adequate and complete on February 14, 2023. The ADOT&PF's request is for the incidental take of small numbers of 11 species or stocks of marine mammals, in the form of Level B harassment for all and, for harbor seals and harbor porpoise, including take by Level A harassment. Neither ADOT&PF nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Proposed Activity

Overview

ADOT&PF is proposing maintenance improvements to the existing Alaska Marine Highway System (AMHS) Auke Bay East Berth marine terminal. The activity includes removal of existing piles and the installation of both temporary and permanent piles of various sizes. Takes of marine mammals by Level A and Level B harassment would occur due to both impact and vibratory pile driving and removal. The project would occur in Auke Bay which is located in southeast Alaska in close proximity to the City of Juneau. Construction activities are expected to over a four month period in fall 2023. It is expected to take up to 61 days to complete the pile driving activities.

The Auke Bay Ferry Terminal is located along the north shore of Auke Bay and is a major hub of the Southeast and Gulf of Alaska routes of the AMHS. The purpose of the Project is to restore the service life of the AMHS Auke Bay East Berth ferry terminal, which was originally built in 1982. The dolphins have undergone several repair projects and are currently in need of full replacement to keep the facility safe and usable for the AMHS vessels that frequent the facility.

Dates and Duration

The proposed activities are expected to occur between October 1, 2023 and September 30, 2024. It is expected to take up to 61 non-consecutive days of in water work over a four month work window to complete the pile driving activities. Pile driving would be completed intermittently throughout the daylight hours. All pile driving is expected to be completed during one phase of construction.

Specific Geographic Region

Auke Bay is an estuary at the southern end of Lynn Canal, located approximately 18 kilometers (km) (11 miles (mi)) north-northwest of downtown Juneau. The bay is one of many that lead to a larger system of

glacial fjords connecting various channels with the open ocean. Auke Bay is approximately 130 km (80.7 mi) inland from the Gulf of Alaska (Figure 1). Auke Bay contains several small islands and reefs within the 11 square kilometer (km^2) (4.25 square mile (mi^2)) embayment. While most of the bay is relatively shallow, reaching depths of 40 to 60 meters (m) (131 to 197 feet (ft)), depths of more than 100 m (328 ft) are found near Coghland Island (see Figure 1–2 in the IHA application). Pile installation and removal at the ferry terminal would occur in waters ranging in depth from less than 1 m (3.3 ft) near shore to approximately 11 m (35 ft).

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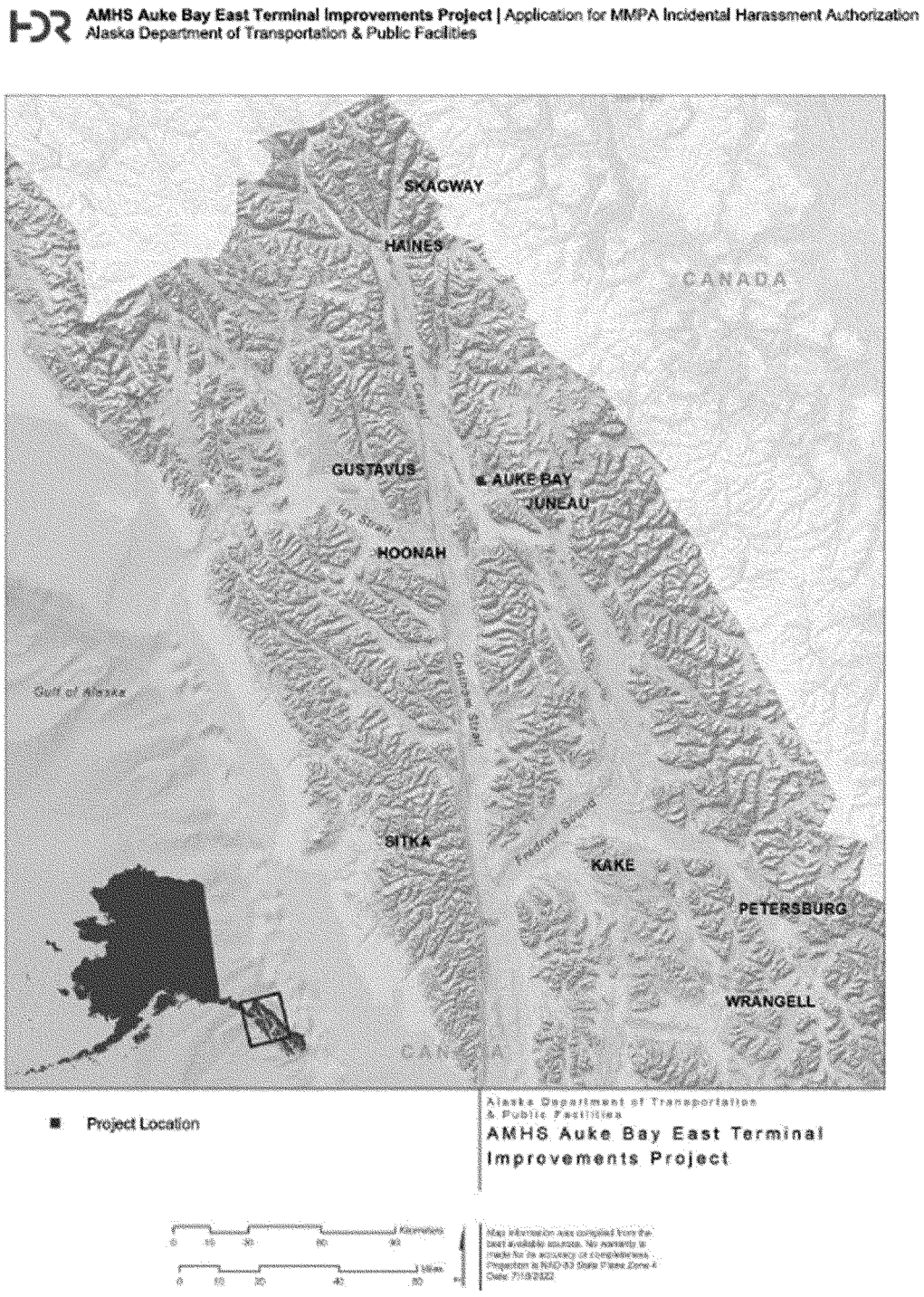


Figure 1. Project Location in Southeast Alaska

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Detailed Description of the Specified Activity

The ferry terminal improvements include the removal of 47 existing steel pipe piles. Once the existing piles are removed, up to 20 new steel pipe piles (30-inch (in) (76.2 centimeters (cm)) diameter; 10 plumb, 10 battered) would be installed as berthing dolphins. Eight new steel pipe piles (24-in diameter (61 cm); 4 plumb, 4 battered) would be installed as float restraints. Four new steel pipe piles (18-in diameter (45.7 cm)) would be installed as gangway and platform support. The installation and removal of 32 temporary 24-in steel pipe piles would be completed to support permanent pile installation. Vibratory and impact hammers will be used for the installation and removal of all piles (Table 1). Removal of piles would be conducted using vibratory hammers. After new piles are set with a vibratory hammer, installed piles would be proofed with an impact hammer to verify the structural capacity of the pile embedment. The work would be completed at the existing Auke Bay Ferry Terminal in Juneau, Alaska. Work on the terminal would be completed within 1-year starting in October and completion in September.

TABLE 1—NUMBER AND TYPES OF PILES TO BE INSTALLED AND REMOVED

Pile diameter and type	Number of piles	Strikes per pile (impact)	Duration per pile (minutes)	Piles per day (range)	Days of activity
Pile Installation					
30 in Steel Plumb Piles (Permanent; Berthing Dolphins)	10	1,000	60	1.5 (1–2)	7
30 in Steel Batter Piles (Permanent; Berthing Dolphins)	10	1,000	60	1.5 (1–2)	7
24 in Steel Plumb Piles (Permanent; Float Restraint)	4	1,000	60	1.5 (1–2)	3
24 in Steel Batter Piles (Permanent; Float Restraint)	4	1,000	60	1.5 (1–2)	3
18 in Steel Plumb Piles (Permanent; Gangway/Platform Support)	4	800	60	1.5 (1–2)	3
24 in Steel Piles (Temporary)	32	500	30	3 (2–4)	11
Pile Removal					
18 in Steel Plumb Piles (Existing)	47	N/A	30	3 (2–4)	16
24 in Steel Piles (Temporary)	32	N/A	30	3 (2–4)	11
Total	143				61

Above-water construction would include replacement of the catwalk access gangway, refurbishment of the catwalks, lighting upgrades along dolphins and catwalk, removal and replacement of electrical components as needed to perform dolphin replacement work, and installation of cathodic protection anodes on all piles. This above-water work is not expected to result in any take. Noise generated above the water would not be transmitted into the water and, there are no major pinniped haulouts located near the project area, therefore airborne noise is therefore not considered further in this document.

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, incorporated here by reference, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs; *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 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. 2021 SARs, and NMFS has reviewed the most current information for all species, including those updated in the Draft 2022 SARs.

On January 24, 2023, NMFS published the draft 2022 SARs (*https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region*). The Alaska and Pacific Ocean SARs include proposed updates to the humpback whale and harbor porpoise stock structures. The new humpback whale stock structure, if finalized, would modify the MMPA-designated stocks to align more closely with the ESA-designated DPSs. The new harbor porpoise stock structure, if finalized, would split the Southeast Alaska stock into three new stocks. Please refer to the draft 2022 Alaska (Young *et al.,* 2023) and Pacific Ocean SARs for additional information.

NMFS Office of Protected Resources, Permits and Conservation Division has generally considered peer-reviewed data in draft SARs (relative to data provided in the most recent final SARs), when available, as the best available science, and has done so in this rule for all species and stocks, with the exception of a new proposal to revise humpback whale stock structure. Given that the proposed changes to the humpback whale stock structure involve application of NMFS's Guidance for Assessing Marine Mammals Stocks and could be revised following consideration of public comments, it is more appropriate to conduct our analysis in this proposed IHA based on the status quo stock structure identified in the most recent final SARs (2021; Carretta *et al.,* 2022; Muto *et al.,* 2022).

All values presented in Table 2 are the most recent available at the time of publication (including from the draft 2022 SARs) and are available online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*).

TABLE 2—SPECIES LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Family Balaenopteridae (rorquals):						
Humpback whale	*Megaptera novaeangliae*	Central North Pacific	-/-; Y	10,103 (0.3, 7,890, 2006)	3.4	4.46
Minke whale	*Balaenoptera acutorostrada*	Alaska	-/-; N	N/A (N/A, N/A, N/A)	UND	0
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae:						
Killer whale	*Orcinus orca*	Alaska Resident	-/-; N	1,920 (N/A, 1,920, 2019)	19	1.3
		West Coast Transient	-/-; N	349 (N/A, 349, 2018)	3.5	0.4
Pacific white-sided dolphin	*Lagenorhynchus obliquidens*	North Pacific	-/-; N	26,880 (N/A, N/A, 1990)	UND	0
Family Phocoenidae (porpoises):						
Harbor porpoise	*Phocoena phocoena*	Southern Southeast Alaska Inland Waters.	-/-; Y	890 (0.37; 610; 2019)	6.1	7.4
Dall's porpoise	*Phocoenoides dalli*	Alaska	-/-; N	UND (UND, UND, 2015)	UND	37
Order Carnivora—Superfamily Pinnipedia						
Family Otariidae (eared seals and sea lions):						
Steller sea lion	*Eumetopias jubatus*	Eastern DPS	-/-; N	43,201 (N/A, 43,201, 2017).	2,592	112
		Western DPS	E/D; Y	52,932 (N/A, 53,932, 2019).	318	254
California sea lion	*Zalophus californianus*	U.S	-/-; N	257,606 (N/A, 233,515, 2014).	14,011	>321
Northern fur seal	*Callorhinus ursinus*	Eastern Pacific	-/-; Y	626,618 (0.2, 530,376, 2019).	11,403	373
Family Phocidae (earless seals):						
Harbor seal	*Phoca vitulina*	Lynn Canal/Stephens Passage	-/-; N	13,388 (N/A, 11,867, 2016).	214	50
Northern Elephant Seal	*Mirounga angustirostris*	California	-/-; N	187,386 (N/A, 85,369, 2013).	5,122	13.7

[1] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] NMFS marine mammal stock assessment reports online at: *www.nmfs.noaa.gov/pr/sars/.* CV is coefficient of variation; Nmin is the minimum estimate of stock abundance. In some cases, CV is not applicable.

[3] 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.

As indicated above, all 11 species (with 13 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 proposed survey areas are included in Table 3–1 of the IHA application. The spatial and temporal occurrence of gray whales and fin whales in the area is such that take is not expected to occur. Sightings of gray whales and fin whales are uncommon in the inland waters of southeast Alaska. These species are typically seen closer to the open waters of the Gulf of Alaska. Additionally, the timing of the project (October–December) coincides with the period when these species are expected to be further south in their respective breeding areas. Take of gray whales and fin whales has not been requested nor is proposed to be authorized and these species are not considered further in this document. The take of Northern fur seals was not requested by the applicant, but further communication with the NMFS Alaska Regional Office resulted in their inclusion in species that inhabit the area as well as being at risk for take during the construction activities (Wright, S., pers. comm.).

Humpback Whale

Humpback whales in the project area are from the Central North Pacific stock but may be of the Hawaii or Mexico Distinct Population Segments (DPS). Humpback whales migrate to southeast Alaska in spring to feed after months of fasting in equatorial breeding grounds in Hawaii and Mexico. Humpback whales found in the project areas are predominantly members of the Hawaii DPS (98 percent probability in

Southeast Alaska), which is not listed under the ESA. However, based on a comprehensive photo-identification study, members of the Mexico DPS, which is listed as threatened, have a small potential to occur in the project location (2 percent probability in Southeast Alaska) (Wade, 2021). Peak abundance of humpback whales in southeast Alaska typically occurs during late summer to early fall. Most humpback whales begin returning to southern breeding grounds in fall or winter. However, due to temporal overlap between whales departing and returning, humpbacks can be found in Alaskan feeding grounds in every month of the year (Baker *et al.,* 1985; Straley, 1990; Wynne and Witteveen, 2009). It is also common for some humpback whales to overwinter in areas of southeast Alaska. It is thought that those humpbacks that remain in southeast Alaska do so in response to the availability of winter schools of fish, such as herring (Straley, 1990).

Southeast Alaska is considered a biologically important area for feeding humpback whales between March and May (Ellison *et al.* 2012). Most humpback whales migrate to other regions during winter to breed, but over-wintering (non-breeding) humpback whales have been noted and may be increasingly common (Straley, 1990). In Alaska, humpback whales filter feed on tiny crustaceans, plankton, and small fish such as walleye pollock, Pacific sand lance, herring, eulachon, and capelin (Witteveen *et al.,* 2012). It is common to observe groups of humpback whales cooperatively bubble feeding.

Use of Auke Bay by humpback whales is intermittent and irregular year-round. During winter, researchers have documented 1 to 19 individual humpback whales per month in waters close to the project area, including Lynn Canal (Moran *et al.,* 2018a; Straley *et al.,* 2018). Group sizes in southeast Alaska generally range from one to four individuals (Dahlheim *et al.,* 2009).

Minke Whale

Minke whales in Southeast Alaska are part of the Alaska stock (Muto *et al.,* 2022). Dedicated surveys for cetaceans in Southeast Alaska found that minke whales were scattered throughout inland waters from Glacier Bay and Icy Strait to Clarence Strait, with small concentrations near the entrance of Glacier Bay. All sightings were of single minke whales, except for a single sighting of multiple minke whales. Surveys took place in spring, summer, and fall, and minke whales were present in low numbers in all seasons and years. No information appears to be available on the winter occurrence of minke whales in Southeast Alaska (Dahlheim *et al.,* 2009). Anecdotal observations suggest that minke whales do not enter Auke Bay but their occurrence in Southeast Alaska could result in their presences in the Project area.

Killer Whale

Killer whales have been observed in all the world's oceans, but the highest densities occur in colder and more productive waters found at high latitudes (NMFS 2016a). Killer whales occur along the entire Alaska coast, in British Columbia and Washington inland waterways, and along the outer coasts of Washington, Oregon, and California (NMFS, 2016a). There are three distinct ecotypes, or forms, of killer whales recognized: resident, transient, and offshore. The three ecotypes differ morphologically, ecologically, behaviorally, and genetically. Based on data regarding association patterns, acoustics, movements, and genetic differences, eight killer whale stocks are now recognized within the Pacific U.S. Exclusive Economic Zone. This application considers only the Eastern North Pacific Alaska Resident Stock (Alaska Resident Stock), Eastern North Pacific Northern Resident Stock (Northern Resident Stock), and West Coast Transient Stock, because all other stocks occur outside the geographic area under consideration (Muto *et al.,* 2022).

Transient killer whales hunt and feed primarily on marine mammals, while residents forage primarily on fish. Transient killer whales feed primarily on harbor seals, Dall's porpoises, harbor porpoises, and sea lions. Resident killer whale populations in the eastern North Pacific feed mainly on salmonids, showing a strong preference for Chinook salmon (NMFS, 2016a).

No systematic studies of killer whales have been conducted in or around Auke Bay. Killer whales were observed infrequently (on 11 of 135 days) during monitoring nearby in Hoonah, 54 km west of Auke Bay, and most were recorded in deeper, offshore waters (Berger ABAM, 2016). Dalheim *et al.* (2009) observed transient killer whales within Lynn Canal, Icy Strait, Stephens Passage, Frederick Sound, and upper Chatham Strait. Transient killer whales tend to transit through Lynn Canal and occasionally enter Auke Bay to target local harbor seal, harbor porpoise, or Steller sea lion populations, but do not linger in the Project area (K. Savage, pers. comm.).

Pacific White-Side Dolphin

Pacific white-sided dolphins are a pelagic species inhabiting temperate waters of the North Pacific Ocean and along the coasts of California, Oregon, Washington, and Alaska (Muto *et al.* 2022). Despite their distribution mostly in deep, offshore waters, they may also be found over the continental shelf and in nearshore waters, including inland waters of Southeast Alaska (Ferrero and Walker, 1996). They prey on squid and small schooling fish such as capelin, sardines, and herring, are known to work in groups to herd schools of fish, and can dive underwater for up to 6 minutes to feed (Morton, 2006).

Scientific studies and data are lacking relative to the presence or abundance of Pacific white-sided dolphins in or near Auke Bay. When Pacific white-sided dolphins have been observed, sighting rates were highest in spring and decreased throughout summer and fall (Dahlheim *et al.,* 2009). Most observations of Pacific white-sided dolphins occur off the outer coast or in inland waterways near entrances to the open ocean. According to NOAA (Muto *et al.,* 2022), aerial surveys in 1997 sighted one group of 164 Pacific white-sided dolphins in the Dixon Entrance to the south of Auke Bay. These observational data, combined with anecdotal information, indicate that there is a small potential for Pacific white-sided dolphins to occur in the Project area.

Harbor Porpoise

The Southeast Alaska stock of harbor porpoises ranges from Cape Suckling to the Canada border (Muto *et al.,* 2022). Harbor porpoises frequent primarily coastal waters in southeast Alaska (Dalheim *et al.,* 2009) and occur most frequently in waters less than 100 m (328 ft) deep (Hobbs and Waite, 2010). Harbor porpoises forage in waters less than 200 m (656 ft) deep on small pelagic schooling fish such as herring, cod, pollock, octopus, smelt, and bottom-dwelling fish, occasionally feeding on squid and crustaceans (Bjørge and Tolley 2009; Wynne *et al.,* 2011). Calving generally occurs from May to August, but can vary by region.

Although there have been no systematic studies or observations of harbor porpoises specific to Auke Bay, there is the potential for them to occur within the project area. Abundance data for harbor porpoises in southeast Alaska were collected during 18 seasonal surveys spanning 22 years, from 1991 to 2012. During that study, a total of 398 harbor porpoises were observed in the northern inland waters of southeast

Alaska, including Lynn Canal (Dahlheim *et al.,* 2015). Recent monitoring from ADOT&PF from within Auke Bay observed a total of 28 animals over a 25 day period (ADOT&PF, 2021. NMFS also completed observations in Auke Bay where 62 groups of harbor porpoises were seen over a 60-hour period. The survey was conducted from March through June in 2021.

Dall's Porpoise

Dall's porpoises are found throughout the North Pacific, from southern Japan to southern California and north to the Bering Sea. All Dall's porpoises in Alaska are members of the Alaska stock, and those off California, Oregon, and Washington are part of a separate stock. This species can be found in offshore, inshore, and nearshore habitat, but prefers waters more than 183 meters deep (Dahlheim *et al.,* 2009; Jefferson, 2009).

No systematic studies of Dall's porpoise abundance or distribution have occurred in Auke Bay; however, Dall's porpoises have been consistently observed in Lynn Canal, Stephens Passage, upper Chatham Strait, Frederick Sound, and Clarence Strait (Dalheim *et al.,* 2000). The species is generally found in waters in excess of 600 feet (183 meters) deep, which do not occur in Auke Bay. Despite generalized water depth preferences, Dall's porpoises may occur in shallower waters. Moran *et al.* (2018a) recently mapped Dall's porpoise distributions in bays, shallow water, and nearshore areas of Prince William Sound, habitats not typically utilized by this species. A lone Dall's porpoise was sighted in the Level B harassment zone during construction activities conducted by ADOT&PF at Auke Bay in 2021 (ADOT&PF, 2021). If Dall's porpoises occur in the Project area, they will likely be present in March or April, given strong seasonal patterns observed in nearby areas of Southeast Alaska (Dalheim *et al.,* 2009).

Steller Sea Lion

Steller sea lions are found throughout the northern Pacific Ocean, including coastal and inland waters from Russia (Kuril Islands and the Sea of Okhotsk), east to Alaska, and south to central California (Año Nuevo Island). Steller sea lions were listed as threatened range-wide under the ESA on November 26, 1990 (55 FR 49204, November 26, 1990); they were subsequently partitioned into the western and eastern DPSs (wDPS and eDPS, respectively) in 1997 (Allen and Angliss, 2010). The eDPS remained classified as threatened (62 FR 24345, May 5, 1997) until it was delisted in November 2013, while the wDPS (those individuals west of 144° W longitude or Cape Suckling, Alaska) was upgraded to endangered status following separation of the stocks, and it remains listed as endangered.

The majority of Steller sea lions that inhabit Southeast Alaska are part of the eDPS; however, branded individuals from the wDPS make regular movements across the 144° longitude boundary to the northern ''mixing zone'' haulouts and rookeries within southeast Alaska (Jemison *et al.,* 2013). While haulouts and rookeries in the northern portion of Southeast Alaska may be important areas for wDPS animals, there continues to be little evidence that their regular range extends to the southern haulouts and rookeries in Southeast Alaska (Jemison *et al.,* 2018). However, genetic data analyzed in Hastings *et al.* (2020) indicated that up to 1.4 percent of Steller sea lions near the Project area may be members of the wDPS, which NMFS recommends using in their 2020 guidance (NMFS, 2020).

Steller sea lions are opportunistic predators, feeding primarily on a wide variety of fishes and cephalopods, including Pacific herring (*Clupea pallasi*), walleye pollock (*Gadus chalogramma*), capelin (*Mallotus villosus*), Pacific sand lance (*Ammodytes hexapterus*), Pacific cod (*Gadus machrocephalus*), salmon (*Oncorhynchus spp.*), and squid (*Teuthida spp.*) (Jefferson *et al.,* 2008; Wynne *et al.,* 2011). Steller sea lions do not generally eat every day, but tend to forage every one to two days and return to haulouts to rest between foraging trips (Merrick and Loughlin, 1997; Rehberg *et al.,* 2009).

The action area is not located in or near designated critical habitat for the wDPS of Steller sea lions. In southeast Alaska, critical habitat for the wDPS includes a terrestrial zone, an aquatic zone, and an in-air zone that extends 3,000 ft (0.9 km) landward, seaward, and above, respectively, any designated major rookery and major haulout. Steller sea lions are common within the project area; however, systematic counts or surveys have not been completed. The species generally occurs in Auke Bay only during winter. In the marine mammal monitoring report for a project completed at the same facility by ADOT, 30 Steller sea lions were observed within the behavioral disturbance zone during pile driving or drilling (*i.e.,* documented as Level B harassment take) (ADOT&PF, 2021). The Auke Bay boating community observes Steller sea lions transiting between Auke Bay and the Benjamin Island haulout regularly during winter and provides anecdotal reports of Steller sea lions utilizing Fritz Cove in winter months. Most individuals that frequent Auke Bay use the major haulout on Benjamin Island in Lynn Canal (approximately 34 mi (54.7 km) from the project location), but several other haulouts are located within 20 to 30 km (12 to 19 mi) of the project area.

California Sea Lion

California sea lions have been separated into five genetically distinct stocks, with the U.S. Stock also known as the Pacific Temperate Stock (Carretta *et al.,* 2022). Male California sea lions disperse widely from their breeding rookeries in southern California to forage as far north as Canada (Carretta *et al.,* 2022), with some individuals observed dispersing farther north.

The U.S. stock of California sea lions have a wide range, typically from the border of the United States and Mexico (NMFS, 2019c). During the winter males commonly migrate to feeding grounds off California, Oregon, Washington, British Columbia and recently Southeast Alaska. There is an active unusual mortality event declared for the U.S. stock of California sea lions but this is mostly limited to southern California. Females and pups on the other hand stay close to breeding colonies until the pups have weened. The furthest north females have been observed is off the coast of Washington and Oregon during warm water years (NMFS, 2019c). While California sea lions aren't common in Alaska, one was present on the docks in Statter Harbor within Auke Bay in 2017 (NOAA, 2017).

California sea lions feed primarily offshore in coastal waters. They are opportunistic predators and eat a variety of prey including squid, anchovies, mackerel, rockfish and sardines (NMFS, 2019c). California sea lion breeding areas are mostly in southern California and are not expected to spatially overlap with the project area.

Northern Fur Seal

Northern fur seals occur from southern California north to the Bering Sea and west to the Sea of Okhotsk and Honshu Island, Japan. During the summer breeding season, most of the worldwide population is found on the Pribilof Islands (St. Paul Island and St. George Island) in the southern Bering Sea, with the remaining animals on rookeries in Russia, on Bogoslof Island in the southern Bering Sea, on San Miguel Island off southern California, and on the Farallon Islands off central California (Muto *et al.* 2022). Northern fur seals feed on a variety of prey including, squid, walleye pollock

(*Gadus chalcogrammus*), Pacific hearing (*Clupea pallasii*), and capelin (*Mallotus villosus*) (Gomez *et al.,* 2015). Breeding and important haulouts areas are not expected to spatially overlap with the project area.

Northern fur seals are rare in the Auke Bay in general, but one lone animal was sighted swimming in the Gastineau Channel in 2019. In 2021 three Northern fur seals were stranded near Juneau, one in Gastineau Channel, one onshore about two miles Northwest of the action area, and a third on the west side of Douglas Island. Early in 2023 another northern fur seal was stranded in Sitka harbor (Wright, S., pers. comm.).

Harbor Seal

Harbor seals range from Baja California north along the west coasts of California, Oregon, Washington, British Columbia, and Southeast Alaska; west through the Gulf of Alaska, Prince William Sound, and the Aleutian Islands; and north in the Bering Sea to Cape Newenham and the Pribilof Islands. Harbor seals occur year-round in the inside passages of southeast Alaska and are regularly sighted in Auke Bay. Harbor seals forage on fish and invertebrates (Orr *et al.,* 2004) including capelin, eulachon (*Thaleichthys pacificus*), cod, pollock, flatfish, shrimp, octopus, and squid (Wynne, 2012). They are opportunistic feeders that forage in marine, estuarine, and occasionally freshwater habitat, adjusting their foraging behavior to take advantage of prey that are locally and seasonally abundant (Payne and Selzer, 1989). Research has demonstrated that harbor seals conduct both shallow and deep dives while foraging (Tollit *et al.,* 1997), depending on prey availability. Harbor seals usually give birth to a single pup between May and mid-July; birthing locations are dispersed over several haulout sites and not confined to major rookeries (Klinkhart *et al.,* 2008). Harbor seals haul out on rocks, reefs, beaches, and drifting glacial ice. They are non-migratory; their local movements are associated with tides, weather, season, food availability, and reproduction, as well as sex and age class (Swain *et al.,* 1996; Lowry *et al.,* 2001; Boveng *et al.,* 2012).

Harbor seals are commonly sighted in the waters of the inside passages throughout Southeast Alaska. They occur year-round within the Project area and are regularly sighted in Auke Bay, including Statter Harbor within Auke Bay. NOAA aerial survey data indicate that groups ranging from 10 to 52 seals could be present within the Project area during summer at haulouts on the western side of Coghlan Island, as well as on Battleship Island (E. Richmond, pers. comm.). Harbor seals were observed in all months of ADOT&PF's 2021 project in Auke Bay (AKDOT&PF, 2021). Harbor seals are known to be curious and may approach novel activity and could enter the Project area during pile installation and removal.

Northern Elephant Seal

Northern elephant seals breed and give birth in California (U.S.) and Baja California (Mexico), primarily on offshore islands, from December to March (Stewart *et al.* 1994). Spatial segregation in foraging areas between males and females is evident from satellite tag data (Le Beouf *et al.,* 2000). Males migrate to the Gulf of Alaska and western Aleutian Islands along the continental shelf to feed on benthic prey, while females migrate to pelagic areas in the Gulf of Alaska and the central North Pacific to feed on pelagic prey (Le Beouf *et al.,* 2000).

Auke Bay is an unlikely area for an occurrence, as northern elephant seals generally feed along the continental shelf break (Le Boeuf *et al.,* 2000) and are not expected to spend time in shallow areas. No sightings of elephant seals have been documented near Auke Bay; however, protected species observers (PSOs) at a ADOT&PF project site in Ketchikan (460 kilometers south of Auke Bay) reported sightings of a northern elephant seal on multiple days (C. Gentemann, pers. comm., April 8, 2022). Additional sightings of northern elephant seals around the state concurrent with the Ketchikan sighting were reported in Seward, King Cove, and Kodiak (L. Davis, pers. comm., April 14, 2022). Breeding and important haulouts areas are not expected to spatially overlap with the project area.

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.). Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 3.

TABLE 3—MARINE MAMMAL HEARING GROUPS

[NMFS, 2018]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, *Kogia,* river dolphins, Cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 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 are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.,* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) 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 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 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 10–20 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 driving, vibratory pile driving, and vibratory pile removal. The sounds produced by these activities fall into one of two general sound types: impulsive and non-impulsive. Impulsive sounds (*e.g.,* explosions, gunshots, sonic booms, impact pile driving) are typically transient, brief (less than 1 second), broadband, and consist of high peak sound pressure with rapid rise time and rapid decay (ANSI, 1986; NIOSH, 1998; ANSI, 2005; NMFS, 2018). Non-impulsive sounds (*e.g.,* aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems) can be broadband, narrowband or tonal, brief or prolonged (continuous or intermittent), and typically do not have the high peak sound pressure with raid rise/decay time that impulsive sounds do (ANSI, 1995; NIOSH, 1998; NMFS, 2018). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (*e.g.,* Ward, 1997 in Southall, *et al.* 2007).

Two types of pile hammers would be used on this project: impact and vibratory. Impact hammers operate by repeatedly dropping a heavy piston onto a pile to drive the pile into the substrate. Sound generated by impact hammers is 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 produce significantly less sound than impact hammers. Peak sound pressure levels (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). Rise time is slower, reducing the probability and severity of injury, and sound energy is distributed over a greater amount of time (Nedwell and Edwards, 2002; Carlson, *et al.* 2005).

The likely or possible impacts of ADOT&PF'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 primarily be acoustic in nature.

Auditory Effects

The introduction of anthropogenic noise into the aquatic environment from pile driving and removal is the primary means by which marine mammals may be harassed from ADOT&PF's specified 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). Exposure to pile driving noise has the potential to result in auditory threshold shifts 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 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 threshold shift (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 threshold shift 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 and vocalization frequency range of the exposed species relative to the signal's frequency spectrum (*i.e.,* how 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).

Permanent Threshold Shift (PTS)—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 2018). Available data from humans and other terrestrial mammals indicate that a 40 dB threshold shift approximates PTS onset (see Ward *et al.,* 1958, 1959; Ward, 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)—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 (see Southall *et al.,* 2007), a TTS of 6 dB is considered the minimum threshold shift 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 (SELcum) in an accelerating fashion: At low exposures with lower SELcum, the amount of TTS is typically small and the growth curves have shallow slopes. At exposures with higher higher SELcum, 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 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.

Currently, TTS data only exist for four species of cetaceans (bottlenose dolphin (*Tursiops truncatus*), beluga whale (*Delphinapterus leucas*), harbor porpoise, and Yangtze finless porpoise (*Neophocoena asiaeorientalis*)) and five species of pinnipeds exposed to a limited number of sound sources (*i.e.,* mostly tones and octave-band noise) in laboratory settings (Finneran, 2015). TTS was not observed in trained spotted (*Phoca largha*) and ringed (*Pusa hispida*) seals exposed to impulsive noise at levels matching previous predictions of TTS onset (Reichmuth *et al.,* 2016). In general, harbor seals and harbor porpoises have a lower TTS onset than other measured pinniped or cetacean species (Finneran, 2015). Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species. No data are available on noise-induced hearing loss for mysticetes. For summaries of data on TTS in marine mammals or for further discussion of TTS onset thresholds, please see Southall *et al.* (2007), Finneran and Jenkins (2012), Finneran (2015), and Table 5 in NMFS (2018).

Installing piles requires a combination of impact pile driving and vibratory pile driving. For the project, these activities would not occur at the same time and there would likely be pauses in activities producing the sound during each day. Given these pauses and that many marine mammals are likely moving through the action area and not remaining for extended periods of time, the potential for TS declines.

Behavioral Effects

Exposure to noise from pile driving and removal 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; 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); avoidance of areas where sound sources are located. Pinnipeds may increase their haul out 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. For a review of studies involving marine mammal behavioral responses to sound, see Southall *et al.,* 2007; Gomez *et al.,* 2016; and Southall *et al.,* 2021 reviews.

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. 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.

The area likely impacted by the project is relatively small compared to the available habitat in the surrounding waters of Lynn Canal. Although Auke Bay is part of an identified Biologically Important Area for feeding humpback whales (Ferguson *et al.,* 2015), the timing of the BIA (March through November) only overlaps with the proposed timing of the in-water construction (October through January) for two months. Additionally, humpback foraging efforts within Auke Bay itself are intermittent and irregular across seasons.

In 2021, ADOT&PF documented observations of marine mammals during construction activities (*i.e.,* pile driving) at the Auke Bay Ferry Terminal (84 FR 56767, October 23, 2019). In the marine mammal monitoring report for that project (State of Alaska, 2021), 30 Steller sea lions were observed within the behavioral disturbance zone during pile driving or drilling (*i.e.,* documented as Level B harassment take). Twenty eight harbor seals were observed within the disturbance zone during pile driving activities. A lone Dall's porpoise was sighted in the Level B harassment zone during construction. During the construction activities six takes by Level B harassment of humpback whales occurred. No signs of disturbance were noted for any of these species that were present in the harassment zones. Given the similarities in activities and habitat and the fact the same species are involved, we expect similar behavioral responses of marine mammals to the specified activity. That is, disturbance, if any, is likely to be temporary and localized (*e.g.,* small area movements). Monitoring reports from other recent pile driving projects have observed similar behaviors.

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. Auke Bay is home to a busy ferry terminal as well as moorage for small private vessels that transit the area on a regular basis; therefore, background sound levels in the harbor are already elevated.

Airborne Acoustic Effects—Pinnipeds that occur near the project site could be exposed to airborne sounds associated with pile driving and removal that have the potential to cause behavioral harassment, depending on their distance from pile driving activities. 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 exceeding the acoustic thresholds. 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 previously have been 'taken' because of exposure to underwater sound above the behavioral harassment thresholds, which are in all cases 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

ADOT&PF's construction activities could have localized, temporary impacts on marine mammal habitat by increasing in-water sound pressure levels and slightly decreasing water quality. Construction activities are of short duration and would likely have temporary impacts on marine mammal habitat through increases in underwater sound. 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, elevated levels of underwater noise would ensonify Auke Bay where both fish and mammals may occur and could affect foraging success.

In-water pile driving and pile removal would also cause short-term effects on water quality due to increased turbidity. Local currents are anticipated to disburse suspended sediments produced by project activities at moderate to rapid rates depending on tidal stage. ADOT&PF would employ standard construction best management practices, thereby reducing any impacts. Considering the nature and duration of the effects, combined with the measures to reduce turbidity, the impact from increased turbidity levels is expected to be discountable.

Pile installation and removal may temporarily increase turbidity resulting from suspended sediments. Any increases would be temporary, localized, and minimal. ADOT&PF must comply with state water quality standards during these operations by limiting the extent of turbidity to the immediate project area. In general, turbidity associated with pile installation is localized to about a 25-foot radius around the pile (Everitt *et al.* 1980). Cetaceans are not expected to enter the harbor and be close enough to the project pile driving areas to

experience effects of turbidity, and any pinnipeds would likely be transiting the area and could avoid localized areas of turbidity. Therefore, the impact from increased turbidity levels is expected to be discountable to marine mammals. Furthermore, pile driving and removal at the project site would not obstruct movements or migration of marine mammals.

Effects on Prey

Construction activities would produce continuous (*i.e.,* vibratory pile driving) and impulsive (*i.e.,* impact driving) sounds. Fish react to sounds that are especially strong and/or intermittent low-frequency sounds. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. 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). Sound pulses at received levels may cause noticeable changes in behavior (Pearson *et al.,* 1992; Skalski *et al.,* 1992). SPLs of sufficient strength have been known to cause injury to fish and fish mortality.

Impacts on marine mammal prey (*i.e.,* fish or invertebrates) of the immediate area due to the acoustic disturbance are possible. The duration of fish or invertebrate avoidance or other disruption of behavioral patterns in this area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution and behavior is anticipated. Further, significantly large areas of fish and marine mammal foraging habitat are available in the nearby vicinity in Lynn Canal.

The duration of the construction activities is relatively short, with pile driving and removal activities expected to take only 61 days. Each day, construction would occur for no more than 12 hours during the day and pile driving activities would be restricted to daylight hours. The most likely impact to fish from pile driving activities at the project area would be temporary behavioral avoidance of the area. In general, impacts to marine mammal prey species are expected to be minor and temporary due to the short timeframe for the project.

Construction activities, in the form of increased turbidity, have the potential to adversely affect fish in the project area. Increased turbidity is expected to occur in the immediate vicinity (on the order of 10 feet (3 meters) or less) of construction activities. However, suspended sediments and particulates are expected to dissipate quickly within a single tidal cycle. Given the limited area affected and high tidal dilution rates any effects on fish are expected to be minor or negligible. In addition, best management practices would be in effect, which would limit the extent of turbidity to the immediate project area.

In summary, given the short daily duration of sound associated with individual pile driving and events and the relatively small areas being affected, pile driving activities associated with the proposed action are not likely to have a permanent, adverse effect on any fish habitat, or populations of fish species. Thus, we conclude that impacts of the specified activity are not likely to have more than short-term adverse effects on any prey habitat or populations of prey species. Further, any impacts to marine mammal habitat are not expected to result in significant or long-term consequences for individual marine mammals, or to contribute to adverse impacts on their populations.

Estimated Take

This section provides an estimate of the number of incidental takes proposed for authorization through this IHA, which would inform both NMFS' consideration of ''small numbers,'' and the negligible impact determinations.

Harassment is the only type of take expected to result from these activities. Authorized takes would primarily be by Level B harassment, as use of the acoustic sources (*i.e.,* impact and vibratory pile driving) 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 high frequency cetaceans and phocids because predicted auditory injury zones are larger than for other hearing groups. Auditory injury is unlikely to occur for other groups. 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 would be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that would 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 Thresholds

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 PTS of some degree (equated to Level A harassment).

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 (root mean square (RMS) SPL) of 120 dB (referenced to 1 micropascal (re 1 microPascal (µPa)) for continuous (*e.g.,* vibratory pile-driving) and above RMS SPL 160 dB re 1 µPa for non-explosive impulsive (*e.g.,* seismic airguns, impact pile driving) 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.

ADOT&PF's proposed activity includes the use of continuous (vibratory pile driving and removal) and impulsive (impact pile driving) sources, and therefore the RMS SPL thresholds of 120 and 160 dB re 1 μPa are applicable.

Level A harassment—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). ADOT&PF's proposed activity includes the use of impulsive (impact pile driving) and non-impulsive (vibratory pile driving and removal) sources.

These thresholds are provided in the table below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS' 2018 Technical Guidance, which may be accessed at: *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 4—ONSET OF PERMANENT THRESHOLD SHIFT (PTS)

[NMFS 2018]

Hearing group	PTS onset thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{p,0\text{-pk,flat}}$: 219 dB; $L_{E,p,\ LF,24h}$: 183 dB	*Cell 2:* $L_{E,p,\ LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	*Cell 3:* $L_{p,0\text{-pk,flat}}$: 230 dB; $L_{E,p,\ MF,24h}$: 185 dB	*Cell 4:* $L_{E,p,\ MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	*Cell 5:* $L_{p,0\text{-pk,flat}}$: 202 dB; $L_{E,p,HF,24h}$: 155 dB	*Cell 6:* $L_{E,p,\ HF,24h}$: 173 dB.
Phocid Pinnipeds (PW)(Underwater)	*Cell 7:* $L_{p,0\text{-pk.flat}}$: 218 dB; $L_{E,p,PW,24h}$: 185 dB	*Cell 8:* $L_{E,p,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW)(Underwater)	*Cell 9:* $L_{p,0\text{-pk,flat}}$: 232 dB; $L_{E,p,OW,24h}$: 203 dB	*Cell 10:* $L_{E,p,OW,24h}$: 219 dB.

* Dual metric thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds are recommended for consideration.

Note: Peak sound pressure level ($L_{p,0\text{-pk}}$) has a reference value of 1 μPa, and weighted cumulative sound exposure level ($L_{E,p}$) has a reference value of 1μPa^{2}s. In this Table, thresholds are abbreviated to be more reflective of International Organization for Standardization standards (ISO 2017). The subscript "flat" is being included to indicate peak sound pressure are flat weighted or unweighted within the generalized hearing range of marine mammals (*i.e.,* 7 Hz to 160 kHz). The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The weighted cumulative sound exposure level thresholds 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 thresholds 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. Marine mammals are expected to be affected via sound generated by the primary components of the project (*i.e.,* impact pile driving, vibratory pile driving and removal). The maximum (underwater) area ensonified above the thresholds for behavioral harassment referenced above is 11.49 km^2 (7.14 mi^2), and is governed by the topography of Auke Bay and the various islands located within and around the bay. The eastern part of Auke Bay is acoustically shadowed by Auke Cape. Coghlan Island, and Suedla Island, and would inhibit sound transmission from reaching the more open waters toward Spuhn Island (see Figure 6–2 in the IHA application). Additionally, 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.

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, 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. Source levels for each pile size and driving method are presented in Table 5. The source levels for vibratory and impact installation of all pile sizes are based on the averaged source level of the same type of pile reported by California Department of Transportation (Caltrans) in pile driving source level compendium documents (Caltrans, 2015 and 2020).

TABLE 5—PROXY SOUND SOURCE LEVELS FOR PILE SIZES AND DRIVING METHODS

Pile size	Method	Proxy source level			Literature source
		dB RMS re 1μPa	dB SEL re 1μPa²sec	dB peak re 1μPa	
30 in	Vibratory	159	N/A	N/A	Caltrans 2020.
24 in	Vibratory	154	N/A	N/A	Caltrans 2020.
18 in	Vibratory	158	N/A	N/A	Caltrans 2020.
30 in	Impact	190	177	210	Caltrans 2015, 2020.
24 in	Impact	190	177	203	Caltrans 2015, 2020.
18 in	Impact	185	175	200	Caltrans 2015, 2020.

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 Technical Guidance that can be used to relatively simply predict an isopleth distance for use in conjunction with marine mammal density or occurrence to help predict potential takes. We note that because of some of the assumptions included in the methods underlying this optional tool, we anticipate that the resulting isopleth estimates are typically going to be overestimates of some degree, which may result in an overestimate of potential take by Level A harassment. However, this optional tool offers the best way to estimate isopleth distances when more sophisticated modeling methods are not available or practical. For stationary sources such as impact or vibratory pile driving and removal, 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 PTS. Inputs used in the optional User Spreadsheet tool (Table 6), and the resulting estimated isopleths and the calculated Level B harassment isopleth (Table 7), are reported below. For source levels of each pile please refer to Table 5.

For impact installation of piles the harassment zones were calculated based on the number of piles to be installed per day. ADOT&PF provided a range of one to four piles per day for impact instillation for all pile sizes. This was done to account for more efficient days of pile installation as not to limit construction activity on those days. If more piles per day are installed it is likely to reduce the number of days impact installation would occur.

TABLE 6—USER SPREADSHEET INPUT PARAMETERS USED FOR CALCULATING LEVEL A HARASSMENT ISOPLETHS

Pile size and installation method	Spreadsheet tab used	Weighting factor adjustment (kHz)	Number of strikes per pile	Number of piles per day	Activity duration (minutes)
30 in vibratory installation	A.1 Vibratory pile driving	2.5	N/A	3	60
24 in vibratory installation	A.1 Vibratory pile driving	2.5	N/A	3	60
24 in vibratory installation (temporary)	A.1 Vibratory pile driving	2.5	N/A	3	30
24 in vibratory removal (temporary)	A.1 Vibratory pile driving	2.5	N/A	3	60
18 in vibratory installation	A.1 Vibratory pile driving	2.5	N/A	3	60
18 in vibratory removal (existing)	A.1 Vibratory pile driving	2.5	N/A	3	30
30 in impact installation	E.1 Impact pile driving	2	1,000	1–4	N/A
24 in impact installation	E.1 Impact pile driving	2	1,000	1–4	N/A
24 in impact installation	E.1 Impact pile driving	2	500	1–4	N/A
18 in impact installation	E.1 Impact pile driving	2	800	1–4	N/A

TABLE 7— CALCULATED LEVEL A AND LEVEL B HARASSMENT ISOPLETHS

Activity	Level A harassment zone (m)					Level B harassment zone (m)
	LF-cetaceans	MF-cetaceans	HF-cetaceans	Phocids	Otariids	
30 in vibratory installation	11	1	16	7	1	3,981
24 in vibratory installation	5	1	8	3	1	1,848
24 in vibratory installation (temporary)	4	1	5	2	1	.....
18 in vibratory installation	9	1	14	6	1	.....
24 in vibratory removal (temporary)	5	1	8	3	1	.....
18 in vibratory removal (existing)	9	1	14	6	1	.....
30 in impact installation (4 piles per day; 1,000 strikes per pile)	1,002	36	1,194	537	39	1,000
30 in impact installation (3 piles per day; 1,000 strikes per pile)	827	30	985	443	33	.....
30 in impact installation (2 piles per day; 1,000 strikes per pile)	632	23	752	338	25	.....

TABLE 7— CALCULATED LEVEL A AND LEVEL B HARASSMENT ISOPLETHS—Continued

Activity	Level A harassment zone (m)					Level B harassment zone (m)
	LF-cetaceans	MF-cetaceans	HF-cetaceans	Phocids	Otariids	
30 in impact installation (1 pile per day; 1,000 strikes per pile)	398	15	474	213	16	
24 in impact installation (4 piles per day; 1,000 strikes per pile)	1,002	36	1,194	537	39	1,000
24 in impact installation (3 piles per day; 1,000 strikes per pile)	827	30	985	443	33	.....
24 in impact installation (2 piles per day; 1,000 strikes per pile)	632	23	752	338	25	.....
24 in impact installation (1 pile per day; 1,000 strikes per pile)	398	15	474	213	16	.....
24 in impact installation (4 piles per day; 500 strikes per pile)	632	23	752	338	25	.....
24 in impact installation (3 piles per day; 500 strikes per pile)	521	19	621	279	21	.....
24 in impact installation (2 piles per day; 500 strikes per pile)	398	15	474	213	16	.....
24 in impact installation (1 pile per day; 500 strikes per pile)	251	9	299	134	10	.....
18 in impact installation (4 piles per day; 800 strikes per pile)	636	23	757	340	25	464
18 in impact installation (3 piles per day; 800 strikes per pile)	525	19	625	281	21	.....
18 in impact installation (2 piles per day; 800 strikes per pile)	401	15	477	215	16	.....
18 in impact installation (1 pile per day; 800 strikes per pile)	252	9	301	135	10	.....

Marine Mammal Occurrence and Take Estimation

In this section, we provide information about the occurrence of marine mammals, including density or other relevant information that would inform the take calculations.

When available, peer-reviewed scientific publications were used to estimate marine mammal abundance in the project area. Data from monitoring reports from previous projects on the Auke Bay Ferry Terminal were used as well as reports from other projects in Juneau, Alaska. However, scientific surveys and resulting data, such as population estimates, densities, and other quantitative information, are lacking for some marine mammal populations and most areas of southeast Alaska, including Auke Bay. Therefore, AKDOT&PF gathered qualitative information from discussions with knowledgeable local people in the Auke Bay area.

Here we describe how the information provided is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and proposed for authorization. Since reliable densities are not available, the applicant requests take based on the maximum number of animals that may occur in the harbor in a specified measure of time multiplied by the total duration of the activity.

Humpback Whale

Use of Auke Bay by humpback whales is intermittent and irregular year-round. During winter, researchers have documented 1 to 19 individual humpback whales per month in waters close to the project area, including Lynn Canal (Moran *et al.,* 2018a; Straley *et al.,* 2018). Group sizes in southeast Alaska generally range from one to four individuals (Dahlheim *et al.,* 2009). Based on this, we predict that two groups of two humpback whales could be exposed to Level B harassment during each day of the 61 days of work for a total of 244 animals. As described previously, 2.4 percent of the humpback whales in Southeast Alaska are members of the Mexico DPS, and therefore six animals would be Mexico DPS individuals and the remaining 238 animals would be Hawaii DPS individuals.

The largest Level A shutdown zone for humpback whales extends 1,002 meters from the noise source (Table 7), and would occur only on days when impact driving of four piles is expected. All construction work would be shut down prior to a humpback whale entering the Level A zone specific to the in-water activity underway at the time. No take by Level A harassment is proposed or requested for humpback whales.

Minke Whales

Dedicated surveys for cetaceans in southeast Alaska found that minke whales were scattered throughout inland waters from Glacier Bay and Icy Strait to Clarence Strait, with small concentrations near the entrance of Glacier Bay. All sightings were of single minke whales, except for a single sighting of multiple minke whales. Surveys took place in spring, summer, and fall, and minke whales were present in low numbers in all seasons and years (Dahlheim *et al.,* 2009). Although minke whales are rarely occur in the project area we are conservatively proposing to authorize take of one minke whale per month by Level B harassment.

The Level A harassment zones for minke whales are the same as for humpback whales, and the shutdown protocols would be the same as well. Therefore, given the low occurrence of minke whales combined with the mitigation, takes by Level A harassment have not been requested and are not proposed to be authorized.

Killer Whale

Killer whales are observed occasionally during summer throughout Lynn Canal, but their presence in Auke Bay is unlikely. As a precaution, because Level B harassment zones extend beyond Auke Bay, ADOT&PF requests take by Level B harassment for one killer whale resident pod and one transient pod. Groups from those pods are likely to be 14 animals and 44 animals, respectively (Dahlheim *et al.,* 2009). ADOT&PF would implement shutdown zones that encompass the largest Level A harassment zones for killer whales during all pile driving activities. Killer whales are generally conspicuous and PSOs are expected to detect killer whales and implement a shutdown before the animals enter the Level A harassment zone. Therefore, takes by Level A harassment have not been requested and are not proposed to be authorized.

Pacific White-Sided Dolphins

Based on occurrence data ADOT&PF requested a total of 92 takes by Level B harassment (the median group size observed in aerial surveys; range from 20 to 164 individuals) (Muto *et al.* 2022). NMFS concurs and has proposed authorization of Level B harassment of one group of Pacific white-sided dolphins to occur over the duration of the project. The largest Level A harassment zone for Pacific white-sided dolphins extends 36 m from the source during impact installation of 30-in piles (Table 7). Pacific white-sided dolphins are expected to be seen by PSOs before entering this zone and shutdown of activity would occur. No take by Level

A harassment is proposed or anticipated.

Harbor Porpoise

Initially ADOT&PF requested a total of 122 takes of harbor porpoise over the course of the 61 day project. ADOT&PF estimated that 25 percent of those takes could be Level A exposures which would equate to 30 over the project duration. After further review of current and previous monitoring results, including unpublished data (Wright, S., pers. comm.), that showed higher numbers of harbor porpoises in the area, we recommended four animals per day equating to 244 takes of harbor porpoise by Level A and Level B harassment. NMFS predicts that up to 25 percent of the total exposures could result in take by Level A harassment for a total of 61. The remaining 183 takes would be by Level B harassment.

Harbor porpoises are known to be an inconspicuous species and are challenging for protected species observers (PSOs) to sight, making any approach to a specific area potentially difficult to detect. Because harbor porpoises move quickly and elusively, it is possible that they may enter the Level A harassment zone without detection. The largest Level A harassment zone results from impact driving of 30-in piles, and extends 1,194 m from the source for high frequency cetaceans (Table 7). ADOT&PF would implement a shutdown zone for harbor porpoises that encompasses the largest Level A harassment zone (see Proposed Mitigation section) but given the sighting challenges for PSOs some take by Level A harassment is expected.

Dall's Porpoise

No systematic studies of Dall's porpoise abundance or distribution have occurred in Auke Bay; however, Dall's porpoises have been consistently observed in Lynn Canal, Stephens Passage, upper Chatham Strait, Frederick Sound, and Clarence Strait (Dalheim *et al.,* 2000). ADOT&PF initially requested take of one group of 20 animals per month in the project area for a total of 80 takes by Level B harassment. After reviewing ADOT&PF's monitoring results from Auke Bay one lone Dall's porpoise was sighted. Thus, we proposed a conservative estimate of two groups of five animals per month. This would result in a maximum of 30 takes by Level B harassment throughout the course of the project.

ADOT&PF would implement shutdown zones for porpoises that encompass the largest Level A harassment zones for each pile driving activity (see Proposed Mitigation section). The largest Level A harassment zone for Dall's porpoise extends 1,194 m from the source during impact installation of 30-in piles (Table 7). Given the more conspicuous rooster-tail generated by swimming Dall's porpoises, which makes them more noticeable than harbor porpoises, PSOs are expected to detect Dall's porpoises prior to them entering the Level A harassment zone (Jefferson 2009). Therefore, takes of Dall's porpoises by Level A harassment have not been requested and are not proposed to be authorized.

Steller Sea Lion

Based on recent monitoring reports for Auke Bay Ferry Terminal and Statter Harbor projects it is estimated that groups of up to 50 animals per day could be exposed to underwater noise. A total of 3,050 exposures to sound levels at or above the Level B harassment threshold could occur over the 61 days of construction. Given the 1.4 percent of Steller sea lions belong to the wDPS in Auke Bay, 43 total exposures are expected from the wDPS and the remaining 3,008 exposures of eDPS Steller sea lions.

The largest Level A harassment zone for otariid pinnipeds extends 39 m from the source (Table 7). ADOT&PF is planning to implement a larger shutdown zones than the Level A harassment zones during all pile installation and removal activities (see Proposed Mitigation section), which is expected to eliminate the potential for take by Level A harassment of Steller sea lions. Therefore, no takes of Steller sea lions by Level A harassment were requested or are proposed to be authorized.

California Sea Lion

California sea lions rarely occur in the project area. In 2017, a lone California sea lion was spotted in the harbor. Recently, monitoring reports from similar construction projects did not observe any California sea lions in Auke Bay. Based on the sighting from 2017, ADOT&PF is estimating one animal per day of construction which would equate to 61 takes by Level B harassment.

Similar to Steller sea lions, the largest Level A harassment zone for otariid pinnipeds extends 39 m from the source (Table 7). ADOT&PF is planning to implement larger shutdown zones than the Level A harassment zones during all pile installation and removal activities (see Proposed Mitigation section), which is expected to eliminate the potential for take by Level A harassment of California sea lions. Therefore, no takes of California sea lions by Level A harassment were requested or are proposed to be authorized.

Northern Fur Seal

Although take of Northern fur seal was not requested by ADOT&PF, the NMFS Alaska Regional Office recommended the inclusion of Northern fur seals in the take estimation. We estimate that five northern fur seals may be present in the action area per month which would result in 15 takes by Level B harassment over the course of the project.

The largest Level A harassment zone for otariid pinnipeds extends 39 m from the source (Table 7). ADOT&PF is planning to implement larger shutdown zones than the Level A harassment zones during all pile installation and removal activities (see Proposed Mitigation section), which is expected to eliminate the potential for take by Level A harassment of Northern fur seals. Therefore, no takes of Northern fur seals by Level A harassment were requested or are proposed to be authorized.

Harbor Seal

Based on monitoring results of ADOT&PF's 2021 project in Auke Bay it is expected that 50 harbor seals per day could be taken during the 61 days of construction (AKDOT&PF, 2021). This would equate to 3,050 takes of harbor seals by Level B harassment during the duration of the project.

The largest Level A harassment zone for phocid pinnipeds results from impact pile driving of 30-in piles and extends 537 m from the source (Table 7). There are no haulouts located within the Level A harassment zone and although it is unlikely that harbor seals would enter this area without detection while pile driving activities are underway, it is possible that harbor seals may approach and enter the Level A harassment zone undetected. Two harbor seals are estimated to approach the site within 537 m of the source each day. Impact pile driving may occur on up to 34 days (Table 1). For this reason, we propose take by Level A harassment of two harbor seals daily on the 34 days of impact pile driving for a total of 68 takes by Level A harassment. The largest Level A harassment zone for phocid pinnipeds from vibratory pile driving extends 30 m from the source (Table 7). ADOT&PF is planning to implement larger shutdown zones than the Level A harassment zones during all pile installation and removal activities (see Proposed Mitigation section), which is expected to eliminate the potential for

Level A harassment of harbor seals from vibratory pile driving.

Northern Elephant Seal

Given the increase in population size and sightings throughout Southeast Alaska ADOT&PF requested one elephant seal take per week. The project is expected to take up to 16 weeks to complete which would equate to 16 takes by Level B harassment.

The largest Level A harassment zone for phocid pinnipeds extends 537 m from the source (Table 7). ADOT&PF is planning to implement larger shutdown zones than the Level A harassment zones during all pile installation and removal activities (see Proposed Mitigation section), which is expected to eliminate the potential for take by Level A harassment of elephant seals. Therefore, no takes of elephant seals by Level A harassment were requested or are proposed to be authorized.

TABLE 8—ESTIMATED TAKE BY LEVEL A AND LEVEL B HARASSMENT, BY SPECIES AND STOCK

Common name	Stock	Stock abundance [a]	Level A	Level B	Total proposed take	Proposed take as percentage of stock
Humpback whale	Central North Pacific	10,103	0	[b] 244	244	2.4
Minke whale	Alaska	N/A	0	4	4	N/A
Killer Whale	Alaska Resident	1,920	0	41	41	2.1
	West Coast Transient	349	0	14	14	4.0
Pacific white-sided dolphin	North Pacific	931,000	0	92	92	<0.01
Harbor porpoise	Southern Southeast Alaska Inland Waters.	890	61	183	244	27.4
Dall's porpoise	Alaska	83,400	0	30	30	0.03
Steller sea lion	Eastern U.S	43,201	0	3,008	3,008	6.9
	Western U.S	52,932	0	43	43	0.08
California sea lion	U.S	257,606	0	61	61	0.02
Northern fur seal	Eastern Pacific	626,618	0	15	15	<0.01
Harbor seal	Lynn Canal/Stephens Passage	13,388	68	2,982	3,050	22.8
Northern Elephant Seal	California	187,386	0	16	16	<0.01

[a] Stock or DPS size is Nbest according to NMFS 2022 Draft Stock Assessment Reports.
[b] For ESA section 7 consultation purposes, 2.4 percent are designated to the Mexico DPS and the remaining are designated to the Hawaii DPS; therefore, we assigned 6 takes by Level B harassment to the Mexico DPS.

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. 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 would 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, impact on operations.

In addition to the measures described later in this section, ADOT&PF would employ the following standard mitigation measures:

- At the start of each day, the Contractor(s) would hold a briefing with the Lead PSO to outline the activities planned for that day.
- If poor weather conditions restrict the PSO's ability to make observations within the Level A and B harassment zone of pile driving (*e.g.,* if there is excessive wind or fog), pile installation and removal would be halted.

The following measures would apply to ADOT&PF's mitigation requirements:

Implementation of Shutdown Zones for Level A Harassment—For all pile driving/removal activities, ADOT&PF would implement shutdowns within designated zones. The purpose of a shutdown zone is generally to define an area within which shutdown of activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). Implementation of shutdowns would be used to avoid or minimize incidental Level A harassment exposures from vibratory and impact pile driving for all 11 species for which take may occur (see Table 8). ADOT&PF has voluntarily implemented a minimum shutdown zone of 30 m during all pile driving and removal activities (Table 9). Shutdown zones for impact pile driving activities are based on the Level A harassment zones and therefore vary by pile size, number of piles installed per day, and marine mammal hearing group (Table 9). Shutdown zones for impact pile driving would be established each day for the greatest number of piles that are expected to be installed that day. The placement of PSOs during all pile driving activities (described in detail in the Monitoring and Reporting section) would ensure the full extent of shutdown zones are visible to PSOs.

TABLE 9—SHUTDOWN ZONES DURING PILE INSTALLATION AND REMOVAL

Activity	Piles per day*	Shutdown zones (m)				
		LF cetaceans	MF cetaceans	HF cetaceans	Phocids	Otariids
All vibratory installation and removal		30				
30-in impact (1,000 strikes)	4	1,100	40	1,200	540	40
	3	830	30	990	450	
	2	640		760	340	30
	1	400		480	220	
24-in impact (1,000 strikes)	4	1,100	40	1,200	540	40
	3	830	30	990	450	30
	2	640	.....	760	340	
	1	400	.....	480	220	
24-in impact (500 strikes)	4	640	30	760	340	30
	3	530		630	280	
	2	400		480	220	
	1	260		300	140	
18-in impact (800 strikes)	4	640	30	760	340	30
	3	530		630	280	
	2	400		480	220	
	1	260		300	140	

*The applicant would chose the number of piles to be driven in any given day before work begins

Establishment of Monitoring Zones—ADOT&PF has identified monitoring zones correlated with the larger of the Level B harassment or Level A harassment zones. Monitoring zones provide utility for observing by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring zones enable observers to be aware of and communicate the presence of marine mammals in the project area outside the shutdown zone and thus prepare for a potential cease of activity should the animal enter the shutdown zone. PSOs would monitor the entire visible area to maintain the best sense of where animals are moving relative to the zone boundaries defined in Tables 9 and 10. Placement of PSOs on the shorelines around Auke Bay allow PSOs to observe marine mammals within and near Auke Bay.

TABLE 10—MARINE MAMMAL MONITORING ZONE

Activity	Monitoring zone (m)
30-in vibratory installation	3,981
24-in and 18-in vibratory installation and removal	1,848
30-in and 24 in impact installation	1,200
18-in impact installation	760

Soft Start—The use of soft-start procedures are believed to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity. For impact pile driving, contractors would be required to provide an initial set of strikes from the hammer at reduced energy, with each strike followed by a 30-second waiting period. This procedure would be conducted a total of three times before impact pile driving begins. Soft start would 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. Soft start is not required during vibratory pile driving and removal activities.

Pre-Activity Monitoring—Prior to the start of daily in-water construction activity, or whenever a break in pile driving/removal 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 that 30-minute period. If a marine mammal is observed within the shutdown zone, a soft-start cannot proceed until the animal has left the zone or has not been observed for 15 minutes. If the monitoring zone has been observed for 30 minutes and marine mammals are not present within the zone, soft-start procedures can commence and work can continue even if visibility becomes impaired within the monitoring zone. When a marine mammal permitted for take by Level B harassment is present in the Level B harassment zone, activities may begin. No work may begin unless the entire shutdown zone is visible to the PSOs. If work ceases for more than 30 minutes, the pre-activity monitoring of both the monitoring zone and shutdown zone would commence.

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 would 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

Monitoring shall be conducted by NMFS-approved observers in accordance with the monitoring plan and section 5 of the IHA. Trained observers shall be placed from the best vantage point(s) practicable to monitor for marine mammals and implement shutdown or delay procedures when applicable through communication with the equipment operator. Observer training must be provided prior to project start, and shall include instruction on species identification (sufficient to distinguish the species in the project area), description and categorization of observed behaviors and interpretation of behaviors that may be construed as being reactions to the specified activity, proper completion of data forms, and other basic components of biological monitoring, including tracking of observed animals or groups of animals such that repeat sound exposures may be attributed to individuals (to the extent possible).

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.

A minimum of two PSOs would be on duty during all impact installation and a minimum of three MMOs during vibratory installation/removal. Locations from which MMOs would be able to monitor for marine mammals are readily available from publicly accessible shoreside areas at the Auke Bay East Ferry Terminal and, if necessary, other public and private points along the Glacier and Douglas highways. 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.

PSOs would scan the waters using binoculars, and/or spotting scopes, and would use a handheld range-finder device to verify the distance to each sighting from the project site. All PSOs would be trained in marine mammal identification and behaviors and are required to have no other project-related tasks while conducting monitoring. In addition, monitoring would be conducted by qualified observers, who would be placed at the best vantage point(s) practicable to monitor for marine mammals and implement shutdown/delay procedures when applicable by calling for the shutdown to the hammer operator via a radio. ADOT&PF would adhere to the following observer qualifications:

(i) Independent observers (*i.e.,* not construction personnel) are required;

(ii) One PSO would be designated as the lead PSO or monitoring coordinator and that observer must have prior experience working as an observer;

(iii) Other observers may substitute education (degree in biological science or related field) or training for experience; and

(iv) ADOT&PF must submit observer Curriculum Vitaes for approval by NMFS.

Additional standard observer qualifications include:

- 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 and times when in-water construction activities were suspended to avoid potential incidental injury from construction sound of marine mammals observed within a defined shutdown zone; 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.

Reporting

A draft marine mammal monitoring report would be submitted to NMFS within 90 days after the completion of pile driving and removal activities. 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 driving) and the total equipment duration for cutting for each pile or total number of strikes for each pile (impact driving).

• 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: Name of PSO who sighted the animal(s) and PSO location and activity at time of sighting; Time of sighting; 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; 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); Estimated number of animals (min/max/best estimate); Estimated number of animals by cohort (adults, juveniles, neonates, group composition, etc.); Animal's closest point of approach and estimated time spent within the harassment zone; 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.
• 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 unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the IHA (if issued), such as an injury, serious injury or mortality, ADOT&PF would immediately cease the specified activities and report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the Alaska Regional Stranding Coordinator. The report would include the following information:
• Description of the incident;
• Environmental conditions (*e.g.,* Beaufort sea state, visibility);
• Description of all marine mammal observations in the 24 hours preceding the incident;
• Species identification or description of the animal(s) involved;
• Fate of the animal(s); and
• Photographs or video footage of the animal(s) (if equipment is available).

Activities would not resume until NMFS is able to review the circumstances of the prohibited take. NMFS would work with ADOT&PF to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. ADOT&PF would not be able to resume their activities until notified by NMFS via letter, email, or telephone.

In the event that ADOT&PF discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (*e.g.,* in less than a moderate state of decomposition as described in the next paragraph), ADOT&PF would immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinator. The report would include the same information identified in the paragraph above. Activities would be able to continue while NMFS reviews the circumstances of the incident. NMFS would work with ADOT&PF to determine whether modifications in the activities are appropriate.

In the event that ADOT&PF discovers an injured or dead marine mammal and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), ADOT&PF would report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinator, within 24 hours of the discovery. ADOT&PF would provide photographs, video footage (if available), or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network.

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 8, 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 removal activities associated with the project as outlined previously, have the potential to disturb or displace marine mammals. Specifically, the specified activities may result in take, in the form of Level A harassment and Level B harassment from underwater sounds generated from pile driving and removal. Potential takes could occur if individuals of these

species are present in zones ensonified above the thresholds for Level A or Level B harassment identified above when these activities are underway.

Take by Level A and Level B harassment would be due to potential behavioral disturbance, TTS, and PTS. No serious injury or mortality is anticipated or proposed for authorization given the nature of the activity and measures designed to minimize the possibility of injury to marine mammals. Take by Level A harassment is only anticipated for harbor porpoise and harbor seal. The potential for harassment is minimized through the construction method and the implementation of the planned mitigation measures (see Proposed Mitigation section).

Based on reports in the literature as well as monitoring from other similar activities, behavioral disturbance (*i.e.,* level B harassment) would likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring) (*e.g.,* Thorson and Reyff, 2006; HDR, Inc. 2012; Lerma, 2014; ABR, 2016). Most likely for pile driving, individuals would simply move away from the sound source and be temporarily displaced from the areas of pile driving, although even this reaction has been observed primarily only in association with impact pile driving. The pile driving activities analyzed here are similar to, or less impactful than, numerous other construction activities conducted in southeast Alaska, which have taken place with no observed severe responses of any individuals or known long-term adverse consequences. Level B harassment would be reduced to the level of least practicable adverse impact through use of mitigation measures described herein and, if sound produced by project activities is sufficiently disturbing, animals are likely to simply avoid the area while the activity is occurring. While vibratory driving associated with the proposed project may produce sound at distances of many kilometers from the project site, thus overlapping with some likely less-disturbed habitat, the project site itself is located in a busy harbor and the majority of sound fields produced by the specified activities are close to the harbor. Animals disturbed by project sound would be expected to avoid the area and use nearby higher-quality habitats.

In addition to the expected effects resulting from authorized Level B harassment, we anticipate that harbor porpoises and harbor seals may sustain some limited Level A harassment in the form of auditory injury. However, animals in these locations that experience PTS would likely only receive slight PTS, *i.e.* minor degradation of hearing capabilities within regions of hearing that align most completely with the energy produced by pile driving, *i.e.* the low-frequency region below 2 kHz, not severe hearing impairment or impairment in the regions of greatest hearing sensitivity. If hearing impairment occurs, it is most likely that the affected animal would lose a few decibels in its hearing sensitivity, which in most cases is not likely to meaningfully affect its ability to forage and communicate with conspecifics. As described above, we expect that marine mammals would be likely to move away from a sound source that represents an aversive stimulus, especially at levels that would be expected to result in PTS, given sufficient notice through use of soft start.

The project also is not expected to have significant adverse effects on affected marine mammals' habitat. The project activities would not modify existing marine mammal habitat for a significant amount of time. The activities may cause some fish or invertebrates to leave the area of disturbance, thus temporarily impacting marine mammals' foraging opportunities in a limited portion of the foraging range; but, because of the short duration of the activities, the relatively small area of the habitat that may be affected, and the availability of nearby habitat of similar or higher value, the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences.

Nearly all inland waters of southeast Alaska, including Auke Bay, are included in the southeast Alaska humpback whale feeding BIA (Ferguson *et al.,* 2015), though humpback whale distribution in southeast Alaska varies by season and waterway (Dahlheim *et al.,* 2009). Humpback whales are present within Auke Bay intermittently and in low numbers. The area of the BIA that may be affected by the proposed project is small relative to the overall area of the BIA. The southeast Alaska humpback whale feeding BIA is active between March and November while the proposed project is scheduled to occur between November and March, resulting in only two months of overlap. Additionally, pile driving associated with the project is expected to take only 61 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. 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 proposed for authorization;
- Any Level A harassment exposures (*i.e.,* to harbor porpoises and harbor seals, only) are anticipated to result in slight PTS (*i.e.,* of a few decibels), within the lower frequencies associated with pile driving;
- The anticipated incidents of Level B harassment would consist of, at worst, temporary modifications in behavior that would not result in fitness impacts to individuals;
- The area impacted by the specified activity is very small relative to the overall habitat ranges of all species, does not include ESA-designated critical habitat, and only temporally overlaps with the southeast Alaska humpback whale feeding BIA for two months of the planned six months of activity; and
- The proposed mitigation measures are expected to reduce the effects of the specified activity to the level of least practicable adverse impact.

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 would have only minor, short-term effects on individuals. The specified activities are not expected to affect the reproduction or survival of any individual marine mammals and, therefore, would not result in impacts on rates of recruitment or survival for any species or stock.

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 would 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.

Table 8 demonstrates the number of animals that could be exposed to received noise levels that could cause Level A and Level B harassment for the proposed work in Auke Bay. Our analysis shows that less than 28 percent of each affected stock could be taken by harassment. The numbers of animals proposed to be taken for these stocks would be considered small relative to the relevant stock's abundances, even if each estimated taking occurred to a new individual—an extremely unlikely scenario.

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 would not have an ''unmitigable adverse impact'' on the subsistence uses of the affected marine mammal species or stocks by Alaskan Natives. NMFS has defined ''unmitigable adverse impact'' in 50 CFR 216.103 as an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) Directly displacing subsistence users; or (iii) Placing physical barriers between the marine mammals and the subsistence hunters; and (2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

The proposed project is not known to occur in an important subsistence hunting area. It is a developed area with regular marine vessel traffic. However, ADOT&PF plans to provide advanced public notice of construction activities to reduce construction impacts on local residents, ferry travelers, adjacent businesses, and other users of the Auke Bay ferry terminal and nearby areas. This would include notification to local Alaska Native tribes that may have members who hunt marine mammals for subsistence. Of the marine mammals considered in this IHA application, only harbor seals are known to be used for subsistence in the project area. If any tribes express concerns regarding project impacts to subsistence hunting of marine mammals, further communication between would take place, including provision of any project information, and clarification of any mitigation and minimization measures that may reduce potential impacts to marine mammals.

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 would not be an unmitigable adverse impact on subsistence uses from ADOT&PF's proposed activities.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 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 wDPS Steller sea lions and Mexico DPS humpback whales, 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 would 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 ADOT&PF for conducting pile installation and removal activities at the Auke Bay East ferry terminal between October 1, 2023 and September 30, 2024, 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 action. 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, one-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 one 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).

(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.

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 would remain the same and appropriate, and the findings in the initial IHA remain valid.

Dated: April 7, 2023.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2023–07729 Filed 4–12–23; 8:45 am]

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DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

[Docket No. 230407–0093]

RIN 0660–XC057

AI Accountability Policy Request for Comment

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice, request for Comment.

SUMMARY: The National Telecommunications and Information Administration (NTIA) hereby requests comments on Artificial Intelligence (''AI'') system accountability measures and policies. This request focuses on self-regulatory, regulatory, and other measures and policies that are designed to provide reliable evidence to external stakeholders—that is, to provide assurance—that AI systems are legal, effective, ethical, safe, and otherwise trustworthy. NTIA will rely on these comments, along with other public engagements on this topic, to draft and issue a report on AI accountability policy development, focusing especially on the AI assurance ecosystem.

DATES: Written comments must be received on or before June 12, 2023.

ADDRESSES: All electronic public comments on this action, identified by *Regulations.gov* docket number NTIA–2023–0005, may be submitted through the Federal e-Rulemaking Portal at *www.regulations.gov.* The docket established for this request for comment can be found at *www.regulations.gov,* NTIA–2023–0005. Click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments. Additional instructions can be found in the ''Instructions'' section below after ''Supplementary Information.''

FOR FURTHER INFORMATION CONTACT: Please direct questions regarding this Notice to Travis Hall at *thall@ntia.gov* with ''AI Accountability Policy Request for Comment'' in the subject line, or if by mail, addressed to Travis Hall, National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Room 4725, Washington, DC 20230; telephone: (202) 482–3522. Please direct media inquiries to NTIA's Office of Public Affairs, telephone: (202) 482–7002; email: *press@ntia.gov.*

SUPPLEMENTARY INFORMATION:

Background and Authority

Advancing trustworthy Artificial Intelligence (''AI'') is an important federal objective.[1] The National AI Initiative Act of 2020[2] established federal priorities for AI, creating the National AI Initiative Office to coordinate federal efforts to advance trustworthy AI applications, research, and U.S. leadership in the development and use of trustworthy AI in the public and private sectors.[3] Other legislation, such as the landmark CHIPS and Science Act of 2022, also support the advancement of trustworthy AI.[4] These initiatives are in accord with Administration efforts to advance American values and leadership in AI[5] and technology platform accountability[6] and to promote ''trustworthy artificial intelligence'' as part of a national security strategy.[7] Endeavors that further AI system governance to combat harmful bias and promote equity and inclusion also support the Administration's agenda on racial equity and support for underserved communities.[8] Moreover, efforts to advance trustworthy AI are core to the work of the Department of Commerce. In recent public outreach, the International Trade Administration noted that the Department ''is focused on solidifying U.S. leadership in emerging technologies, including AI'' and that the ''United States seeks to promote the development of innovative and trustworthy AI systems that respect human rights, [and] democratic values, and are designed to enhance privacy protections.'' [9]

To advance trustworthy AI, the White House Office of Science and Technology Policy produced a Blueprint for an AI Bill of Rights (''Blueprint''), providing guidance on ''building and deploying automated systems that are aligned with democratic values and protect civil rights, civil liberties, and privacy.'' [10] The National Institute of Standards and Technology (NIST) produced an AI Risk Management Framework, which provides a voluntary process for managing a wide range of potential AI risks.[11] Both of these initiatives

[1] *See generally,* Laurie A Harris, Artificial Intelligence: Background, Selected Issues, and Policy Considerations, CRS 46795, U.S. Library of Congress: Congressional Research Service, (May 19, 2021), at 16–26, 41–42, *https://crsreports.congress.gov/product/pdf/R/R46795* (last visited Feb. 1, 2023).

[2] The National Artificial Intelligence Initiative Act of 2020, Pub. L. 116–283, 134 Stat. 3388 (Jan. 1, 2021).

[3] U.S. National Artificial Intelligence Initiative Office, Advancing Trustworthy AI Initiative, *https://www.ai.gov/strategic-pillars/advancing-trustworthy-ai* (last visited Jan. 19, 2023).

[4] *See, e.g.,* CHIPS and Science Act of 2022, Pub. L. 117–167, 136 Stat. 1392 (Aug. 9, 2022) (providing support and guidance for the development of safe, secure, and trustworthy AI systems, including considerations of fairness and bias as well as the ethical, legal, and societal implications of AI more generally).

[5] *Supra* note 2 (implemented though the National Artificial Intelligence Initiative, *https://ai.gov* (last visited Jan. 19, 2023)).

[6] White House, Readout of White House Listening Session on Tech Platform Accountability (Sept. 8, 2022) [Tech Platform Accountability], *https://www.whitehouse.gov/briefing-room/statements-releases/2022/09/08/readout-of-white-house-listening-session-on-tech-platform-accountability* (last visited Feb. 1, 2023).

[7] White House, Biden-Harris Administration's National Security Strategy (Oct. 12, 2022) at 21, *https://www.whitehouse.gov/wp-content/uploads/2022/10/Biden-Harris-Administrations-National-Security-Strategy-10.2022.pdf* (last visited Feb. 1, 2023) (identifying ''trusted artificial intelligence'' and ''trustworthy artificial intelligence'' as priorities). *See also* U.S. Government Accountability Office; Artificial Intelligence: An Accountability Framework for Federal Agencies and Other Entities, GAO–21–519SP (June 30, 2021) (proposing a framework for accountable AI around governance, data, performance, and monitoring).

[8] *See* Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, Exec. Order No. 13985, 86 FR 7009 (Jan. 25, 2021) (revoking Exec. Order No. 13058); Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, Exec. Order No. 14091, 88 FR 10825, 10827 (Feb. 16, 2023) (specifying a number of equity goals related to the use of AI, including the goal to ''promote equity in science and root out bias in the design and use of new technologies, such as artificial intelligence.'').

[9] International Trade Administration, Request for Comments on Artificial Intelligence Export Competitiveness, 87 FR 50288, 50288 (Oct. 17, 2022) (''ITA is broadly defining AI as both the goods and services that enable AI systems, such as data, algorithms and computing power, as well as AI-driven products across all industry verticals, such as autonomous vehicles, robotics and automation technology, medical devices and healthcare, security technology, and professional and business services, among others.'').

[10] White House, Blueprint for an AI Bill of Rights: Making Automated Systems Work for the American People (Blueprint for AIBoR) (Oct. 2022), *https://www.whitehouse.gov/ostp/ai-bill-of-rights.*

[11] National Institute for Standards and Technology, Artificial Intelligence Risk Management Framework 1.0 (AI RMF 1.0) (Jan. 2023), *https://nvlpubs.nist.gov/nistpubs/ai/NIST.AI.100-1.pdf. See also* National Artificial Intelligence Research Resource Task Force, Strengthening and Democratizing the U.S. Artificial Intelligence Innovation Ecosystem: An Implementation Plan for a National Artificial

Continued

contemplate mechanisms to advance the trustworthiness of algorithmic technologies in particular contexts and practices.[12] Mechanisms such as measurements of AI system risks, impact assessments, and audits of AI system implementation against valid benchmarks and legal requirements, can build trust. They do so by helping to hold entities accountable for developing, using, and continuously improving the quality of AI products, thereby realizing the benefits of AI and reducing harms. These mechanisms can also incentivize organizations to invest in AI system governance and responsible AI products. Assurance that AI systems are trustworthy can assist with compliance efforts and help create marks of quality in the marketplace.

NTIA is the President's principal advisor on telecommunications and information policy issues. In this role, NTIA studies and develops policy on the impacts of information and communications technology on civil rights; [13] transparency in software components; [14] and the use of emerging digital technologies.[15] NTIA's statutory authority, its role in advancing sound internet, privacy, and digital equity policies, and its experience leading stakeholder engagement processes align with advancing sound policies for trustworthy AI generally and AI accountability policies in particular.

Definitions and Objectives

Real accountability can only be achieved when entities are held responsible for their decisions. A range of AI accountability processes and tools (*e.g.,* assessments and audits, governance policies, documentation and reporting, and testing and evaluation) can support this process by proving that an AI system is legal, effective, ethical, safe, and otherwise trustworthy—a function also known as providing AI assurance.

The term ''trustworthy AI'' is intended to encapsulate a broad set of technical and socio-technical attributes of AI systems such as safety, efficacy, fairness, privacy, notice and explanation, and availability of human alternatives. According to NIST, ''trustworthy AI'' systems are, among other things, ''valid and reliable, safe, secure and resilient, accountable and transparent, explainable and interpretable, privacy-enhanced, and fair with their harmful bias managed.'' [16] Along the same lines, the Blueprint identifies a set of five principles and associated practices to help guide the design, use, and deployment of AI and other automated systems. These are: (1) safety and effectiveness, (2) algorithmic discrimination protections, (3) data privacy, (4) notice and explanation, and (5) human alternatives, consideration and fallback.[17] These principles align with the trustworthy AI principles propounded by the Organisation for Economic Co-operation and Development (OECD) in 2019, which 46 countries have now adopted.[18] Other formulations of principles for responsible or trustworthy AI containing all or some of the above-stated characteristics are contained in industry codes,[19] academic writing,[20] civil society codes,[21] guidance and frameworks from standards bodies,[22] and other governmental instruments.[23] AI assurance is the practical implementation of these principles in applied settings with adequate internal or external enforcement to provide for accountability.

Many entities already engage in accountability around cybersecurity, privacy, and other risks related to digital technologies. The selection of AI and other automated systems for particular scrutiny is warranted because of their unique features and fast-growing importance in American life and commerce. As NIST notes, these systems are

> ''trained on data that can change over time, sometimes significantly and unexpectedly, affecting system functionality and trustworthiness in ways that are hard to understand. AI systems and the contexts in which they are deployed are frequently complex, making it difficult to detect and respond to failures when they occur. AI systems are inherently socio-technical in nature, meaning they are influenced by societal dynamics and human behavior. AI risks—and benefits—can emerge from the interplay of technical aspects combined with societal factors related to how a system is used, its interactions with other AI systems, who operates it, and the social context in which it is deployed.'' [24]

Intelligence Research Resource (Jan. 2023), *https://www.ai.gov/wp-content/uploads/2023/01/NAIRR-TF-Final-Report-2023.pdf* (last visited Feb. 1, 2023) (presenting a roadmap to developing a widely accessible AI research cyberinfrastructure, including support for system auditing).

[12] *See, e.g.,* AI RMF 1.0, *supra* note 11 at 11 (graphically showing test, evaluation, verification, and validation (TEVV) processes, including assessment and audit, occur throughout an AI lifecycle); Blueprint for AIBoR, *supra* note 10 at 27–28 (referring to ''independent'' and ''third party'' audits, as well as ''best practices'' in audits and assessments to ensure high data quality and fair and effective AI systems). *See also* Tech Platform Accountability (Sept. 8, 2022) (including the goal of promoting transparency in platform algorithms and preventing discrimination in algorithmic decision-making).

[13] National Telecommunications and Information Administration, Data Privacy, Equity and Civil Rights Request for Comments, 88 FR 3714 (Jan. 20, 2023).

[14] National Telecommunications and Information Administration, Software Bill of Materials (Apr. 27, 2021), *https://ntia.gov/page/software-bill-materials* (last visited Feb. 1, 2023).

[15] *See, e.g.,* National Telecommunications and Information Administration, Spectrum Monitoring—Institute for Telecommunications Sciences, *https://its.ntia.gov/research-topics/spectrum-management-r-d/spectrum-monitoring* (last visited Feb. 1, 2023).

[16] AI RMF 1.0, *supra* note 11.

[17] White House, Blueprint for AIBoR, *supra* note 10.

[18] Organisation for Economic Co-operation and Development (OECD), Recommendation of the Council on Artificial Intelligence (May 22, 2019), *https://www.oecd.org/gov/pcsd/recommendation-on-policy-coherence-for-sustainable-development-eng.pdf* (last visited Feb. 1, 2023) (AI systems should (1) drive inclusive growth, sustainable development and well-being; (2) be designed to respect the rule of law, human rights, democratic values, and diversity; (3) be transparent; (4) be robust, safe, and secure; (5) and be accountable).

[19] *See, e.g.,* Microsoft, Microsoft Responsible AI Standard Reference Guide Version 2.0 (June 2022), *https://query.prod.cms.rt.microsoft.com/cms/api/am/binary/RE4ZPmV* (last visited Feb. 1, 2023) (identifying accountability, transparency, fairness, reliability and safety, privacy and security, and inclusiveness goals).

[20] *See, e.g.,* Jessica Newman, Univ. of Cal. Berkeley Center for Long-Term Cybersecurity, A Taxonomy of Trustworthiness for Artificial Intelligence White Paper (Jan. 2023), Univ. of Cal. Berkeley Center for Long-Term Cybersecurity, *https://cltc.berkeley.edu/wp-content/uploads/2023/01/Taxonomy_of_AI_Trustworthiness.pdf* (mapping 150 properties of trustworthiness, building on NIST AI Risk Management Framework); Thilo Hagendorff, The Ethics of AI Ethics: An Evaluation of Guidelines, Minds & Machines 30, 99–120 (2020), *https://doi.org/10.1007/s11023-020-09517-8;* Jeannette M. Wing, Trustworthy AI, Communications of the ACM, Vol. 64 No. 10 (Oct. 2021), *https://cacm.acm.org/magazines/2021/10/255716-trustworthy-ai/fulltext.*

[21] *See generally,* Luciano Floridi, and Josh Cowls, A Unified Framework of Five Principles for AI in Society, Harvard Data Science Review, Issue1.1 (July 01, 2019), *https://doi.org/10.1162/99608f92.8cd550d1* (synthesizing ethical AI codes); Algorithm Watch, The AI Ethics Guidelines Global Inventory (2022), *https://inventory.algorithmwatch.org* (last visited Feb. 1, 2023) (listing 165 sets of ethical AI guidelines).

[22] *See, e.g.,* Institute of Electrical and Electronics Engineers (IEEE), IEEE Global Initiative on Ethics of Autonomous & Intelligent Systems (Feb. 2022), *http://standards.ieee.org/develop/indconn/ec/ead_v2.pdf;* IEEE, IEEE P7014: Emulated Empathy in Autonomous and Intelligent Systems Working Group, *https://sagroups.ieee.org/7014* (last visited Feb. 1, 2023). *C.f.* Daniel Schiff et al., IEEE 7010: A New Standard for Assessing the Well-Being Implications of Artificial Intelligence, IEEE Int'l Conf. on Sys., Man & Cybernetics 1 (2020). There also efforts to harmonize and compare tools for trustworthy AI. *See, e.g.,* OECD, OECD Tools for Trustworthy AI: A Framework to Compare Implementation Tools for Trustworthy AI Systems, OECD Digital Economy Papers No. 312 (June 2021), *https://www.oecd-ilibrary.org/docserver/008232ec-en.pdf?expires=1674495915&id=id&accname=guest&checksum=F5D10D29FCE205F3F32F409A679571FE.*

[23] *See, e.g.,* European Commission, High-Level Expert Group on Artificial Intelligence (AI HLEG), Ethics Guidelines for Trustworthy AI (Apr. 8, 2019), *https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai.*

[24] AI Risk Mgmt. Framework 1.0, *supra* note 11 at 1.

The objective of this engagement is to solicit input from stakeholders in the policy, legal, business, academic, technical, and advocacy arenas on how to develop a productive AI accountability ecosystem. Specifically, NTIA hopes to identify the state of play, gaps, and barriers to creating adequate accountability for AI systems, any trustworthy AI goals that might not be amenable to requirements or standards, how supposed accountability measures might mask or minimize AI risks, the value of accountability mechanisms to compliance efforts, and ways governmental and non-governmental actions might support and enforce AI accountability practices.

This Request for Comment uses the terms AI, algorithmic, and automated decision systems without specifying any particular technical tool or process. It incorporates NIST's definition of an ''AI system,'' as ''an engineered or machine-based system that can, for a given set of objectives, generate outputs such as predictions, recommendations, or decisions influencing real or virtual environments.'' [25] This Request's scope and use of the term ''AI'' also encompasses the broader set of technologies covered by the Blueprint: ''automated systems'' with ''the potential to meaningfully impact the American public's rights, opportunities, or access to critical resources or services.'' [26]

Accountability for Trustworthy AI

1. Growing Regulatory Interest in AI Accountability Mechanisms

Governments, companies, and civil society organizations are developing AI governance tools to mitigate the risks of autonomous systems to individuals and communities. Among these are accountability mechanisms to show that AI systems are trustworthy, which can help foster responsible development and deployment of algorithmic systems, while at the same time giving affected parties (including customers, investors, affected individuals and communities, and regulators) confidence that the technologies are in fact worthy of trust.[27] Governments around the world, and within the United States, are beginning to require accountability mechanisms including audits and assessments of AI systems, depending upon their use case and risk level. For example, there are relevant provisions in the European Union's Digital Services Act requiring audits of very large online platforms' systems,[28] the draft EU Artificial Intelligence Act requiring conformity assessments of certain high-risk AI tools before deployment,[29] and New York City Law 144 requiring bias audits of certain automated hiring tools used within its jurisdiction.[30] Several bills introduced in the U.S. Congress include algorithmic impact assessment or audit provisions.[31] In the data and consumer protection space, policies focus on design features of automated systems by requiring in the case of privacy-by-design,[32] or prohibiting in the case of ''dark patterns,'' certain design choices to secure data and consumer protection.[33] Governments are mandating accountability measures for government-deployed AI systems.[34] Related tools are also emerging in the private sector from non-profit entities such as the Responsible AI Institute (providing system certifications) [35] to startups and well-established companies, such as Microsoft's Responsible AI Standard [36] and Datasheets for Datasets,[37] the Rolls-Royce Alethia Framework,[38] Google's Model Card Toolkit,[39] and many others.

Federal regulators have been addressing AI system risk management in certain sectors for more than a decade. For example, the Federal Reserve in 2011 issued SR–11–7 Guidance on Algorithmic Model Risk

[25] *Id.*

[26] Blueprint for AIBoR, *supra* note 10 at 8.

[27] *See, e.g.,* Michael Kearns and Aaron Roth, Ethical Algorithm Design Should Guide Technology Regulation, Brookings (Jan. 13, 2020), *https://www.brookings.edu/research/ethical-algorithm-design-should-guide-technology-regulation* (noting that ''more systematic, ongoing, and legal ways of auditing algorithms are needed'').

[28] European Union, Amendments Adopted by the European Parliament on 20 January 2022 on the Proposal for a Regulation of the European Parliament and of the Council on a Single Market For Digital Services (Digital Services Act) and amending Directive 2000/31/EC, OJ C 336, *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022AP0014* (Article 28 provides that ''[v]ery large online platforms shall ensure auditors have access to all relevant data necessary to perform the audit properly.'' Further, auditors must be ''recognised and vetted by the Commission and . . . [must be] legally and financially independent from, and do not have conflicts of interest with'' the audited platforms.).

[29] European Union, Proposal for a Regulation of the European Parliament and Of The Council Laying Down Harmonised Rules On Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts, 2021/0106(COD), *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0206. See also* European Parliament Special Committee on Artificial Intelligence in a Digital Age, Report on Artificial Intelligence in a Digital Age, A9–0088/2022, *https://www.europarl.europa.eu/doceo/document/A-9-2022-0088_EN.html* (setting forth European Parliament positions on AI development and governance).

[30] The New York City Council, Automated Employment Decision Tools, Int 1894–2020 (effective Apr. 2023), *https://legistar.council.nyc.gov/LegislationDetail.aspx?ID=4344524&GUID=B051915D-A9AC-451E-81F8-6596032FA3F9&Options=ID%7CText%7C&Search=.* A similar law has been proposed in New Jersey. Bill A4909 (Sess. 2022–2023), *https://legiscan.com/NJ/text/A4909/2022. See also,* Colorado SB 21–169, Protecting Consumers from Unfair Discrimination in Insurance Practices (2021) (requiring insurers to bias test big data systems, including algorithms and predictive models, and to demonstrate testing methods and nondiscriminatory results to the Colorado Division of Insurance); State of Connecticut Insurance Dept., Notice to All Entities and Persons Licensed by the Connecticut Insurance Department Concerning the Usage of Big Data and Avoidance of Discriminatory Practices (April 20, 2022) (expressing potential regulatory concerns with ''[h]ow Big Data algorithms, predictive models, and various processes are inventoried, risk assessed/ranked, risk managed, validated for technical quality, and governed throughout their life cycle to achieve the mandatory compliance'' with non-discrimination laws and reminding insurers to submit annual data certifications), *https://portal.ct.gov/-/media/CID/1_Notices/Technologie-and-Big-Data-Use-Notice.pdf.*

[31] *See, e.g.,* American Data Privacy and Protection Act, H.R. 8152, 117th Cong. § 207(c) (2022) (proposing to require large data holders using covered algorithms posing consequential risk of harm to individuals or groups to conduct risk assessment and report on risk mitigation measures); Algorithmic Accountability Act of 2022, H.R. 6580, 117th Cong. (2022) (would require covered entities to produce impact assessments for the Federal Trade Commission).

[32] *See, e.g.,* Council Regulation 2016/679, of the European Parliament and of the Council of Apr. 27, 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the free Movement of Such Data, and Repealing Directive 95/46/EC (General Data Protection Regulation), Art. 25 (implementing data protection by design principles).

[33] *See, e.g.,* Cal. Civ. Code § 1798.140, subd. (l), (h) (effective Jan. 1, 2023) (regulating the use of a ''dark pattern'' defined as a ''user interface designed or manipulated with the substantial effect of subverting or impairing user autonomy, decision-making, or choice, as further defined by regulation'' and noting that ''agreement obtained through use of dark patterns does not constitute consent.'').

[34] *See, e.g.,* Treasury Board of Canada Secretariat, Algorithmic Impact Assessment Tool, Government of Canada (modified April 19, 2022), *https://www.canada.ca/en/government/system/digital-government/digital-government-innovations/responsible-use-ai/algorithmic-impact-assessment.html;* Treasury Board of Canada Secretariat, Directive on Automated Decision-Making, Government of Canada (modified April 1, 2021), *https://www.tbssct.canada.ca/pol/doc-eng.aspx?id=32592.*

[35] Responsible Artificial Intelligence Institute, *https://www.responsible.ai/* (last visited Apr. 2, 2023).

[36] Microsoft, Microsoft Responsible AI Standard, v2 General Requirements (June 2022), *https://blogs.microsoft.com/wp-content/uploads/prod/sites/5/2022/06/Microsoft-Responsible-AI-Standard-v2-General-Requirements-3.pdf.*

[37] Microsoft, Aether Data Documentation Template (Draft 08/25/2022), *https://www.microsoft.com/en-us/research/uploads/prod/2022/07/aether-datadoc-082522.pdf. See also* Timnit Gebru et. Al., Datasheets for Datasets, Communications of the ACM, Vol. 64, No. 12, 86–92 (Dec. 2021).

[38] Rolls Royce, Aletheia Framework, *https://www.rolls-royce.com/innovation/the-aletheia-framework.aspx* (last visited Mar. 3, 2023).

[39] GitHub, Tensorflow/model-card-toolkit, *https://github.com/tensorflow/model-card-toolkit* (last visited Jan. 30, 2023) (''A toolkit that streamlines and automates the generation of model cards'').

Management, noting that reducing risks requires ''critical analysis by objective, informed parties that can identify model limitations and produce appropriate changes'' and, relatedly, the production of testing, validation, and associated records for examination by independent parties.[40] As financial agencies continue to explore AI accountability mechanisms in their areas,[41] other federal agencies such as the Equal Employment Opportunities Commission have begun to do the same.[42] Moreover, state regulators are considering compulsory AI accountability mechanisms.[43]

2. AI Audits and Assessments

AI systems are being used in human resources and employment, finance, health care, education, housing, transportation, law enforcement and security, and many other contexts that significantly impact people's lives. The appropriate goal and method to advance AI accountability will likely depend on the risk level, sector, use case, and legal or regulatory requirements associated with the system under examination. Assessments and audits are among the most common mechanisms to provide assurance about AI system characteristics. Guidance, academic, and regulatory documents use the terms ''assessments'' (including risk, impact, and conformity) and ''audits'' in various ways and without standard definition.[44] Often in these references, ''assessment'' refers to an entity's internal review of an AI system to identify risks or outcomes. An ''audit'' often refers to an external review of an AI system at a point in time to assess performance against accepted benchmarks. Assessments and audits may both be conducted on a continuous basis, and may be conducted either by internal or external reviewers.

Common areas of focus for AI audits and assessments include harmful bias and discrimination, effectiveness and validity, data protection and privacy, and transparency and explainability (how understandable AI system predictions or decisions are to humans). For information services like social media, large language and other generative AI models, and search, audits and assessments may also cover harms related to the distortion of communications through misinformation, disinformation, deep fakes, privacy invasions, and other content-related phenomena.[45]

Audits may be conducted internally or by independent third parties.[46] An internal audit may be performed by the team that developed the technology or by a separate team within the same entity. Independent audits may range from ''black box'' adversarial audits conducted without the help of the audited entity[47] to ''white box'' cooperative audits conducted with substantial access to the relevant models and processes.[48] Audits may be made public or given limited circulation, for example to regulators.[49] They may be conducted by professional experts or undertaken by impacted lay people.[50]

While some audits and assessments may be limited to technical aspects of a particular model, it is widely understood that AI models are part of larger systems, and these systems are embedded in socio-technical contexts. How models are implemented in practice could depend on model interactions, employee training and recruitment, enterprise governance, stakeholder mapping and engagement,[51] human agency, and many other factors.[52] The most useful audits and assessments of these systems, therefore, should extend beyond the technical to broader questions about governance and purpose. These might include whether the people affected by AI systems are meaningfully consulted in their design[53] and whether the choice to use the technology in the first place was well-considered.[54]

Some accountability mechanisms may use legal standards as a baseline. For

[40] Board of Governors of the Federal Reserve System, Supervisory Guidance on Model Risk Management, Federal Reserve SR Letter 11–7 (Apr. 4, 2011), *https://www.federalreserve.gov/supervisionreg/srletters/sr1107.htm.*

[41] Department of Treasury, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, Bureau of Consumer Financial Protection, and National Credit Union Administration, Request for Information and Comment on Financial Institutions' Use of Artificial Intelligence, Including Machine Learning, 86 FR 16837 (Mar. 31, 2021).

[42] *See* U.S. Equal Employment Opportunity Commission, The Americans with Disabilities Act and the Use of Software, Algorithms, and Artificial Intelligence to Assess Job Applicants and Employees (May 12, 2022) (issuing technical guidance on algorithmic employment decisions in connection with the Americans with Disabilities Act), *https://www.eeoc.gov/laws/guidance/americans-disabilities-act-and-use-software-algorithms-and-artificial-intelligence.*

[43] *See, e.g.,* Colorado Department of Regulatory Agencies Division of Insurance, Draft Proposed New Regulation: Governance and Risk Management Framework Requirements for Life Insurance Carriers' Use of External Consumer Data and Information Sources, Algorithms and Predictive models (Feb. 1, 2023), *https://protect-us.mimecast.com/s/V0LqCVOVw1Hl6g5xSNSwGG?domain=lnks.gd.*

[44] *See, e.g.,* Louis An Yeung, Guidance for the Development of AI Risk & Impact Assessments, Center for Long-Term Cybersecurity (July 2021), at 5, *https://cltc.berkeley.edu/wp-content/uploads/2021/08/AI_Risk_Impact_Assessments.pdf* (surveying definitions and concluding that AI risk and impact assessments ''may be used interchangeably.'').

[45] Jack Bandy, Problematic Machine Behavior: A Systematic Literature Review of Algorithm Audits, Proceedings of the ACM on Human-Computer Interaction, Vol.5. No. 74, 1–34 (April 2021), *https://doi.org/10.1145/3449148* (identifying discrimination and distortion as the most commonly audited-for outputs of algorithm systems).

[46] Responsible Artificial Intelligence Institute, Responsible AI Certification Program—White Paper (Oct. 2022), *https://assets.ctfassets.net/rz1q59puyoaw/5pyXogKSKNUKRkqOP4hRfy/5c5b525d0a77a1017643dcb6b5124634/RAII_Certification_Guidebook.pdf.*

[47] Danae Metaxa et al., Auditing Algorithms: Understanding Algorithmic Systems from the Outside In, ACL Digital Library (Nov. 25, 2021), *https://dl.acm.org/doi/10.1561/1100000083.*

[48] *See, e.g.,* Christo Wilson, et al., Building and Auditing Fair Algorithms: A Case Study in Candidate Screening, FAccT '21 (March 1–10, 2021), *https://evijit.github.io/docs/pymetrics_audit_FAccT.pdf.*

[49] *See, e.g.,* Council of the District of Columbia, Stop Discrimination by Algorithms Act of 2021, B24–558, *https://oag.dc.gov/sites/default/files/2021-12/DC-Bill-SDAA-FINAL-to-file-.pdf* (proposing law that would require audits of certain algorithmic systems to be shared with the Attorney General of the District of Columbia).

[50] *See, e.g.,* Michelle S. Lam et al., End-User Audits: A System Empowering Communities to Lead Large-Scale Investigations of Harmful Algorithmic Behavior, Proceedings of the ACM Human-Computer Interaction, Vol. 6, Issue CSCW2, Article 512, 1–32 (November 2022), *https://doi.org/10.1145/3555625* (describing an ''end-user audit'' deployed in the content moderation setting to audit Perspective API toxicity predictions).

[51] *See, e.g.,* Alan Turing Institute, Human Rights, Democracy, and the Rule of Law Assurance Framework for AI Systems: A Proposal Prepared for the Council of Europe's Ad hoc Committee on Artificial Intelligence, 211–223 (2021), *https://rm.coe.int/huderaf-coe-final-1-2752-6741-5300-v-1/1680a3f688* (exemplifying what stakeholder mapping might entail).

[52] *See, e.g.,* Inioluwa Deborah Raji et al., Closing the AI Accountability Gap: Defining an End-to-End Framework for Internal Algorithmic Auditing, FAT* '20: Proceedings of the 2020 Conference on Fairness, Accountability, and Transparency, 33–44, 37 (January 2020), *https://doi.org/10.1145/3351095.3372873;* Inioluwa Deborah Raji et al., Outsider Oversight: Designing a Third Party Audit Ecosystem for AI Governance, AIES '22: Proceedings of the 2022 AAAI/ACM Conference on AI, Ethics, and Society 560, 566 (June 9, 2022), *https://dl.acm.org/doi/pdf/10.1145/3514094.3534181.*

[53] Adriano Koshiyama et al., Towards Algorithm Auditing: A Survey on Managing Legal, Ethical and Technological Risks of AI, ML and Associated Algorithms (Feb. 2021), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3778998.*

[54] *See, e.g.,* Alene Rhea et al., Resume Format, LinkedIn URLs and Other Unexpected Influences on AI Personality Prediction in Hiring: Results of an Audit, Proceedings of the 2022 AAAI/ACM Conference on AI, Ethics, and Society (AIES '22), Association for Computing Machinery, 572–587 (July 2022), *https://doi.org/10.1145/3514094.3534189* (finding that personality tests used in automated hiring decisions cannot be considered valid); Sarah Bird, Responsible AI Investments and Safeguards for Facial Recognition, Microsoft Azure, (June 21, 2022), *https://azure.microsoft.com/en-us/blog/responsible-ai-investments-and-safeguards-for-facial-recognition* (announcing phase-out of emotion recognition from Azure Face API facial recognition services because of lack of evidence of effectiveness).

example, standards for employment discrimination on the basis of sex, religion, race, color, disability, or national origin may serve as benchmarks for AI audits,[55] as well as for legal compliance actions.[56] Civil society groups are developing additional operational guidance based on such standards.[57] Some firms and startups are beginning to offer testing of AI models on a technical level for bias and/or disparate impact. It should be recognized that for some features of trustworthy AI, consensus standards may be difficult or impossible to create.

3. Policy Considerations for the AI Accountability Ecosystem

Among the challenges facing policymakers in the AI accountability space are tradeoffs among trustworthy AI goals, barriers to implementing accountability mechanisms, complex AI lifecycle and value chains, and difficulties with standardization and measurement.

Accountability ecosystems that might serve as models for AI systems range from financial assurance, where there are relatively uniform financial auditing practices,[58] to environmental, social, and governance (ESG) assurance, where standards are quite diverse.[59] Considering the range of trustworthy AI system goals and deployment contexts, it is likely that at least in the near term, AI accountability mechanisms will be heterogeneous. Commentators have raised concerns about the validity of certain accountability measures. Some audits and assessments, for example, may be scoped too narrowly, creating a ''false sense'' of assurance.[60] Given this risk, it is imperative that those performing AI accountability tasks are sufficiently qualified to provide credible evidence that systems are trustworthy.[61]

There may be other barriers to providing adequate and meaningful accountability. Some mechanisms may require datasets built with sensitive data that puts privacy or security at risk, raising questions about trade-offs among different values. In addition, there may be insufficient access to the subject system or its data, insufficient qualified personnel to audit systems, and/or inadequate audit or assessment standards to benchmark the work.[62]

Timing is another complication for AI accountability, and especially for providing assurance of AI systems. The point in an AI system lifecycle at which an audit or assessment is conducted, for example, will impact what questions it answers, how much accountability it provides, and to whom that accountability is offered. The General Services Administration has depicted an AI lifecycle that starts with pre-design (*e.g.,* problem specification, data identification, use case selection), progresses through design and development (*e.g.,* model selection, training, and testing), and then continues through deployment.[63] Other federal agencies use substantially similar lifecycle schema.[64] Throughout this lifecycle, dynamic interactions with data and iterative learning create many moments for evaluation of specific models and the AI system as a whole.[65]

The AI value chain, including data sources, AI tools, and the relationships among developers and customers, can also be complicated and impact accountability. Sometimes a developer will train an AI tool on data provided by a customer, or the customer may in turn use the tool in ways the developer did not foresee or intend. Data quality is an especially important variable to examine in AI accountability.[66] A developer training an AI tool on a customer's data may not be able to tell how that data was collected or organized, making it difficult for the developer to assure the AI system. Alternatively, the customer may use the tool in ways the developer did not foresee or intend, creating risks for the developer wanting to manage downstream use of the tool. When responsibility along this chain of AI system development and deployment is fractured, auditors must decide whose

[55] *See, e.g.,* Christo Wilson et. al., Building and Auditing Fair Algorithms: A Case Study in Candidate Screening, FAccT '21 (Mar 1–10, 2021), *https://evijit.github.io/docs/pymetrics_audit_FAccT.pdf* (auditing the claims of an automated hiring tool that it satisfied Title VII of the Civil Rights Act's four-fifths rule). *C.f.* Pauline Kim, Data-Driven Discrimination at Work, 58 Wm. & Mary L. Rev. 857 (2017) (addressing limitations of Title VII liability provisions as an adequate means to prevent classification bias in hiring); U.S. Equal Employment Opportunity Commission, Navigating Employment Discrimination in AI and Automated Systems: A New Civil Rights Frontier, Meetings of the Commission, Testimony of Manish Raghavan, (Jan. 31, 2023), *https://www.eeoc.gov/meetings/meeting-january-31-2023-navigating-employment-discrimination-ai-and-automated-systems-new/raghavan* (highlighting data-related and other challenges of auditing AI systems used in hiring according to the four-fifths rule).

[56] *See, e.g.,* U.S. Equal Employment Opportunity Commission, The Americans with Disabilities Act and the Use of Software, Algorithms, and Artificial Intelligence to Assess Job Applicants and Employees (May 12, 2022) (issuing technical guidance on algorithmic employment decisions in connection with the Americans with Disabilities Act), *https://www.eeoc.gov/laws/guidance/americans-disabilities-act-and-use-software-algorithms-and-artificial-intelligence;* U.S. Department of Justice, Justice Department Files Statement of Interest in Fair Housing Act Case Alleging Unlawful Algorithm-Based Tenant Screening Practices, Press Release (Jan. 9, 2023), *https://www.justice.gov/opa/pr/justice-department-files-statement-interest-fair-housing-act-case-alleging-unlawful-algorithm.*

[57] *See, e.g.,* Matt Scherer and Ridhi Shetty, Civil Rights Standards for 21st Century Employment Selection Procedures, Center for Democracy and Technology, (Dec. 2022), *https://cdt.org/insights/civil-rights-standards-for-21st-century-employment-selection-procedures* (guidance on pre-deployment and post-deployment audits and assessments of algorithmic tools in the employment context to detect and mitigate adverse impacts on protected classes).

[58] *See generally,* Financial Accounting Standards Board, Generally Accepted Accounting Principles, *http://asc.fasb.org/home.*

[59] *See generally,* Elizabeth Pollman, ''Corporate Social Responsibility, ESG, and Compliance'' in Benjamin Van Rooij and D. Daniel Sokol (Eds.) The Cambridge Handbook of Compliance (2021) (''Companies have flexibility to create their own structures for internal governance, their own channels for stakeholder engagement, their own selection of third-party guidelines or standards, and in many jurisdictions, their own level of disclosure.'').

[60] *See, e.g.,* Brandie Nonnecke and Philip Dawson, Human Rights Implications of Algorithmic Impact Assessments: Priority Considerations to Guide Effective Development and Use, Harvard Kennedy School—Carr Center for Human Rights Policy, Carr Center Discussion Paper (Oct. 21, 2021), *https://carrcenter.hks.harvard.edu/files/cchr/files/nonnecke_and_dawson_human_rights_implications.pdf.*

[61] *See, e.g.,* Sasha Costanza-Chock et al., Who Audits the Auditors? Recommendations from a Field Scan of the Algorithmic Auditing Ecosystem, FaccT'22: Proceedings of the 2022 Association for Computing Machinery Conference on Fairness, Accountability, and Transparency, 1571–1583 (June 21–24, 2022), *https://doi.org/10.1145/3531146.3533213.*

[62] Centre for Data Ethics and Innovation, Industry Temperature Check: Barriers and Enablers to AI Assurance (Dec. 2022), *https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1122115/Industry_Temperature_Check_-_Barriers_and_Enablers_to_AI_Assurance.pdf.*

[63] For other lifecycle models, *see* International Organization for Standardization, Information Technology—Artificial Intelligence—AI System Life Cycle Processes (ISO/IEC DIS 5338), Edition 1, *https://www.iso.org/standard/81118.html* (under development as of Oct. 22, 2022).

[64] *See, e.g.,* U.S. Department of Energy, DOE AI Risk Management Playbook, *https://www.energy.gov/ai/doe-ai-risk-management-playbook-airmp* (last visited Jan 30, 2023) (identifying AI lifecycle stages as (0) problem identification, (1) supply chain, (2) data acquisition, (3) model development, (4) model deployment, and (5) model performance).

[65] *See generally,* Norberto Andrade et al., Artificial Intelligence Act: A Policy Prototyping Experiment—Operationalizing the Requirements for AI Systems—Part I, 24–33 (Nov. 2022) *https://openloop.org/reports/2022/11/Artificial_Intelligence_Act_A_Policy_Prototyping_Experiment_Operationalizing_Reqs_Part1.pdf* (providing examples of interactions between data and algorithmic outputs along the AI lifecycle and value chain).

[66] *See, e.g.,* European Union Agency for Fundamental Rights, Data Quality and Artificial Intelligence—Mitigating Bias and Error to Protect Fundamental Rights (June 7, 2019), *https://fra.europa.eu/sites/default/files/fra_uploads/fra-2019-data-quality-and-ai_en.pdf* (noting the importance for managing downstream risk of high-quality data inputs, including completeness, accuracy, consistency, timeliness, duplication, validity, availability, and whether the data are fit for the purpose).

data and which relevant models to analyze, whose decisions to examine, how nested actions fit together, and what is within the audit's frame.

Public and private bodies are working to develop metrics or benchmarks for trustworthy AI where needed.[67] Standards-setting bodies such as IEEE [68] and ISO,[69] as well as research organizations focusing on measurements and standards, notably NIST,[70] are devising technical standards that can improve AI governance and risk management and support AI accountability. These include standards for general technology process management (*e.g.,* risk management), standards applicable across technologies and applications (*e.g.,* transparency and anti-bias), and standards for particular technologies (*e.g.,* emotion detection and facial recognition). For some trustworthy AI goals, it will be difficult to harmonize standards across jurisdictions or within a standard-setting body, particularly if the goal involves contested moral and ethical judgements. In some contexts, *not* deploying AI systems at all will be the means to achieve the stated goals.

To address these barriers and complexities, commentators have suggested that policymakers and others can foster AI accountability by: mandating impact assessments [71] and audits,[72] defining ''independence'' for third-party audits,[73] setting procurement standards,[74] incentivizing effective audits and assessments through bounties, prizes, and subsidies,[75] creating access to data necessary for AI audits and assessments,[76] creating consensus standards for AI assurance,[77] providing auditor certifications,[78] and making test data available for use.[79] We particularly seek input on these policy proposals and mechanisms.

Instructions for Commenters:

Through this Request for Comment, we hope to gather information on the following questions. These are not exhaustive, and commenters are invited to provide input on relevant questions not asked below. Commenters are not required to respond to all questions. When responding to one or more of the questions below, please note in the text of your response the number of the question to which you are responding. Commenters should include a page number on each page of their submissions. Commenters are welcome to provide specific actionable proposals, rationales, and relevant facts.

Please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. All comments received are a part of the public record and will generally be posted to *Regulations.gov* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible.

Questions

AI Accountability Objectives

1. What is the purpose of AI accountability mechanisms such as certifications, audits, and assessments? Responses could address the following:

a. What kinds of topics should AI accountability mechanisms cover? How should they be scoped?

b. What are assessments or internal audits most useful for? What are external assessments or audits most useful for?

c. An audit or assessment may be used to verify a claim, verify compliance with legal standards, or assure compliance with non-binding trustworthy AI goals. Do these differences impact how audits or assessments are structured, credentialed, or communicated?

d. Should AI audits or assessments be folded into other accountability mechanisms that focus on such goals as human rights, privacy protection, security, and diversity, equity, inclusion, and access? Are there

[67] *See, e.g.,* Centre for Data Ethics and Innovation, The Roadmap to an Effective AI Assurance Ecosystem—extended version (Dec 8, 2021), *https://www.gov.uk/government/publications/the-roadmap-to-an-effective-ai-assurance-ecosystem/the-roadmap-to-an-effective-ai-assurance-ecosystem-extended-version;* Digital Regulation Cooperation Forum, Auditing algorithms: The Existing Landscape, Role of Regulators and Future Outlook (Sept. 23, 2022), *https://www.gov.uk/government/publications/findings-from-the-drcf-algorithmic-processing-workstream-spring-2022/auditing-algorithms-the-existing-landscape-role-of-regulators-and-future-outlook.*

[68] *See e.g.,* Institute of Electrical and Electronics Engineers Standards Association, CertifAIEd, *https://engagestandards.ieee.org/ieeecertifaied.html* (last visited Jan 31, 2023) (a certification program for assessing ethics of Autonomous Intelligent Systems).

[69] *See, e.g.,* International Organization for Standardization, Information Technology—Artificial intelligence—Transparency Taxonomy of AI Systems (ISO/IEC AWI 12792), Edition 1, *https://www.iso.org/standard/84111.html* (under development as of Jan. 30, 2023).

[70] *See, e.g.,* NIST, AI Standards: Federal Engagement, *https://www.nist.gov/artificial-intelligence/ai-standards-federal-engagement* (last visited Jan 31, 2023) (committing to standards work related to accuracy, explainability and interpretability, privacy, reliability, robustness, safety, security resilience, and anti-bias so as to ''help the United States to speed the pace of reliable, robust, and trustworthy AI technology development.'').

[71] *See, e.g.,* Andrew D. Selbst, An Institutional View of Algorithmic Impact Assessments, 35 Harv. J.L. & Tech. 117 (2021).

[72] *See, e.g.,* Alex Engler, How the Biden Administration Should Tackle AI Oversight, Brookings (Dec. 10, 2020), *https://www.brookings.edu/research/how-the-biden-administration-should-tackle-ai-oversight* (advocating government audits of ''highly impactful, large-scale AI systems''); Danielle Keats Citron and Frank Pasquale, The Scored Society: Due Process for Automated Predictions, 89 Wash U. L. Rev.1, 20–22 (2014) (advocating audit requirements for algorithmic systems used in employment, insurance, and health care contexts).

[73] *See, e.g.,* Ifeoma Ajunwa, An Auditing Imperative for Automated Hiring Systems, 34 Harv. J. L. & Tech 621, 668–670 (2021).

[74] *See, e.g.,* Deirdre K. Mulligan and Kenneth A. Bamberger, Procurement as Policy: Administrative Process for Machine Learning, 34 Berkeley Tech. L. J. 773, 841–44 (2019) (discussing public procurement processes); Jennifer Cobbe et al., Reviewable Automated Decision-Making: A Framework for Accountable Algorithmic Systems, Proceedings of the 2021 Association for Computing Machinery Conference on Fairness, Accountability, and Transparency, 598–609, 604 (March 2021), *https://dl.acm.org/doi/10.1145/3442188.3445921* (discussing relevance of procurement records to accountability relationships).

[75] *See, e.g.,* Miles Brundage et al., Toward Trustworthy AI Development: Mechanisms for Supporting Verifiable Claims, arXiv, 16–17, (April 20, 2020) *https://arxiv.org/abs/2004.07213* (proposing the expanded use of bounties to help detect safety, bias, privacy, and other problems with AI systems); *see also* Rumman Chowdhury and Jutta Williams, Introducing Twitter's First Algorithmic Bias Bounty Challenge, Twitter Engineering (Jul. 30, 2021), *https://blog.twitter.com/engineering/en_us/topics/insights/2021/algorithmic-bias-bounty-challenge.*

[76] *See, e.g.,* Sonia González-Bailón, & Yphtach Lelkes, Do Social Media Undermine Social Cohesion? A Critical Review, Social Issues and Policy Review, Vol. 17, Issue 1, 1–180, 21 (2022), *https://doi.org/10.1111/sipr.12091* (arguing that for investigations of social media algorithms, ''[p]olicy makers should consider sponsoring academic-industry partnerships allowing researchers to access this research and the data generated in the process to produce evidence of public value while securing privacy'').

[77] *See, e.g.,* Jakob Mökander and Maria Axente. Ethics-Based Auditing of Automated Decision-Making Systems: Intervention Points and Policy Implications, AI & Society, 28, 153–171 (Oct. 2021), *https://doi.org/10.1007/s00146-021-01286-x.*

[78] *See, e.g.,* United Nations Educational, Scientific and Cultural Organization (UNESCO), Recommendation on the Ethics of Artificial Intelligence (Nov. 23, 2021) at 27, *https://unesdoc.unesco.org/ark:/48223/pf0000380455* (''Member States are encouraged to . . . consider forms of soft governance such as a certification mechanism for AI systems and the mutual recognition of their certification, according to the sensitivity of the application domain and expected impact on human rights, the environment and ecosystems, and other ethical considerations . . . [including] different levels of audit of systems, data, and adherence to ethical guidelines and to procedural requirements in view of ethical aspects.'').

[79] *See, e.g.,* National Artificial Intelligence Research Resource Task Force, Strengthening and Democratizing the U.S. Artificial Intelligence Innovation Ecosystem: An Implementation Plan for a National Artificial Intelligence Research Resource, 32–36 (Jan. 2023), *https://www.ai.gov/wp-content/uploads/2023/01/NAIRR-TF-Final-Report-2023.pdf* (proposing the federal curation of datasets for use in training and testing AI systems).

benchmarks for these other accountability mechanisms that should inform AI accountability measures?

e. Can AI accountability practices have meaningful impact in the absence of legal standards and enforceable risk thresholds? What is the role for courts, legislatures, and rulemaking bodies?

2. Is the value of certifications, audits, and assessments mostly to promote trust for external stakeholders or is it to change internal processes? How might the answer influence policy design?

3. AI accountability measures have been proposed in connection with many different goals, including those listed below. To what extent are there tradeoffs among these goals? To what extent can these inquiries be conducted by a single team or instrument?

a. The AI system does not substantially contribute to harmful discrimination against people.

b. The AI system does not substantially contribute to harmful misinformation, disinformation, and other forms of distortion and content-related harms.

c. The AI system protects privacy.

d. The AI system is legal, safe, and effective.

e. There has been adequate transparency and explanation to affected people about the uses, capabilities, and limitations of the AI system.

f. There are adequate human alternatives, consideration, and fallbacks in place throughout the AI system lifecycle.

g. There has been adequate consultation with, and there are adequate means of contestation and redress for, individuals affected by AI system outputs.

h. There is adequate management within the entity deploying the AI system such that there are clear lines of responsibility and appropriate skillsets.

4. Can AI accountability mechanisms effectively deal with systemic and/or collective risks of harm, for example, with respect to worker and workplace health and safety, the health and safety of marginalized communities, the democratic process, human autonomy, or emergent risks?

5. Given the likely integration of generative AI tools such as large language models (*e.g.,* ChatGPT) or other general-purpose AI or foundational models into downstream products, how can AI accountability mechanisms inform people about how such tools are operating and/or whether the tools comply with standards for trustworthy AI? [80]

6. The application of accountability measures (whether voluntary or regulatory) is more straightforward for some trustworthy AI goals than for others. With respect to which trustworthy AI goals are there existing requirements or standards? Are there any trustworthy AI goals that are not amenable to requirements or standards? How should accountability policies, whether governmental or non-governmental, treat these differences?

7. Are there ways in which accountability mechanisms are unlikely to further, and might even frustrate, the development of trustworthy AI? Are there accountability mechanisms that unduly impact AI innovation and the competitiveness of U.S. developers?

8. What are the best definitions of and relationships between AI accountability, assurance, assessments, audits, and other relevant terms?

Existing Resources and Models

9. What AI accountability mechanisms are currently being used? Are the accountability frameworks of certain sectors, industries, or market participants especially mature as compared to others? Which industry, civil society, or governmental accountability instruments, guidelines, or policies are most appropriate for implementation and operationalization at scale in the United States? Who are the people currently doing AI accountability work?

10. What are the best definitions of terms frequently used in accountability policies, such as fair, safe, effective, transparent, and trustworthy? Where can terms have the same meanings across sectors and jurisdictions? Where do terms necessarily have different meanings depending on the jurisdiction, sector, or use case?

11. What lessons can be learned from accountability processes and policies in cybersecurity, privacy, finance, or other areas? [81]

12. What aspects of the United States and global financial assurance systems provide useful and achievable models for AI accountability?

13. What aspects of human rights and/or industry Environmental, Social, and Governance (ESG) assurance systems can and should be adopted for AI accountability?

14. Which non-U.S. or U.S. (federal, state, or local) laws and regulations already requiring an AI audit, assessment, or other accountability mechanism are most useful and why? Which are least useful and why?

Accountability Subjects

15. The AI value or supply chain is complex, often involving open source and proprietary products and downstream applications that are quite different from what AI system developers may initially have contemplated. Moreover, training data for AI systems may be acquired from multiple sources, including from the customer using the technology. Problems in AI systems may arise downstream at the deployment or customization stage or upstream during model development and data training.

a. Where in the value chain should accountability efforts focus?

b. How can accountability efforts at different points in the value chain best be coordinated and communicated?

c. How should vendors work with customers to perform AI audits and/or assessments? What is the role of audits or assessments in the commercial and/or public procurement process? Are there specific practices that would facilitate credible audits (*e.g.,* liability waivers)?

d. Since the effects and performance of an AI system will depend on the context in which it is deployed, how can accountability measures accommodate unknowns about ultimate downstream implementation?

16. The lifecycle of any given AI system or component also presents distinct junctures for assessment, audit, and other measures. For example, in the case of bias, it has been shown that ''[b]ias is prevalent in the assumptions about which data should be used, what AI models should be developed, where the AI system should be placed—or if AI is required at all.'' [82] How should AI accountability mechanisms consider the AI lifecycle? Responses could address the following:

a. Should AI accountability mechanisms focus narrowly on the technical characteristics of a defined model and relevant data? Or should they feature other aspects of the socio-

[80] *See, e.g.*, Jakob Mökander et. al., Auditing Large Language Models: A Three-layered Approach (prepring 2003), ArXiv, *https://diu.org/10.48550/ARXIV.2302.08500*.

[81] *See, e.g.*, Megan Gray, Understanding and Improving Privacy 'Audits' Under FTC Orders (April 18, 2018), at 4–8, *http://doi.org/10.2139/ssrn.3165143* (critquing the implementation of third-party privacy audit mandates). For an example of more recent provisions for privacy audits, *see United States* v. *Epic Games*, Stipulated Order for Permanent Injunction, Civ. No. 5:22–cv–00518–BO (E.D.N.C. Dec. 19, 2022), 22–25 (requiring assessments by independent third-party auditors in a children's privacy settlement), *https://www.ftc.gov/system/files/ftc_gov/pdf/2223087EpicGamesSettlement.pdf*.

[82] Reva Schwartz et al., Towards a Standard for Identifyng and Managing Bias in Artificial Intelligence, NIST Special Publication 1270, at 6, *https://doi.or/10.6028/NIST.SP.1270*.

technical system, including the system in which the AI is embedded? [83] When is the narrower scope better and when is the broader better? How can the scope and limitations of the accountability mechanism be effectively communicated to outside stakeholders?

b. How should AI audits or assessments be timed? At what stage of design, development, and deployment should they take place to provide meaningful accountability?

c. How often should audits or assessments be conducted, and what are the factors that should inform this decision? How can entities operationalize the notion of continuous auditing and communicate the results?

d. What specific language should be incorporated into governmental or non-governmental policies to secure the appropriate timing of audits or assessments?

17. How should AI accountability measures be scoped (whether voluntary or mandatory) depending on the risk of the technology and/or of the deployment context? If so, how should risk be calculated and by whom?

18. Should AI systems be released with quality assurance certifications, especially if they are higher risk?

19. As governments at all levels increase their use of AI systems, what should the public expect in terms of audits and assessments of AI systems deployed as part of public programs? Should the accountability practices for AI systems deployed in the public sector differ from those used for private sector AI? How can government procurement practices help create a productive AI accountability ecosystem?

Accountability Inputs and Transparency

20. What sorts of records (*e.g.,* logs, versions, model selection, data selection) and other documentation should developers and deployers of AI systems keep in order to support AI accountability? [84] How long should this documentation be retained? Are there design principles (including technical design) for AI systems that would foster accountability-by-design?

21. What are the obstacles to the flow of information necessary for AI accountability either within an organization or to outside examiners? What policies might ease researcher and other third-party access to inputs necessary to conduct AI audits or assessments?

22. How should the accountability process address data quality and data voids of different kinds? For example, in the context of automated employment decision tools, there may be no historical data available for assessing the performance of a newly deployed, custom-built tool. For a tool deployed by other firms, there may be data a vendor has access to, but the audited firm itself lacks. In some cases, the vendor itself may have intentionally limited its own data collection and access for privacy and security purposes. How should AI accountability requirements or practices deal with these data issues? What should be the roles of government, civil society, and academia in providing useful data sets (synthetic or otherwise) to fill gaps and create equitable access to data?

23. How should AI accountability ''products'' (*e.g.,* audit results) be communicated to different stakeholders? Should there be standardized reporting within a sector and/or across sectors? How should the translational work of communicating AI accountability results to affected people and communities be done and supported?

Barriers to Effective Accountability

24. What are the most significant barriers to effective AI accountability in the private sector, including barriers to independent AI audits, whether cooperative or adversarial? What are the best strategies and interventions to overcome these barriers?

25. Is the lack of a general federal data protection or privacy law a barrier to effective AI accountability?

26. Is the lack of a federal law focused on AI systems a barrier to effective AI accountability?

27. What is the role of intellectual property rights, terms of service, contractual obligations, or other legal entitlements in fostering or impeding a robust AI accountability ecosystem? For example, do nondisclosure agreements or trade secret protections impede the assessment or audit of AI systems and processes? If so, what legal or policy developments are needed to ensure an effective accountability framework?

28. What do AI audits and assessments cost? Which entities should be expected to bear these costs? What are the possible consequences of AI accountability requirements that might impose significant costs on regulated entities? Are there ways to reduce these costs? What are the best ways to consider costs in relation to benefits?

29. How does the dearth of measurable standards or benchmarks impact the uptake of audits and assessments?

AI Accountability Policies

30. What role should government policy have, if any, in the AI accountability ecosystem? For example:

a. Should AI accountability policies and/or regulation be sectoral or horizontal, or some combination of the two?

b. Should AI accountability regulation, if any, focus on inputs to audits or assessments (*e.g.,* documentation, data management, testing and validation), on increasing access to AI systems for auditors and researchers, on mandating accountability measures, and/or on some other aspect of the accountability ecosystem?

c. If a federal law focused on AI systems is desirable, what provisions would be particularly important to include? Which agency or agencies should be responsible for enforcing such a law, and what resources would they need to be successful?

d. What accountability practices should government (at any level) itself mandate for the AI systems the government uses?

31. What specific activities should government fund to advance a strong AI accountability ecosystem?

32. What kinds of incentives should government explore to promote the use of AI accountability measures?

33. How can government work with the private sector to incentivize the best documentation practices?

34. Is it important that there be uniformity of AI accountability requirements and/or practices across the United States? Across global jurisdictions? If so, is it important only within a sector or across sectors? What is the best way to achieve it? Alternatively, is harmonization or interoperability sufficient and what is the best way to achieve that?

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[83] *See, generally,* Inioluwa Deborah Raji and Joy Buolamwini, Actionable Auditing: Investigating the Impat of Publicly Naming Biased Performance Results of Commercial AI Products, AIES 2019—Proceedings of the 2019 AAAI/ACM Conference on AI, Ethics, and Society, 429–435 (2019), *https://doi.org/10.1145/3306618.3314244* (discussing scoping questions).

[84] *See, e.g.,* Miles Brundage et al., Toward Trustworthy AI Development: Mechanisms for Supporting Verifiable Claims at 24–25 (2020), *http://www,twardtrustworthyai.com/* (last visited Jan. 30, 2023) (discussing audit trail components). *See also* AI Risk Mgmt. Framework 1.0, *supra* note 11 at 15 (noting that transparent AI informs individuals about system characteristics and functions ranging from ''design decisions and training data to model training, the struture of the model, its intended use cases, and how and when deployment, post-deployment, or end user decisions were made and by whom''); *id.* at 16 (defining related terms: ''Explainability refers to a representation of the mechanisms underlying AI systems' operation, whereas *interpretability* refers to the meaning of AI systems' output in the context of their designed functional purposes'').

Dated: April 7, 2023.

Stephanie Weiner,

Acting Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2023–07776 Filed 4–12–23; 8:45 am]

BILLING CODE 3510–60–P

COMMISSION OF FINE ARTS

Notice of Meeting

Per 45 CFR chapter XXI 2102.3, the next meeting of the U.S. Commission of Fine Arts is scheduled for April 20, 2023, at 9:00 a.m. and will be held via online videoconference. Items of discussion may include buildings, infrastructure, parks, memorials, and public art.

Draft agendas, the link to register for the online public meeting, and additional information regarding the Commission are available on our website: *www.cfa.gov.* Inquiries regarding the agenda, as well as any public testimony, should be addressed to Thomas Luebke, Secretary, U.S. Commission of Fine Arts, at the above address; by emailing *cfastaff@cfa.gov;* or by calling 202–504–2200. Individuals requiring sign language interpretation for the hearing impaired should contact the Secretary at least 10 days before the meeting date.

Dated April 3, 2023 in Washington, DC.

Susan M. Raposa,

Technical Information Specialist.

[FR Doc. 2023–07833 Filed 4–12–23; 8:45 am]

BILLING CODE 6330–01–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Record of Decision for the Foreign Military Sales Pilot Training Center at Ebbing Air National Guard Base, Arkansas, Environmental Impact Statement

ACTION: Notice of Availability of Record of Decision.

SUMMARY: On March 11, 2022, the Department of the Air Force (DAF) signed the Record of Decision (ROD) for the Record of Decision for the Foreign Military Sales (FMS) Pilot Training Center at Ebbing Air National Guard (ANG) Base, Arkansas, Environmental Impact Statement.

ADDRESSES: Mr. David Martin, AFCEC/CZN, Building 1 Bay 8 Room 8009, 3515 S General McMullen, San Antonio TX 78226–1710, (210) 925–4266; *david.martin.127@us.af.mil.*

SUPPLEMENTARY INFORMATION: The DAF has selected to beddown 12 Royal Singapore Air Force F–16 aircraft and 24 F–35 FMS aircraft at Ebbing ANG Base, Arkansas.

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 February 3, 2023, through a Notice of Availability in the **Federal Register** (Volume 88, Number 23, Page 7445) with a waiting period that ended on March 7, 2023.

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. 2023–07742 Filed 4–12–23; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2023–SCC–0023]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Student Assistance General Provision—Subpart E—Verification Student Aid Application Information

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before May 15, 2023.

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 Beth Grebeldinger, 202–377–4018.

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: Student Assistance General Provision—Subpart E—Verification Student Aid Application Information.

OMB Control Number: 1845–0041.

Type of Review: An extension without change of a currently approved ICR.

Respondents/Affected Public: Private Sector; Individuals and Households; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 23,855,169.

Total Estimated Number of Annual Burden Hours: 3,835,338.

Abstract: This request is for an extension of the information collection supporting the policies and reporting requirements contained in subpart E of part 668—Verification and Updating of Student Aid Application Information. Sections 668.53, 668.54, 668.55, 668.56, 668.57, 668.59 and 668.61 contain information collection requirements (OMB control number 1845–0041). This subpart governs the verification and updating of information provided on the Free Application for Federal Student Aid (FAFSA) which is used to calculate an applicant's Expected Family Contribution (EFC) for purposes of determining an applicant's need for student financial assistance under Title IV of Higher Education Act of 1965, as amended (HEA). The collection of this

documentation helps ensure that students (and parents in the case of PLUS loans) receive the correct amount of Title IV program assistance by providing accurate information to calculate an applicant's expected family contribution. There has been no change to the regulatory language since the prior information collection filing.

Dated: April 10, 2023.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2023–07819 Filed 4–12–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Oak Ridge

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an in-person/virtual hybrid meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Oak Ridge. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, May 10, 2023; 6 p.m.–8 p.m. EDT.

ADDRESSES: This hybrid meeting will be in-person at the Department of Energy (DOE) Information Center (address below) and virtually via Zoom. To provide a safe meeting environment, seating may be limited. To attend virtually or to register for in-person attendance, please send an email to: *orssab@orem.doe.gov* by 5 p.m. EDT on Wednesday, May 3, 2023.

Board members, DOE representatives, agency liaisons, and Board support staff will participate in-person, following COVID–19 precautionary measures, at: DOE Information Center, Office of Science and Technical Information, 1 *Science.gov* Way, Oak Ridge, Tennessee 37831.

Attendees should check the website listed below for any meeting format changes due to COVID–19 protocols.

FOR FURTHER INFORMATION CONTACT: Melyssa P. Noe, Deputy Designated Federal Officer, U.S. Department of Energy, Oak Ridge Office of Environmental Management (OREM), P.O. Box 2001, EM–942, Oak Ridge, TN 37831; Phone (865) 241–3315; or E-Mail: *Melyssa.Noe@orem.doe.gov.* Or visit the website at *www.energy.gov/orssab.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

- Comments from the Deputy Designated Federal Officer
- Comments from DOE, Tennessee Department of Environment and Conservation, and Environmental Protection Agency liaisons
- Presentation
- Public Comment Period
- Motions/Approval of February 8, 2023 Meeting Minutes and March 8, 2023 Meeting Minutes
- Status of Outstanding Recommendations
- Subcommittee Reports

Public Participation: This meeting is open to the public. The EM SSAB, Oak Ridge, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Melyssa P. Noe at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board via email either before or after the meeting. Public comments received by no later than 5 p.m. EDT on Wednesday, May 3, 2023, will be read aloud during the meeting.

Comments will be accepted after the meeting, by no later than 5 p.m. EDT on Monday, May 15, 2023. Please submit comments to *orssab@orem.doe.gov.* Please put ''Public Comment'' in the subject line. Individuals who wish to make oral statements should contact Melyssa P. Noe at the email address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to submit written public comments should email them as directed above. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by emailing or calling Melyssa P. Noe at the email address and telephone number listed above. Minutes will also be available at the following website: *https://www.energy.gov/orem/listings/oak-ridge-site-specific-advisory-board-meetings.*

Signed in Washington, DC, on April 10, 2023.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2023–07849 Filed 4–12–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL23–57–001.

Applicants: Lee County Generating Station, LLC v. PJM Interconnection, L.L.C.

Description: Motion for Stay, or in the Alternative Limited Waiver or Remedial Relief, Request for Immediate Alternative Dispute Resolution, and Request for Waivers and Expedited Action of Lee County Generating Station, LLC.

Filed Date: 4/5/23.

Accession Number: 20230405–5183.

Comment Date: 5 p.m. ET 4/20/23.

Docket Numbers: EL23–59–000.

Applicants: Lincoln Generating Facility, LLC v. PJM Interconnection, L.L.C.

Description: Complaint of Lincoln Generating Facility, LLC v. PJM Interconnection, L.L.C.

Filed Date: 4/6/23.

Accession Number: 20230406–5213.

Comment Date: 5 p.m. ET 5/8/23.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER23–807–001.

Applicants: Southern California Edison Company.

Description: Tariff Amendment: Response to Deficiency, BCE Los Alamitos 2 First Amend GIA–DSA, WDT1583 to be effective 3/13/2023.

Filed Date: 4/7/23

Accession Number: 20230407–5038.

Comment Date: 5 p.m. ET 4/28/23.

Docket Numbers: ER23–1575–000.

Applicants: Homer Solar Energy Center, LLC.

Description: Homer Solar Energy Center, LLC Petitions for a Limited, Prospective Waiver of Section 30.4.4.5.1 of the NYISO OATT.

Filed Date: 4/3/23.

Accession Number: 20230403–5359.

Comment Date: 5 p.m. ET 4/24/23.

Docket Numbers: ER23–1588–000.

Applicants: ISO New England Inc., New England Power Pool Participants Committee.

Description: § 205(d) Rate Filing: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii: ISO–NE/NEPOOL; Revisions to Update the Inventoried Energy Program to be effective 6/6/2023.

Filed Date: 4/7/23.

Accession Number: 20230407–5030.

Comment Date: 5 p.m. ET 4/28/23.

Docket Numbers: ER23–1589–000.

Applicants: AES ES Westwing, LLC.

Description: Baseline eTariff Filing: AES ES Westwing, LLC MBR Tariff to be effective 5/1/2023.

Filed Date: 4/7/23.

Accession Number: 20230407–5067.

Comment Date: 5 p.m. ET 4/28/23.

Docket Numbers: ER23–1590–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2023–04–07_SA 3393 Ameren IL-Sapphire Sky Wind 4th Rev GIA (J826 J1022) to be effective 3/28/2023.

Filed Date: 4/7/23.

Accession Number: 20230407–5068.

Comment Date: 5 p.m. ET 4/28/23.

Docket Numbers: ER23–1591–000.

Applicants: Westlands Transmission, LLC.

Description: § 205(d) Rate Filing: Second Amended TSA with Castanea Project LLC transfer from Chestnut to be effective 4/8/2023.

Filed Date: 4/7/23.

Accession Number: 20230407–5074.

Comment Date: 5 p.m. ET 4/28/23.

Docket Numbers: ER23–1592–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original WMPA, SA No. 6868; Queue No. AF2–165 to be effective 3/14/2023.

Filed Date: 4/7/23.

Accession Number: 20230407–5076.

Comment Date: 5 p.m. ET 4/28/23.

Docket Numbers: ER23–1593–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Tariff Clean-Up Filing for Evergy Metro, Inc.—Effective 20210401 to be effective 4/1/2021.

Filed Date: 4/7/23.

Accession Number: 20230407–5094.

Comment Date: 5 p.m. ET 4/28/23.

Docket Numbers: ER23–1594–000.

Applicants: Hecate Energy Desert Storage 1 LLC.

Description: Baseline eTariff Filing: Application for Market-Based Rate Authority to be effective 6/7/2023.

Filed Date: 4/7/23.

Accession Number: 20230407–5103.

Comment Date: 5 p.m. ET 4/28/23.

Docket Numbers: ER23–1595–000.

Applicants: LRE Energy Services, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 6/7/2023.

Filed Date: 4/7/23.

Accession Number: 20230407–5125.

Comment Date: 5 p.m. ET 4/28/23.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 7, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–07778 Filed 4–12–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC23–6–000]

Commission Information Collection Activities (FERC–153), 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 (PRA), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–153, *Generic Clearance for the Collection of Qualitative Feedback on Commission Service Delivery.*

DATES: Comments on the collection of information are due June 12, 2023.

ADDRESSES: You may submit your comments (identified by Docket No. IC23–6–000) 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, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery:

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

○ *Hand (including courier) delivery:* Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission,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: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC–153, *Generic Clearance for the Collection of Qualitative Feedback on Commission Service Delivery.*

OMB Control No.: 1902–0293.

Type of Request: Generic information collection.

Abstract: This information collection provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback, we mean data that provides useful insights on perceptions and opinions but are not statistical surveys that yield quantitative results that can be generalized to the population of study. The feedback provides insights into customer or stakeholder perceptions, experiences, and expectations. The feedback provides an early warning of service issues and helps focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. This collection allows for ongoing, collaborative and actionable

communications between FERC and its customers and stakeholders. It also allows feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target topics such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Commission's services will be unavailable.

The Commission will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low burden for respondents (based on considerations of total burden hours, total number of respondents, or burden hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program soon;
- Personal identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered is intended to be used only internally for general service improvement and program management purposes and is not intended for release outside of the Commission (if released, the Commission must indicate the qualitative nature of the information);
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study.

As a general matter, this information collection will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Type of Respondents/Affected Public: Individuals and households; Businesses or other for-profit and not-for-profit organizations; State, Local, or Tribal government.

Estimate of Annual Burden: [1] The Commission estimates the annual public reporting burden for the information collection as:

ESTIMATED ANNUAL BURDEN FOR GENERIC CLEARANCE FOR FERC–153

	Number of respondents	Number of responses per respondent	Total number of responses	Average burden minutes per response	Total burden hours
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)
Generic Clearance	27,000	1	27,000	10 minutes	4,500 hours.[2]

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: April 7, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–07807 Filed 4–12–23; 8:45 am]

BILLING CODE 6717–01–P

[1] Burden is defined as 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 Code of Federal Regulations 1320.3.

[2] 4,500 hours = 270,000 minutes.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP22–466–000]

WBI Energy Transmission, Inc.; Notice of Availability of the Final Environmental Impact Statement for the Proposed Wahpeton Expansion Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared a final environmental impact statement (EIS) for the Wahpeton Expansion Project, proposed by WBI Energy Transmission, Inc. (WBI Energy) in the above-referenced docket. WBI Energy requests

authorization to construct and operate the Wahpeton Expansion Project to provide firm transportation service for about 20,600 equivalent dekatherms of natural gas per day to meet a growing demand for natural gas in southeastern North Dakota. The project is supported by a binding Precent Agreement with Montana-Dakota Utilities (MDU) for 20,000 equivalent dekatherms of natural gas per day from the existing Mapleton Compressor Station to the proposed MDU-Kindred and MDU-Wahpeton Border Stations to provide natural gas services to the communities of Kindred and Wahpeton, North Dakota.

The final EIS assesses the potential environmental effects of the construction and operation of the Wahpeton Expansion Project in accordance with the requirements of the National Environmental Policy Act (NEPA). The FERC staff concludes that approval of the proposed project, with the mitigation measures recommended in the EIS, would result in some adverse environmental impacts. Most of these impacts would be temporary and occur during construction (*e.g.,* impacts on wetlands, land use, traffic, and noise). With the exception of climate change impacts, that are not characterized in the EIS as significant or insignificant, staff conclude that project effects would not be significant. As part of the analysis, Commission staff developed specific mitigation measures (included in the final EIS as recommendations). Staff recommend that these mitigation measures be attached as conditions to any authorization issued by the Commission.

No agencies elected to participate as a cooperating agency in the preparation of the EIS.

The final EIS addresses the potential environmental effects of the construction and operation of the following project facilities:

- a new 60.2-mile-long, 12-inch-diameter natural gas pipeline;
- minor modifications to WBI Energy's existing Mapleton Compressor Station;
- a new MDU-Wahpeton Border Station;
- a new MDU-Kindred Border Station:
- seven new block valve settings:
- four new pig launcher/receiver settings; and
- ancillary facilities.

The Commission mailed a copy of the *Notice of Availability* to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; and newspapers and libraries in the project area. The final EIS is only available in electronic format. It may be viewed and downloaded from the FERC's website (*www.ferc.gov*), on the natural gas environmental documents page (*https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents*). In addition, the final EIS may be accessed by using the eLibrary link on the FERC's website. Click on the eLibrary link (*https://elibrary.ferc.gov/eLibrary/search*), select ''General Search,'' and enter the docket number in the ''Docket Number'' field, excluding the last three digits (*i.e.,* CP22–466). Be sure you have selected an appropriate date range. 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.

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website (*www.ferc.gov*) using the eLibrary link. 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. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

Dated: April 7, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–07809 Filed 4–12–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP23–57–000]

Texas Eastern Transmission, LP; Notice of Schedule for the Preparation of an Environmental Assessment for the Grand Chenier Compressor Station Abandonment Project

On February 10, 2023, Texas Eastern Transmission, LP (Texas Eastern) filed an application in Docket No. CP23–57–000 requesting an Authorization pursuant to section 7(b) of the Natural Gas Act to abandon certain natural gas facilities. The proposed project is known as the Grand Chenier Compressor Station Abandonment Project (Project) and would authorize Texas Eastern to abandon its existing Grand Chenier Compressor Station. In 2019, the Commission issued orders approving abandonment of certain segments of Texas Eastern's Cameron System under Docket Nos. CP18–485–000, CP18–486–000, and CP18–505–000. According to Texas Eastern, the abandonment of these Cameron System segments removed the need for the Grand Chenier Compressor Station.

On February 17, 2023, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the Project. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's environmental document for the Project.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the Project and the planned schedule for the completion of the environmental review.[1]

Schedule for Environmental Review

Issuance of EA—August 8, 2023

90-day Federal Authorization Decision Deadline [2]—November 6, 2023

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

Texas Eastern proposes to abandon its existing 27,500 horsepower Grand Chenier Compressor Station in Cameron Parish, Louisiana. Texas Eastern would disconnect and remove aboveground structures and associated appurtenances along with all piping and other buried structures to a depth of two feet below grade. Texas Eastern's Line 41 and associated mainline valve would remain in-service.

[1] 40 CFR 1501.10 (2020).

[2] The Commission's deadline applies to the decisions of other federal agencies, and state agencies acting under federally delegated authority, that are responsible for federal authorizations, permits, and other approvals necessary for proposed projects under the Natural Gas Act. Per 18 CFR 157.22(a), the Commission's deadline for other agency's decisions applies unless a schedule is otherwise established by federal law.

Background

On March 10, 2023, the Commission issued a *Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed Grand Chenier Compressor Station Abandonment Project* (Notice of Scoping). The Notice of Scoping was sent to affected landowners (as defined by the Commission's regulations); federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. In response to the Notice of Scoping, the Commission to date has received comments from RESTORE, and the Environmental Protection Agency. The primary issues raised by the commenters are post-construction use of the site. All substantive comments will be addressed in the EA.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This service provides automatic notification of filings made to subscribed dockets, document summaries, and direct links to the documents. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC website (*www.ferc.gov*). Using the ''eLibrary'' link, select ''General Search'' from the eLibrary menu, enter the selected date range and ''Docket Number'' (*i.e.,* CP23–57), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: April 7, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–07808 Filed 4–12–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1889–085; Project No. 2485–071]

Notice of Settlement Agreement and Soliciting Comments; FirstLight MA Hydro LLC; Northfield Mountain LLC

Take notice that the following settlement agreement has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Settlement Agreement.

b. *Project Nos.:* 1889–085 and 2485–071.

c. *Date Filed:* March 31, 2023.

d. *Applicant:* FirstLight MA Hydro LLC and Northfield Mountain LLC (collectively FirstLight).

e. *Name of Projects:* Turners Falls Hydroelectric Project and Northfield Mountain Pumped Storage Project (collectively, projects).

f. *Location:* The existing projects are located on the Connecticut River in the counties of Windham, Vermont; Cheshire, New Hampshire; and Franklin, Massachusetts. There are approximately 20 acres of federal land within the current Turners Falls Project boundary, associated with the U.S. Geological Survey's Silvio Conte Anadromous Fish Laboratory. There are no federal lands within the Northfield Mountain Project boundary.

g. *Filed Pursuant to:* Rule 602 of the Commission's Rules of Practice and Procedure, 18 CFR 385.602.

h. *Applicant Contact:* Alan Douglass, Regulatory Compliance Manager, FirstLight MA Hydro LLC and Northfield Mountain LLC, 99 Millers Falls Road, Northfield, MA 01360; (413) 659–4416 or *alan.douglass@firstlightpower.com.*

i. *FERC Contact:* Steve Kartalia, (202) 502–6131, *stephen.kartalia@ferc.gov.*

j. *Deadline for filing comments:* May 7, 2023. Reply comments due May 22, 2023.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket numbers P–1889–085 and P–2485–071.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. FirstLight filed the Settlement Agreement for the projects' relicense proceedings, on behalf of itself, the National Marine Fisheries Service, U.S. Fish and Wildlife Service, Massachusetts Division of Fisheries and Wildlife, Nature Conservancy, American Whitewater, Appalachian Mountain Club, Crabapple Whitewater, Inc., New England FLOW, and Zoar Outdoor. The purpose of the Settlement Agreement is to resolve, among the signatories, relicensing issues related to fish passage, flows for the fishery, ecological conservation, recreation, and protected, threatened, and endangered species. The Settlement Agreement includes proposed license articles that reflect agreement among the parties concerning the recommendations, terms, conditions, and fishway prescriptions to be submitted to the Commission pursuant to sections 10(a), 10(j), and 18 of the Federal Power regarding these topics. FirstLight requests, and the Settlement Agreement includes a proposed term of 50 years for any new licenses issued for the projects. FirstLight requests that the Commission accept and incorporate all of the proposed license articles in any new licenses for the projects, and issue new licenses for terms of 50 years.

l. A copy of the Settlement Agreement may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number, excluding the last three digits, in the docket number field to access the document (*i.e.,* P–1889 and P–2485). At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the

proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC Online Support.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Dated: April 7, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–07806 Filed 4–12–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas & Oil Pipeline Rate and Refund Report filings:

Filings in Existing Proceedings

Docket Numbers: RP23–621–000.

Applicants: Northern Border Pipeline Company.

Description: Report Filing: Supplement to NBPL 2023 CUS Filing to be effective N/A.

Filed Date: 4/6/23.

Accession Number: 20230406–5139.

Comment Date: 5 p.m. ET 4/18/23.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 7, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–07777 Filed 4–12–23; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10855–01–OMS]

Cross-Media Electronic Reporting: Authorized Program Revision Approval, New Jersey Department of Environmental Protection (NJDEP)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the Environmental Protection Agency's (EPA) approval of the New Jersey Department of Environmental Protection (NJDEP) request to revise/modify certain of its EPA-authorized programs to allow electronic reporting.

DATES: EPA approves the authorized program revisions/modifications as of April 13, 2023.

FOR FURTHER INFORMATION CONTACT: Shirley M. Miller, U.S. Environmental Protection Agency, Office of Information Management, Mail Stop 2824T, 1200 Pennsylvania Avenue NW, Washington, DC 20460, (202) 566–2908, *miller.shirley@epa.gov.*

SUPPLEMENTARY INFORMATION: On October 13, 2005, the final Cross-Media Electronic Reporting Rule (CROMERR) was published in the **Federal Register** (70 FR 59848) and codified as part 3 of title 40 of the CFR. CROMERR establishes electronic reporting as an acceptable regulatory alternative to paper reporting and establishes requirements to assure that electronic documents are as legally dependable as their paper counterparts. Subpart D of CROMERR requires that state, tribal or local government agencies that receive, or wish to begin receiving, electronic reports under their EPA-authorized programs must apply to EPA for a revision or modification of those programs and obtain EPA approval. Subpart D provides standards for such approvals based on consideration of the electronic document receiving systems that the state, tribe, or local government will use to implement the electronic reporting. Additionally, § 3.1000(b) through (e) of 40 CFR part 3, subpart D provides special procedures for program revisions and modifications to allow electronic reporting, to be used at the option of the state, tribe or local government in place of procedures available under existing program-specific authorization regulations. An application submitted under the subpart D procedures must show that the state, tribe or local government has sufficient legal authority to implement the electronic reporting components of the programs covered by the application and will use electronic document receiving systems that meet the applicable subpart D requirements.

On March 13, 2023, the New Jersey Department of Environmental Protection (NJDEP) submitted an application titled National Pollutant Discharge Elimination System (NPDES) Electronic Reporting Tool (NeT) for revisions/modifications to its EPA-approved programs under title 40 CFR to allow new electronic reporting. EPA reviewed NJDEP's request to revise/modify its EPA-authorized programs and, based on this review, EPA determined that the application met the standards for approval of authorized program revisions/modifications set out in 40 CFR part 3, subpart D. In accordance with 40 CFR 3.1000(d), this notice of EPA's decision to approve NJDEP's request to revise/modify its following EPA-authorized programs to allow electronic reporting under 40 CFR is being published in the **Federal Register**:

Part 123: EPA-Administered Permit Programs: the National Pollutant Discharge Elimination System (NPDES) Reporting under 40 CFR 122 and 125.

NJDEP was notified of EPA's determination to approve its application with respect to the authorized programs listed above.

Dated: April 6, 2023.

Jennifer Campbell,

Director, Office of Information Management.

[FR Doc. 2023–07725 Filed 4–12–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2013–0244; FRL–10818–01–OCSPP]

Pesticide Registration Review; Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of and solicits public comment on EPA's proposed interim registration review decision and draft risk assessment addendum for ethylene oxide.

DATES: Comments must be received on or before June 12, 2023.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2013–0244, 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: The Chemical Review Manager for ethylene oxide as listed in table 1.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental and human health advocates; distributors and users of medical devices; owners and operators of commercial sterilization facilities; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager for ethylene oxide identified in table 1 in unit IV.

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 on a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. 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.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to ethylene oxide (EtO) discussed in this document, compared to the general population.

II. Background

Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed a proposed interim decision and draft risk assessment addendum for ethylene oxide (table 1). Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

III. Authority

EPA is conducting its registration review of ethylene oxide pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

IV. What action is the Agency taking?

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's proposed interim registration review decisions for ethylene oxide and the draft risk assessment addendum and opens a 60-day public comment period on these documents.

TABLE 1—ETHYLENE OXIDE REGISTRATION REVIEW DOCKET DETAILS

Registration review case name and No.	Docket ID No.	Chemical review manager and contact information
Ethylene oxide Case Number 2275	EPA–HQ–OPP–2013–0244	Jessica Bailey *OPPethyleneoxideinquiries@epa.gov.*

The registration review docket for a pesticide includes earlier documents related to the registration review case. For example, the review opened with a Preliminary Work Plan, for public comment. A Final Work Plan was placed in the docket following public comment on the Preliminary Work Plan.

The documents in the docket describe EPA's rationales for conducting additional risk assessments for the registration review of ethylene oxide, as well as the Agency's subsequent risk findings and consideration of possible risk mitigation measures. The proposed interim registration review decision is supported by the rationale included in those documents. Following public comment, the Agency will issue an interim or final registration review decision for ethylene oxide.

The registration review final rule at 40 CFR 155.58(a) provides for a minimum 60-day public comment period on all proposed interim registration review decisions. This comment period is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the proposed interim decision. All comments should be submitted using the methods in **ADDRESSES** and must be received by EPA on or before the closing date. These comments will become part of the docket for ethylene oxide. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

The Agency will carefully consider all comments received by the closing date and may provide a ''Response to Comments Memorandum'' in the docket. The interim registration review decision will explain the effect that any comments had on the interim decision and provide the Agency's response to significant comments.

Background on the registration review program is provided at: *https://www.epa.gov/pesticide-reevaluation.*

Authority: 7 U.S.C. 136 *et seq.*

Dated: March 28, 2023.

Anita Pease,

Director, Antimicrobials Division, Office of Pesticide Programs.

[FR Doc. 2023–07727 Filed 4–12–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10881–01–OA]

Local Government Advisory Committee (LGAC) and Small Communities Advisory Subcommittee (SCAS) Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), EPA herby provides notice of a meeting for the Local Government Advisory Committee (LGAC) and its Small Communities Advisory Subcommittee (SCAS) on the date and time described below. This meeting will be open to the public. For information on public attendance and participation, please see the registration information under

DATES: The LGAC will have a hybrid meeting on May 22nd 2023, from 1 to 5 p.m. Eastern Daylight Time and May 23rd, 2023 from 8:30 a.m. to 12 p.m. Eastern Daylight Time. The SCAS will have a hybrid meeting prior to the LGAC on May 22nd, 2023, from 10:30 a.m. to 12 p.m. Eastern Daylight Time.

FOR FURTHER INFORMATION CONTACT: Paige Lieberman, Designated Federal Officer (DFO), at *LGAC@epa.gov* or 202–564–9957.

Information on Accessibility: For information on access or services for individuals requiring accessibility accommodations, please contact Paige Lieberman by email at *LGAC@epa.gov.* To request accommodation, please do so five (5) business days prior to the meeting, to give EPA as much time as possible to process your request.

SUPPLEMENTARY INFORMATION:

Content

The LGAC will discuss several priority issues at EPA, including providing draft recommendations on proposed national drinking water quality standards for PFAS, continuing discussions on climate mitigation, environmental justice and risk communications regarding PFAS. The SCAS will review these issues, as well as discuss recommendations on land use and transportation issues for small communities. Both the LGAC and SCAS will hear from EPA leadership regarding several new proposed charges. Details on the charges will be posted online (link below) one week prior to the meeting.

Registration

The meeting will be held virtually as well as in person. Members of the public who wish to participate should register by contacting the Designated Federal Officer (DFO) at *LGAC@epa.gov* by May 19, 2023. Online participation will be via Microsoft Teams. In person participation will be at EPA Headquarters, 1200 Constitution Ave. NW, Washington, DC.

Once available, the agenda and other supportive meeting materials will be available online at *https://www.epa.gov/ocir/local-government-advisory-committee-lgac* and will be emailed to all registered. In the event of cancellation for unforeseen circumstances, please contact the DFO or check the website above for reschedule information.

Dated: April 3, 2023.

Paige Lieberman,

Designated Federal Officer, U.S. Environmental Protection Agency.

[FR Doc. 2023–07758 Filed 4–12–23; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality; Notice of Meetings

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of Five AHRQ Subcommittee Meetings.

SUMMARY: The subcommittees listed below are part of AHRQ's Health Services Research Initial Review Group (IRG) Committee. Grant applications are to be reviewed and discussed at these meetings. Each subcommittee meeting will be closed to the public.

DATES: See below for dates of meetings:

1. *Healthcare Research Training (HCRT)*
   Date: May 18–19, 2023
   July 14, 2023
2. *Healthcare Safety and Quality Improvement Research (HSQR)*
   Date: The date of the HSQR meeting is yet to be determined and will be published in an upcoming notice.
3. *Healthcare Information Technology Research (HITR)*
   Date: June 1–2, 2023
4. *Healthcare Effectiveness and Outcomes Research (HEOR)*
   Date: June 7–8, 2023
5. *Health System and Value Research (HSVR)*
   Date: June 15–16, 2023

ADDRESSES: Agency for Healthcare Research and Quality (Virtual Review for HCRT, HEOR & HSVR) 5600 Fishers Lane, Rockville, Maryland 20857, *and* Bethesda North Marriott Hotel & Conference Center (HITR in person review), 5701 Marinelli Road, Rockville, MD 20852–2785.

FOR FURTHER INFORMATION CONTACT: (to obtain a roster of members, agenda or minutes of the non-confidential portions of the meetings.)

Jenny Griffith, Committee Management Officer, Office of Extramural Research Education and Priority Populations, Agency for Healthcare Research and Quality (AHRQ), 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 427–1557.

SUPPLEMENTARY INFORMATION: In accordance with section 10 (a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. 2), AHRQ announces meetings of the above-listed scientific peer review groups, which are subcommittees of AHRQ's Health Services Research Initial Review Group Committee. The subcommittee meetings will be closed to the public in accordance with the provisions set forth in 5 U.S.C. App. 2 section 10(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6). The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Agenda items for these meetings are subject to change as priorities dictate.

Dated: April 7, 2023.

Marquita Cullom,

Associate Director.

[FR Doc. 2023–07747 Filed 4–12–23; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0970–0160]

Submission for Office of Management and Budget Review; Procedures for Requests From Tribal Lead Agencies To Use Child Care and Development Fund Funds for Construction or Major Renovation of Child Care Facilities

AGENCY: Office of Child Care, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for Public Comments.

SUMMARY: The Administration for Children and Families (ACF) is proposing to collect data for the Procedures for Requests from Tribal Lead Agencies to use Child Care and Development Fund (CCDF) Funds for Construction or Major Renovation of Child Care Facilities. This information collection was previously approved by the Office of Management and Budget (OMB). The Office of Child Care is proposing to reinstate the information collection with changes.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: 42 U.S.C. 9858m(c)(6) of the Child Care and Development Block Grant Act allows Tribal Lead Agencies to use CCDF grant awards for construction and renovation of child care facilities. A tribal grantee must first request and receive approval from the ACF before using funds for construction or major renovation. To use CCDF funds awarded in a given fiscal year (FY) on construction or major renovation, a Tribal Lead Agency must submit an application prior to July 1 of that FY. The application deadline applies to direct funded tribes and tribes with CCDF funds integrated into a 477 plan.

This information collection contains the statutorily mandated uniform procedures for the solicitation and consideration of requests, protection of federal interest, and instructions for preparation of environmental assessments in conjunction with the National Environmental Policy Act.

Changes requested to the form clarify the process to align with ACF Real Property Guidance, update language regarding submission of the Standard Form (SF)-429 cover page, include technical changes regarding the official title of Public Law 102–477 to reflect as the Indian Employment, Training and Related Services Consolidation Act of 2017, and include the correct contact for submission of SF–429 information and updated OMB circular references.

Respondents: Tribal Child Care Lead Agencies acting on behalf of tribal governments.

ANNUAL BURDEN ESTIMATES

Instrument	Type of burden	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Procedures for Requests from Tribal Lead Agencies to use CCDF Funds for Construction or Major Renovation of Child Care Facilities.	Reporting	75	2	5	750	250
	Record-keeping			15	2,250	750

Estimated Total Annual Burden Hours: 1000.

Authority: 42 U.S.C. 9858(c)(6).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–07763 Filed 4–12–23; 8:45 am]

BILLING CODE 4184–81–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget (OMB) Review; Tribal Maternal, Infant, and Early Childhood Home Visiting Program: Implementation Plan Guidance for Development and Implementation and Implementation and Expansion Grantees

AGENCY: Office of Early Childhood Development, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for Public Comments.

SUMMARY: The Administration for Children and Families (ACF), Office of Early Childhood Development (ECD) is requesting Office of Management and Budget (OMB) approval of Tribal Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Implementation Plan Guidance for Tribal Home Visiting Development and Implementation Grants (DIG) and Tribal Home Visiting Implementation and Expansion Grants (IEG).

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect

if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Section 511(e)(8)(A) of Title V of the Social Security Act requires that grantees under the Tribal MIECHV program, in the first year of their grants, submit an implementation plan on how they will meet the requirements of the program. Section 511(h)(2)(A) further states that the requirements for the MIECHV grants to tribes, tribal organizations, and urban Indian organizations are to be consistent, to the greatest extent practicable, with the requirements for grantees under the MIECHV program for states and jurisdictions.

The ACF Office of Early Childhood Development, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau awarded grants for the Tribal MIECHV Program to support cooperative agreements to conduct community needs assessments; plan for and implement high-quality, culturally relevant, evidence-based home visiting programs in at-risk tribal communities; establish, measure, and report on progress toward meeting performance measures in six legislatively mandated benchmark areas; and conduct rigorous evaluation activities to build the knowledge base on home visiting among Native populations.

During the first grant year, Tribal Home Visiting DIG and IEG grantees must comply with the requirement to submit an implementation plan that should feature planned activities to be carried out under the program in years 2–5 of their cooperative agreements. To assist grantees with meeting these requirements, ACF created guidance for grantees to use when writing their plans. The DIG and IEG guidance specify that grantees must provide a plan to address the following areas:

- Community Needs and Readiness Assessment
- Program Design
- Program Blueprint
- Plan for Data Collection, Management and Performance Measurement
- Fidelity Monitoring and Quality Assurance

Respondents: Tribal Home Visiting Managers (information collection does not include direct interaction with individuals or families that receive the services).

TOTAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Implementation Plan Guidance for Development and Implementation Grantees	13	1	1000	13,000
Implementation Plan Guidance for Implementation and Expansion Grantees	35	1	1000	35,000
Estimated Total Annual Burden Hours:				48,000

Authority: Title V of the Social Security Act, Sections 511(e)(8)(A) and 511(h)(2)(A).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–07845 Filed 4–12–23; 8:45 am]

BILLING CODE 4184–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1188]

Over-the-Counter Monograph Order Requests: Format and Content; 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 ''Over-the-Counter Monograph Order Requests (OMORs): Format and Content.'' This draft guidance provides recommendations on the format and content of the information that a requestor should provide in an over-the-counter (OTC) monograph order request (OMOR) and identifies relevant guidance documents to assist requestors in preparing their OMORs.

DATES: Submit either electronic or written comments on the draft guidance by June 12, 2023 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–1188 for ''Over-the-Counter Monograph Order Requests (OMORs): Format and Content.'' 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: Trang Tran, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–7945.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Over-the-Counter Monograph Order Requests (OMORs): Format and Content.'' This draft guidance is intended to assist requestors in preparing OMORs for submission to FDA under section 505G of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h). This draft guidance provides recommendations on the format and content of the information that a requestor should provide in an OMOR and identifies relevant guidance documents to assist requestors in preparing their OMORs.

Section 505G of the FD&C Act was added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136), which was enacted on March 27, 2020. As required by section 505G(l) of the FD&C Act, this draft guidance, when finalized, will discuss the format and content of data submissions, specifically OMORs, to FDA.

In support of the CARES Act, FDA agreed to specific performance goals and procedures described in the document ''Over-the-Counter Monograph User Fee Program Performance Goals and Procedures—Fiscal Years 2018–2022,'' commonly referred to as the OMUFA Commitment Letter (the document can be accessed at *https://www.fda.gov/media/106407/download* and the document with updated goal dates for fiscal years 2021–2025 can be accessed at *https://www.fda.gov/media/146283/download*). In the OMUFA Commitment Letter, FDA committed to issuing this draft guidance under specific timelines.

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 ''Over-the-Counter Monograph Order Requests (OMORs): Format and Content.'' 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 section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 (chapter 35 of title 44, United States Code) does not apply to collections of information made under section 505G of the FD&C Act. The information collections described in this guidance implement the following provisions of section 505G:

(1) Section 505G(b)(5) of the FD&C Act, which allows submission of administrative orders, OMORs, initiated at the request of a requestor.

(2) Section 505G(b)(6) of the FD&C Act, which allows requestors to provide certain information regarding safe nonprescription product marketing and use as a condition for filing a generally recognized as safe and effective request.

(3) Section 505G(d) of the FD&C Act confidentiality of information submitted to the Secretary, which requires FDA to make information submitted in support of an OMORs available to the public no later than the date of the proposed order unless it meets certain limitations on public availability.

(4) Section 505G(j) of the FD&C Act, which requires that all submissions under section 505G must be in electronic format.

(5) Section 505G(l)(1) of the FD&C Act, which requires FDA to issue guidance that specifies the procedures and principles for formal meetings between the Secretary and sponsors or requestors for drugs subject to section 505G.

(6) Section 505G(1)(2) of the FD&C Act, which requires FDA to issue guidance that specifies the format and content of data submissions to the Secretary under section 505G.

(7) Section 505G(1)(3) of the FD&C Act, which requires FDA to issue guidance that specifies the format of electronic submissions to the Secretary under section 505G.

Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for these collections of information. In addition, this guidance refers to previously approved FDA collections of information. The previously approved collections of information are subject to review by OMB under the PRA. The collections of

information for OTC monograph products, OTC monograph order requests, and the OTC Monograph User Fee Program have been approved under OMB control number 0910–0340. The information collections for submission of new drug applications and abbreviated new drug applications in 21 CFR part 314 are approved under OMB control number 0910–0001. The collections of information used by FDA to assess the environmental impact of Agency actions and to ensure that the public is informed of environmental analyses under 21 CFR part 25 have been approved under OMB control number 0910–0322.

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: April 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07767 Filed 4–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1052]

Food and Drug Administration Data and Technology Strategic Plan; Request for Information and Comments

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

ACTION: Notice; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a request for information and comments on the development of an FDA Data and Technology Strategic Plan. As part of our User Fee Program commitments and Omnibus Bill requirements, FDA will develop and publish an FDA Data and Technology Strategic Plan by September 30, 2023. This plan will define and shape the future course of FDA's data and technology capabilities, building on the existing FDA Modernization Framework. The plan will also integrate Agency and center strategies.

DATES: Submit either electronic or written comments on the request for information and comments by May 15, 2023 to ensure that the Agency considers your comments before it begins work on the final version of the strategy.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2023–N–1052 for ''FDA Data and Technology Strategic Plan.'' 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.

FOR FURTHER INFORMATION CONTACT: Casi Alexander, Office of Digital Transformation, Food and Drug Administration, FDA Library, 5630 Fishers Lane, Rm. 1087, Rockville, MD 20857, 240–402–5171, email: *Casi.Alexander@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a request for information and comments entitled ''FDA Data and Technology Strategic Plan; Request for Information and Comments.''

The Office of Digital Transformation (ODT) was established in September 2021 and reports directly to the Office of the Commissioner. ODT provides the vision and leadership in information technology, data, and cybersecurity needed to advance FDA's mission and strategic priorities. ODT has published a series of strategy documents known as

the FDA Modernization Framework. The framework includes the Technology Modernization Action Plan, Data Modernization Action Plan, Enterprise Modernization Action Plan, Cybersecurity Modernization Action Plan, and the Leadership Modernization Action Plan. The FDA Modernization Framework aims to develop an integrated technology, data, cybersecurity, business, and leadership approach to advancing FDA's public health mission in collaboration with industry.

As part of the FDA's fulfillment of requirements in section 3627 of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), and commitments described in section IV.A.2. of the ''PDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027'' (PDUFA VI commitment letter), FDA will work with industry as it develops a comprehensive framework for guiding the Agency's work and allocating annual technology budgets and resources. The FDA Data and Technology Strategic Plan, covering Fiscal Years 2024–2027, will define and shape the future course of FDA's data and technology capabilities as FDA transitions to the next phase of its journey. FDA will take an iterative approach to strategy development, starting with gathering input, then, sharing a draft of the strategic plan for comment and finally, considering inputs provided before publishing a final version of the strategic plan. FDA will focus on the outcomes to empower the Agency to meet its mission, building on the existing FDA Modernization Framework and integrating Agency and center strategies. FDA will engage internal and external stakeholders early and often throughout this process. FDA plans to incorporate stakeholder input as the Agency engages with internal and external stakeholders across the remainder of this fiscal year including through two **Federal Register** notices for information and comment (this one and a second one for comment on the draft strategy). Stakeholder input is crucial for developing a comprehensive plan that best meets the needs and goals of industry and the Agency.

II. Requested Information and Comments

Interested persons are invited to provide detailed comments to ODT (see **ADDRESSES**) on the following aspects of the development of FDA's Agency-wide Data and Technology Strategic Plan. To facilitate input, FDA has developed a series of questions in this section. The questions are not meant to be exhaustive, and FDA is also interested in any other pertinent information stakeholders would like to share on this topic. This feedback will help inform the Agency's strategy development. FDA encourages stakeholders to provide the specific rationale and basis for their comments, including any available supporting data and information. FDA will publish another notice in the **Federal Register** requesting comments once the Data and Technology Modernization Strategy is developed.

1. What are up to three outcomes the FDA Data and Technology Strategic Plan can help you achieve, *e.g.,* speed to market?
2. What are up to three challenges you are facing while trying to achieve these outcomes?
3. What data and technical capabilities could FDA strengthen to help support its public health mission?
4. What opportunities or risks do you foresee for the FDA Data and Technology Strategic Plan?
5. What changes or trends in your industry could impact the FDA Data and Technology Strategic Plan?
6. How might FDA best communicate and engage stakeholders in developing and implementing the strategy?

Dated: April 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07766 Filed 4–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1043]

Exemption of Certain Categories of Biological Products From Certain Reporting Requirements Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is issuing a final order to exempt certain categories of biological products from certain reporting requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). Specifically, each person who registers with FDA with regard to a drug is required to report annually to FDA on the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution; however, certain biological products or categories of biological products may be exempted by order from these reporting requirements if FDA determines that applying such reporting requirements is not necessary to protect the public health. This final order exempts two categories of biological products from these reporting requirements because the Agency has determined that applying such requirements is not necessary to protect the public health.

DATES: This order is effective May 15, 2023.

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

FOR FURTHER INFORMATION CONTACT: Jessica 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—Reporting Requirements Under Section 510(j)(3) of the FD&C Act

On March 27, 2020, the CARES Act (Pub. L. 116–136) was enacted to aid response efforts and ease the economic impact of the Coronavirus Disease 2019. In addition, the CARES Act included authorities to enhance FDA's ability to identify, prevent, and mitigate possible drug shortages by, among other things, enhancing FDA's visibility into drug supply chains.

Section 3112(e) of the CARES Act added new paragraph (3) to section 510(j) of the FD&C Act (21 U.S.C. 360(j)(3)), which requires that each person who registers with FDA under section 510 of the FD&C Act with regard to a drug must report annually to FDA on the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution. These reporting requirements in section 510(j)(3)(A) of the FD&C Act enhance FDA's ability to address drug shortages by enabling the Agency to identify manufacturing sites impacted and develop potential options to remediate shortage risks to the product supply chain.

Under section 510(j)(3)(B) of the FD&C Act, FDA may exempt certain

biological products or categories of biological products regulated under section 351 of the Public Health Service Act (42 U.S.C. 262) from some or all of the reporting requirements under section 510(j)(3)(A) of the FD&C Act, if FDA determines that applying such reporting requirements is not necessary to protect the public health.

In the **Federal Register** of October 27, 2021 (86 FR 59395), FDA published a proposed order entitled ''Exemption of Certain Categories of Biological Products from Certain Reporting Requirements Under the Federal Food, Drug, and Cosmetic Act'' in which FDA proposed to exempt certain categories of biological products from certain reporting requirements under FD&C Act as amended by the CARES Act. Specifically, FDA proposed to exempt the following two categories of biological products from all of the reporting requirements under section 510(j)(3)(A) of the FD&C Act pursuant to section 510(j)(3)(B) of the FD&C Act because the Agency determined that applying such requirements is not necessary to protect the public health: (1) Blood and blood components for transfusion and (2) cell and gene therapy products, where one lot treats a single patient.

II. Comments on the Proposed Order and FDA Response

In response to the October 27, 2021, proposed order, FDA received one comment by the close of the comment period. We describe and respond to the comment in this section of the document.

(Comment 1) One comment recommends that FDA expand the proposed order to also exempt ''made-to-stock'' cell and gene therapy products. The comment asserts that the supply chains for such products are ''well-established and well-understood'' from information in the biologics license applications (BLAs), and generally do not involve wholesale distributors, brokers, or other intermediaries.

(Response) We decline to expand the order to exempt ''made to stock'' cell and gene therapy products. ''Made-to-stock'' cell and gene therapy products are generally manufactured in lots or batches for commercial distribution, based on projected product demand, and they are not typically for use where one lot treats a single patient. We disagree that the supply chains for ''made-to-stock'' cell and gene therapy products are well-established and well-understood. Even though they may not involve wholesale distributors, brokers, or other intermediaries, FDA has limited visibility into the supply chains for such products. We reiterate that the CARES Act included authorities to enhance FDA's ability to identify, prevent, and mitigate possible drug shortages by, among other things, improving FDA's visibility into drug supply chains. When FDA is notified of an impending manufacturing problem that could lead to a supply interruption,[1] having information about the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed for commercial distribution, as reported under section 510(j)(3)(A) of the FD&C Act, can provide insight into how much manufacturing typically occurs at the affected facility and whether the problem may lead to a drug shortage. Furthermore, these data can help the Agency to identify and measure supply chain vulnerabilities that could be longer term risk factors for drug shortages. We anticipate that requiring registrants to report annually under section 510(j)(3)(A) of the FD&C Act on the amount of ''made-to-stock'' cell and gene therapy products manufactured, prepared, propagated, compounded, or processed for commercial distribution will improve FDA's visibility into the supply chains for these products and enhance the Agency's ability to identify, prevent, and mitigate possible shortages. There is not an adequate basis at this time for FDA to determine that applying such reporting requirements to this category of biological products is not necessary to protect the public health. Thus, there is not an adequate basis to exempt ''made-to-stock'' cell and gene therapy products from the reporting requirements under section 510(j)(3)(A) of the FD&C Act pursuant to section 510(j)(3)(B) of the FD&C Act.

III. Exempted Categories of Biological Products

FDA is finalizing the order to exempt the following two categories of biological products from all of the reporting requirements under section 510(j)(3)(A) of the FD&C Act pursuant to section 510(j)(3)(B) of the FD&C Act because FDA has determined that applying such reporting requirements is not necessary to protect the public health:

- Blood and blood components for transfusion; and
- Cell and gene therapy products, where one lot treats a single patient.

[1] See, *e.g.,* section 506C(a) of the FD&C Act (21 U.S.C. 355d) (notifications of discontinuance or interruption in the production of life-saving drugs).

A. Blood and Blood Components for Transfusion

In accordance with section 510(j)(3)(B) of the FD&C Act, this order exempts blood and blood components for transfusion from the reporting requirements under section 510(j)(3)(A) of the FD&C Act. In light of FDA's existing visibility into the supply chain for this category of products, requiring registrants to report annually under section 510(j)(3)(A) of the FD&C Act on the amount of such products manufactured, prepared, propagated, compounded, or processed for commercial distribution is not needed to enhance the Agency's ability to identify, prevent, and mitigate possible shortages. As such, FDA has determined that applying the reporting requirements under section 510(j)(3)(A) of the FD&C Act to this category of biological products is not necessary to protect the public health.

Generally, registered blood establishments are inspected on a biennial basis by the Agency. There are approximately 1,900 registered blood establishments that manufacture blood and blood components for transfusion, all located in the United States, as well as a small number of United States military blood establishments that are located internationally in order to provide blood and blood components to United States military personnel onsite when needed. The supply chains for blood and blood components for transfusion are well-established and well-understood based on the nature of the products; namely, blood is collected from human donors via venipuncture, separated into components (if applicable), and stored at specified temperatures and under the complete control of each blood establishment. Additionally, supply chains for blood and blood components for transfusion are controlled and secure from initial donation to final product delivery to the transfusion site and, generally, do not involve wholesale distributors, brokers, or other intermediaries. Further, many registered blood establishments voluntarily submit the amount of blood and blood components for transfusion manufactured as part of the Health and Human Services National Blood Collection and Utilization Survey (NBCUS), which, historically, has a high response rate.[2]

[2] See *https://doi.org/10.1111/trf.16449.* The response rate for the 2019 NBCUS was 94 percent for community-based blood collection facilities and 84 percent for hospital-based blood collection facilities.

B. Cell and Gene Therapy Products, Where One Lot Treats a Single Patient

In accordance with section 510(j)(3)(B) of the FD&C Act, this order exempts cell and gene therapy products, where one lot treats a single patient, from the reporting requirements under section 510(j)(3)(A) of the FD&C Act. In light of FDA's existing visibility into the supply chain for this category of products, requiring registrants to report annually under section 510(j)(3)(A) of the FD&C Act on the amount of such products manufactured, prepared, propagated, compounded, or processed for commercial distribution, is not needed to enhance the Agency's ability to identify, prevent, and mitigate possible shortages. As such, FDA has determined that applying the reporting requirements under section 510(j)(3)(A) of the FD&C Act to this category of biological products is not necessary to protect the public health.

Manufacturers of cell and gene therapy products, where one lot treats a single patient, maintain a highly controlled and secure supply chain from initial request for treatment of a patient to final product delivery to the site where the treatment occurs. This is because, due to the nature of these products, manufacturers implement strict chain of identity procedures to track products through the manufacturing process, to make sure the correct product gets to the correct patient. Additionally, the supply chains for these products are well-established and well-understood from information described in the BLA, and generally do not involve wholesale distributors, brokers, or other intermediaries.

Additionally, pursuant to § 600.81 (21 CFR 600.81), the Agency generally receives lot distribution reports every 6 months from BLA holders. Specifically, reports submitted to the Agency under § 600.81 include, among other information, the fill lot numbers for the total number of dosage units of each strength or potency distributed, the label lot number (if different from fill lot number), the number of doses in fill lot/label lot, and the date of release of fill lot/label lot for distribution. For this category of biological products, because one lot treats a single patient, the lot distribution reports submitted to the Agency under § 600.81 represent the amount of product manufactured for commercial distribution, and additional reporting of such information under section 510(j)(3)(A) of the FD&C Act would be redundant.

IV. Paperwork Reduction Act of 1995

This final order 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 information collection provisions of this final order are approved under 0910–0045.

V. Effective Date

This final order is effective 30 days after its date of publication in the **Federal Register**.

Dated: April 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07772 Filed 4–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1254]

Assessing Adhesion With Transdermal and Topical Delivery Systems for Abbreviated New Drug Applications; Revised 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 revised draft guidance for industry entitled ''Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs'' (Revision 2). This draft guidance (Revision 2) revises the Revision 1 draft guidance of the same name, which was announced in the **Federal Register** on October 10, 2018. This revised draft guidance provides recommendations for the design and conduct of studies evaluating the adhesion performance of a transdermal or topical delivery system (collectively referred to as TDS). Depending on the objectives of a generic TDS product development program, applicants may choose to evaluate TDS adhesion in studies performed to evaluate TDS adhesion only, or in studies performed with a combined purpose (*e.g.,* for the simultaneous evaluation of adhesion and bioequivalence (BE) with pharmacokinetic (PK) endpoints). The recommendations in this revised draft guidance relate to studies submitted in support of an abbreviated new drug application (ANDA).

DATES: Submit either electronic or written comments on the draft guidance by June 12, 2023 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 2016–D–1254 for ''Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs.'' 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: Melissa Mannion, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1611, Silver Spring, MD 20993–0002, 301–796–2747.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs'' (Revision 2). This revised draft guidance (Revision 2) revises the Revision 1 draft guidance of the same name, which was announced in the **Federal Register** on October 10, 2018 (83 FR 50942). FDA received five comments on the revised draft guidance (Revision 1), which were considered before publication of this revised draft guidance (Revision 2).

This revised draft guidance (Revision 2) provides recommendations for the design and conduct of studies evaluating the adhesion performance of a TDS submitted in support of an ANDA. Depending on the objectives of a TDS product development program, applicants may choose to evaluate TDS adhesion in studies performed to evaluate TDS adhesion only or in studies performed with a combined purpose (*e.g.,* for the simultaneous evaluation of adhesion and BE with PK endpoints). FDA recommends that applicants consult this revised draft guidance (Revision 2) in conjunction with any relevant product-specific guidances for industry when considering the design and conduct of studies that may be appropriate to support the BE of a proposed generic TDS product to its reference listed drug and/or reference standard product.

Specifically, in response to the comments received from industry, FDA is clarifying the following components of the guidance. When recording measurements of TDS adhesion, applicants may use appropriate methods (*e.g.,* a trained visual assessment and/or dot matrix templates) and are encouraged to explore the use of alternative scales (other than the five-point adhesion scale) to estimate the percentage of the entire TDS surface area that is adhered to the skin. At each adhesion assessment time point, applicants should also record photographic evidence showing the extent of TDS adhesion to the skin. Because percent adhesion can span a range and yet be classified as a single score, the photographic evidence can be used to support the visual observation of the percent adhesion reported at each time point and is not intended to be used for automated or photometric analysis at this time. Additional clarity is also provided related to the statistical analysis of data. Finally, FDA recommends that an applicant who seeks to use an alternative approach to FDA's recommendations for the design and conduct of studies evaluating the adhesion performance of a TDS to contact the Agency to discuss the proposed alternative approach to evaluate adhesion performance for that particular drug product.

This revised draft guidance (Revision 2) is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on ''Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs.'' 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 revised draft guidance (Revision 2) contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.regulations.gov,* or *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

Dated: April 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07770 Filed 4–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3546]

Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs; Revised 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 revised draft guidance for industry entitled ''Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs.'' This revised draft guidance provides recommendations for the design and conduct of studies to evaluate the in vivo skin irritation and sensitization (I/S) potential of a proposed transdermal or topical delivery system (collectively referred to as TDS). The recommendations in this revised draft guidance relate to studies submitted in support of an abbreviated new drug application (ANDA). The revised draft guidance is intended to clarify FDA's recommendations and expectations related to in vivo skin I/S studies. This guidance revises the October 2018 draft guidance entitled ''Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs.''

DATES: Submit either electronic or written comments on the draft guidance by June 12, 2023 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–2018–D–3546 for ''Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs.'' 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: Melissa Mannion, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1611, Silver Spring, MD 20993–0002, 301–796–2747.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs.'' This guidance revises the draft guidance entitled ''Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs'' that was published in the **Federal Register** on October 10, 2018 (83 FR 50945). FDA received eight comments on the draft guidance, which were considered before publication of this revised draft guidance.

The components and composition of a TDS formulation, including the nature of the drug substance and/or the occlusivity of the TDS materials, in conjunction with other factors such as the environmental humidity or the condition of the skin, may have the potential to irritate the skin or lead to a sensitization reaction. Such reactions can be unpleasant to the patient and may affect patient compliance, skin permeability, and/or adhesion of the TDS to the skin. The collective consequence of these potential effects could create uncertainty about the resulting drug delivery profile and uncertainty about the rate and extent of drug absorption from the TDS. Therefore, when appropriate, applicants should perform a comparative assessment of the test (T) and reference

(R) TDS products using an appropriately designed skin I/S study with human subjects to demonstrate that the potential for a skin irritation or sensitization reaction with the T TDS is no worse than the reaction observed with the R TDS.

This revised draft guidance provides the following updates to the original draft guidance:

(1) Clarifies recommendations for the design and conduct of studies to evaluate the in vivo skin I/S potential of a proposed TDS.

(2) Clarifies when an in vivo study to assess the sensitization potential of a TDS product may not be needed.

(3) Provides guidance to applicants intending to utilize alternative scoring scales or alternative approaches to compare irritation and sensitization between the T and R TDS.

The recommendations in this revised draft guidance relate to studies submitted in support of an ANDA. The Agency is seeking comments on the recommendations reflected in the revised draft guidance announced in this notice. In addition, FDA invites comments on the scoring scales and any alternative approaches, including those recommended by international regulatory agencies, that may have been used for the comparative assessment of the I/S potential for proposed generic TDS products. FDA also specifically invites comments regarding the comparative assessment of sensitization itself, *i.e.,* whether there are clinical scenarios where a comparative sensitization assessment may be uninformative when conducted in addition to a comparative irritation assessment.

This revised 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 ''Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs.'' 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 revised draft guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 relating to the submission of abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information relating to good clinical practice have been approved under OMB control number 0910–0843.

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: April 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07769 Filed 4–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0915–0379 Revision]

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Questionnaire and Data Collection Testing, Evaluation, and Research for the Health Resources and Services Administration

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than June 12, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the acting HRSA Information Collection Clearance Officer, at (301) 594–4394.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Questionnaire and Data Collection Testing, Evaluation, and Research for HRSA—OMB No. 0915–0379—Revision

Abstract: The purpose of information collections under this generic umbrella ICR package is to allow HRSA to continue collecting feedback from members of the public for HRSA to use when developing new questions, questionnaires, and tools; pilot/pre-test instruments to be deployed by HRSA; and to identify problems in instruments currently in use.

This generic clearance is limited to data collection for the development or revision of HRSA tools and data collection instruments, as well as reports for internal decision-making and development purposes. Information collected under this generic clearance will not be used for data collection, reports, or policy documents to be released to the public. It is anticipated that data collection approved under this generic clearance will rely heavily on qualitative techniques and not the collection of numerical data. In general, these activities are not designed to yield results that meet generally accepted standards of statistical rigor but designed to obtain information to develop clearer and more effective and efficient data collection tools that will yield more accurate results and decrease public non-response. The forms submitted under this generic clearance will be voluntary, low-burden, and uncontroversial.

HRSA originally developed this generic umbrella ICR to support similar needs across HRSA's bureaus and offices as reflected in their specific activities informed by their specific authorizing statutes. The purpose is to collect qualitative data from small groups of people in response to short questionnaires, using questions posed on HRSA's website, through focus groups and individual interviews of HRSA staff and members of the public. The abbreviated clearance process of the generic clearance helps ensure timely data gathering on current issues HRSA is addressing (*e.g.,* allows program offices to gather a suitable pool of

candidates for piloting future instruments).

HRSA seeks to extend OMB approval of this ICR and existing ICRs that fall under it while including a slight increase in the burden estimate to account for HRSA's implementation of Executive Order 13985, which calls on agencies to advance racial equity and support for underserved communities through identifying and addressing barriers to equal opportunity that underserved communities may face; HRSA will likely conduct additional information collection requests so that HRSA may effectively implement this Executive Order.

Need and Proposed Use of the Information: HRSA conducts interviews, focus groups, usability tests, and field tests/pilot interviews for data collection instrument development and evaluation (including assessment of response errors in data collection instruments). HRSA staff use various techniques to evaluate interviewer-administered, self-administered, telephone, Computer Assisted Personal Interviewing, Computer Assisted Self-Interviewing, Audio Computer-Assisted Self-Interviewing, and web-based questionnaires.

Each information collection under this generic clearance will specify the specific testing and evaluation procedures to be used. Participation will be fully voluntary, and non-participation will not affect eligibility for, or receipt of, future HRSA health services research activities or grant awards, recruitment, or participation. Appropriate consent procedures will be customized and used for each information collection activity and any collection of personal, privacy-protected information will be handled in accordance with all applicable federal requirements. If HRSA wishes to record the encounter, the respondent's permission to record will be obtained before beginning the interview. If consent is not provided, the interview either will not be recorded or not be conducted. When screening is used (*e.g.,* quota sampling), the screening will be as brief as possible, and the screening questionnaire will be provided to OMB for review.

Collection methods—The particular information collection methods used will vary, but may include the following:

- Individual in-depth interviews—In-depth interviews will commonly be used to ensure that the respondent understands the meaning of a questionnaire or strategy. When in-depth interviewing is used, the interview guide will be provided to OMB for review.
- Focus groups—Focus groups will be used to obtain insights into beliefs and understandings of the target audience early in the development of a questionnaire or tool. When focus groups are used, the focus group discussion guide will be provided to OMB for review.
- Expert/Gatekeeper review of tools—In some instances, medical providers or other gatekeepers may review tools to provide feedback on the acceptability and usability of a particular tool. This will usually be in addition to an individual user pretesting the tool.
- Record abstractions—On occasion, the development of a tool or other information collection requires review and interaction with records, rather than individuals.
- ''Dress rehearsal'' of a specific protocol—In some instances, the proposed pre-testing will constitute a walkthrough of the intended data collection procedure. In these cases, the request will mirror what is expected to occur for the larger scale data collection.

Professionally recognized procedures are followed in each information collection activity to ensure collection of high-quality information. Examples of these procedures could include the following:

- Monitoring by supervisory staff of some telephone interviews;
- Conducting interviews using methods including ''think-aloud'' techniques and debriefings;
- Computerizing data-entry from mail or paper-and-pencil surveys using scannable forms or double-key entry (*i.e.,* two people input the data from mail or paper-and-pencil surveys into an electronic format, and then comparing the two sets of entries for anomalies);
- Monitoring by observers of focus groups and recording (*e.g.,* video recording, audio recording) of focus group proceedings (subject to participant consent); and
- Employing commonly used statistical validation techniques to ensure accuracy (such as disallowing out-of-range values) of data submitted through on-line surveys.

HRSA is requesting approval for generic information collections previously approved by OMB. These include:

- Health Center Workforce Well-Being Survey: Listening Sessions
- Health Center Workforce Well-Being Survey: Cognitive Sessions
- Health Center Workforce Well-Being Survey: Pilot Testing
- Health Center Workforce Survey Evaluation and Technical Assistance: Pilot Survey
- Fast Track Interviews with National Hypertension Control Initiative Group 2 Participants.

HRSA notes that the previously approved collections are mostly unchanged, except that they may have updates to include any advances in burden estimation or information collection protocols. HRSA also anticipates conducting additional collections as the agency implements Executive Order 13985. To identify areas for improvement, HRSA anticipates collecting and aggregating data by race, ethnicity, gender, disability, income, veteran status, or other key demographic variables, while protecting individual privacy, so that HRSA can use the information to help increase equity in its programs for people from a robust range of demographic groups.

Likely Respondents: Participation in any collections under this clearance will be entirely voluntary, and the privacy of respondents will be preserved to the extent requested by participants and as permitted by law.

Respondents will be recruited by means of advertisements in public venues or through techniques that replicate prospective data collection activities that are the focus of the project. For instance, a survey on physician communication, designed to be administered following an office visit, might be pretested using the same procedure. Each ICR will specify the recruitment procedure to be used.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. HRSA anticipates that the total burden of collections under this generic package will be slightly greater than under the prior approval, due to HRSA's efforts to comply with Executive Order 13985. HRSA also reduced the number of hours for in-person testing as it has become a less popular option among prospective survey participants. The total annual

burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Type of information collection	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Mail/email [1]	1,000	1	1,000	0.26	260
Telephone	1,000	1	1,000	0.26	260
Web-based	1,200	1	1,200	0.25	300
Focus Groups	925	1	925	1.00	925
In-person	250	1	250	1.00	250
Automated [2]	500	1	500	1.00	500
Cognitive Testing	700	1	700	1.41	987
Total	5,575		5,575		3482

[1] May include telephone non-response follow-up in which case the burden will not change.
[2] May include testing of database software, Computer Assisted Personal Interviewing software, or other automated technologies.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–07774 Filed 4–12–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Carlo Spirli, Ph.D. (Respondent), who was an Assistant Professor of Medicine, Department of Digestive Diseases, Yale University (YU). Respondent engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), grants R01 DK079005 and P30 DK034989. The administrative actions, including debarment for a period of four (4) years, were implemented beginning on March 28, 2023, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Sheila Garrity, JD, MPH, MBA, Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Carlo Spirli, Ph.D., Yale University: Based on the report of an investigation conducted by YU and additional analysis conducted by ORI in its oversight review, ORI found that Carlo Spirli, Ph.D., former Assistant Professor of Medicine, Department of Digestive Diseases, YU, engaged in research misconduct in research supported by PHS funds, specifically NIDDK, NIH, grants R01 DK079005 and P30 DK034989.

ORI found that Respondent engaged in research misconduct by knowingly, intentionally, or recklessly falsifying and/or fabricating data included in the following four (4) published papers, two (2) presentations, and three (3) grant applications submitted for PHS funds:

- Cyclic AMP/PKA-dependent Paradoxical Activation of Raf/MEK/ERK Signaling in Polycystin-2 Defective Mice Treated with Sorafenib. *Hepatology.* 2012 Dec;56(6):2363–74. doi: 10.1002/hep.25872 (hereafter referred to as ''*Hepatology* 2012a'').
- Altered Store Operated Calcium Entry Increases Cyclic 3′,5′-Adenosine Monophosphate Production and Extracellular Signal-Regulated Kinases 1 and 2 Phosphorylation in Polycystin-2-Defective Cholangiocytes. *Hepatology.* 2012 Mar;55(3):856–68. doi: 10.1002/hep.24723 (hereafter referred to as ''*Hepatology* 2012b'').
- Protein Kinase A-Dependent pSer(675)-β-catenin, a Novel Signaling Defect in a Mouse Model of Congenital Hepatic Fibrosis. *Hepatology.* 2013 Nov;58(5):1713–23. doi:10.1002/hep.26554 (hereafter referred to as ''*Hepatology* 2013'').
- Posttranslational Regulation of Polycystin-2 Protein Expression as a Novel Mechanism of Cholangiocyte Reaction and Repair from Biliary Damage. *Hepatology.* 2015 Dec; 62(6):1828–39. doi: 10.1002/hep.28138 (hereafter referred to as ''*Hepatology* 2015''). Retraction in: *Hepatology.* 2022 Dec;76(6):1904. doi: 10.1002/hep.32595.
- PKA-Dependent p-SER675-b-Catenin Phosphorylation Increases Cholangiocyte Motility in Pkhd1del4/del4 Mouse, a Model of Fibropolycystic Liver Diseases Caused by Defective Fibrocystin Function. Presented at the European Association for the Study of the Liver (EASL) (hereafter referred to as ''EASL Presentation 2011'').
- Cyclic-AMP-Dependent, Rac1-Mediated Nuclear Translocation Of P-Ser-675β-Catenin, A Novel Signaling Defect in Congenital Hepatic Fibrosis (CHF) and Caroli's Disease (CD). Presented at the American Association for the Study of Liver Diseases (AASLD) Annual Meeting, Boston, MA, in November 2012 (hereafter referred to as ''AASLD Presentation 2011'').
- R01 DK079005–11A1, ''Epithelial Angiogenic Signaling in Biliary Pathophysiology and in Polycystic Disease,'' submitted to NIDDK, NIH, on December 13, 2018. Administratively withdrawn by the funding agency on March 1, 2021.
- R01 DK090021–01 ''Mechanisms of fibrosis in fibrocystin-deficiency associated cholangiopathies'' submitted to NIDDK, NIH, on February 2, 2010. Administratively withdrawn by the funding agency on July 1, 2012.
- R01 DK090021–01A1 ''Mechanisms of fibrosis in fibrocystin-deficiency associated cholangiopathies'' submitted to NIDDK, NIH, on November 11, 2010.

Administratively withdrawn by the funding agency on July 1, 2015.

Respondent knowingly, intentionally, or recklessly falsified and/or fabricated Western blot image data for cholangiopathies in a murine model of Congenital Hepatic Fibrosis (CHF) by reusing blot images, with or without manipulating them to conceal their similarities, and falsely relabeling them as data representing different experiments or proteins and falsifying quantitative data in associated graphs purportedly derived from those images in twenty-one (21) figures included in four (4) papers, two (2) presentations, and three (3) grant applications. In the absence of reliable image and numerical data, the figures, statistical analyses, and related text also are false.

Specifically, the respondent reused Western blot images from the same source and falsely relabeled them to represent different proteins and/or experimental results in:

- *Hepatology* 2012a:

—Figure 3, representing different concentrations of sorafenib treatment in:
  - ➢ pERK blot panel, lanes 1–2 and 3–4 are the same
  - ➢ pERK blot panel, lanes 2, 4, and 5 are the same

—Figure 4C and Figure 6C (left), representing different concentrations of sorafenib treatment in:
  - ➢ CC3 blot panel, lanes 1 and 2 are the same

—Figure 4C, representing different concentrations of sorafenib treatment in:
  - ➢ Actin blot panel, lanes 3–7 for wild type (WT) and lanes 8–12 for Pkd2cKO cholangiocytes are the same

—Figure 5A (left), representing B-Raf kinase activity with different concentrations of sorafenib treatment in WT:
  - ➢ ERK1/2 blot panel, lanes 1–2 and lanes 3–4 are the same

—Figure 5A (right), representing and Raf-1 kinase activity with different concentrations of sorafenib treatment in WT:
  - ➢ ERK1/2 blot panel, lanes 1–2 and lanes 3–4 are the same

- *Hepatology* 2012b:

—Figure 6A, representing thapsigargin treatment in WT and Pkd2KO cholangiocytes:
  - ➢ ERK blot panel, lanes 1–3 WT and lanes 4–6 Pkd2KO are the same

- *Hepatology* 2013:

—Figure 1A in:
  - ➢ pSer^{675}-β-Cat blot panel, lanes 1–3 for WT are a mirror image of lanes 4–6 for PC–KO
  - ➢ pSer^{675}-β-Cat blot panel, lane 1 for WT control and lane 9 for Pkhd1$^{del4/del4}$, PKA inhibitor are the same

—Figure 5A:
  - ➢ Actin blot panel, lanes 1–4 for WT and lanes 6–9 for Pkhd1$^{del4/del4}$ are the same

- *Hepatology* 2015:

—Figure 2A:
  - ➢ PC2 blot panel, lane 4 for ''TNFα'' and lane 5 for ''Mix'' are the same
  - ➢ PC2 blot panel, lane 6 for ''DETA'' and lane 7 for ''Thapsi'' are the same
  - ➢ Actin blot panel, lane 6 for ''DETA'' and lane 7 for ''Thapsi'' are the same

—Figure 4A:
  - ➢ PC2 blot panel, lane 1 for ''Ctrl'' and lane 8 for ''Mix+MG+GHX'' are the same
  - ➢ PC2 blot panel, lane 3 for ''Mix,'' lane 4 for ''Mix+CHX,'' and lane 5 for ''MG'' are the same

—Figure 4C:
  - ➢ NEK1 blot panel, lane 6 for ''Thapsi'' and lane 7 for ''DETA'' are the same

—Figure 5 (left):
  - ➢ PC2, blot panel, lane 1 for ''Ctrl'' and lane 2 for ''MG'' are the same
  - ➢ PC2 blot panel, lanes 3–4 for ''TNFα'' and ''TNFα+MG'' and lanes 7–8 for ''Mix,'' and ''Mix+MG'' are the same
  - ➢ Actin blot panel, lanes 1–4 for ''Ctrl,'' ''MG,'' ''TNFα,'' and ''TNFα+MG'' and lanes 5–8 for ''INFγ,'' ''INFγ+MG,'' ''Mix,'' and ''Mix+MG'' are the same

—Figure 5 (right):
  - ➢ Actin blot panel, lanes 5–6 for ''INFγ'' and ''INFγ+MG'' and lanes 7–8 for ''Mix'' and ''Mix+MG'' are the same

—Figure 6D:
  - ➢ LC3–II blot panel, lane 2 for ''Thapsi'' and lane 8 for ''Chloroq'' are the same

—Figure 7B:
  - ➢ PC2 blot panel, lanes 11–12, 13–14, and 15–16 are the same representing six repeat experiments of ''DDC'' mice
  - ➢ PC2 blot panel, lanes 5–6, 7–8, and 9–10 are the same representing six repeat experiments of ''DDC+Bort'' mice
  - ➢ Actin blot panel, lanes 1–4 for ''Ctrl,'' lanes 5–8 for ''DDC,'' and lanes 11–14 for ''DDC+Bort'' are the same
  - ➢ Actin blot panel, lanes 9–10 for ''DDC'' and lanes 15–16 for ''DDC+Bort'' are the same

—Figure 8B:
  - ➢ Actin blot panel, lanes 1–5 for ''WT'' and lanes 6–10 for *Mdr2-/-* are the same

- AASLD Presentation 2012:

—Slide 7:
  - ➢ pSer^{675} β-Cat blot panel, lanes 1–3 WT are the same as pSer^{675} β-Cat blot panel, lanes 4–6 PC–KO in Figure 1A of *Hepatology* 2013
  - ➢ pSer^{675} β-Cat blot panel, lanes 4–6 WT are the same as pSer^{675} β-Cat blot panel, lanes 7–9 Pkhd1$^{del4/del4}$ in Figure 1A of *Hepatology* 2013
  - ➢ β-Cat blot panel, lanes 1–3 WT are the same as β-Cat blot panel, lanes 4–6 Pkhd1$^{del4/del4}$ in Figure 1A of *Hepatology* 2013
  - ➢ β-Cat blot panel, lanes 4–6 WT are the same as β-Cat blot panel, lanes 7–9 Pkhd1$^{del4/del4}$ in Figure 1A of *Hepatology* 2013

- R01 DK090021–01 and R01 DK090021–01A1:

—Figure 8 (and Slide 9 of EASL Presentation 2011):
  - ➢ p^{675}-β-Cat blot panel, lanes 8 and 9 are spliced in over the bands from unrelated sources
  - ➢ H3 Hyst blot, lane 8 is spliced in over the bands from unrelated sources

- R01 DK079005–11A1:

—Figure 12A:
  - ➢ VEGFR2 blot panel, lanes 5 and 6–8 are spliced in from unrelated sources

—Figure 12B:
  - ➢ VEGFR2 blot panel, lanes 7 and 8 are spliced in from unrelated sources

Dr. Spirli entered into a Voluntary Exclusion Agreement (Agreement) and voluntarily agreed to the following:

(1) Respondent will exclude himself voluntarily for a period of four (4) years beginning on March 28, 2023 (the ''Exclusion Period'') from any contracting or subcontracting with any agency of the United States Government and from eligibility for or involvement in nonprocurement or procurement transactions referred to as ''covered transactions'' in 2 CFR parts 180 and 376 (collectively the ''Debarment Regulations'').

(2) During the Exclusion Period, Respondent will exclude himself voluntarily from serving in any advisory or consultant capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee.

(3) Respondent will request that the following papers be corrected or retracted:

- *Hepatology* 2012;56:2363–74. doi: 10.1002/hep.25872

- *Hepatology* 2012;55(3):856–68. doi:10.1002/hep.24723
- *Hepatology* 2013;58(5):1713–23. doi: 10.1002/hep.26554

Respondent will copy ORI and the Research Integrity Officer at YU on the correspondence with the journal.

Dated: April 10, 2023.

Sheila Garrity,

Director, Office of Research Integrity, Office of the Assistant Secretary for Health.

[FR Doc. 2023–07850 Filed 4–12–23; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Global Affairs: Stakeholder Listening Session for the G7 Health Ministers' Meeting

ACTION: Notice of public listening session; request for comments.

DATES: The listening session will be held on Thursday, May 4, 2023, from 12:00 p.m. to 2:00 p.m., Eastern Daylight Time.

Place: The session will be held virtually, with online and dial-in information shared with registered participants.

Status: This meeting is open to the public but requires RSVP to *OGA.RSVP1@hhs.gov* by April 28, 2023. *See RSVP section below for details.*

SUPPLEMENTARY INFORMATION:

Purpose: The U.S. Department of Health and Human Services (HHS), with support from relevant health-related U.S. Government offices, is charged with leading the U.S. delegation to the Group of 7 (G7) Health Ministers' Meeting and will convene an informal Stakeholder Listening Session.

The Stakeholder Listening Session is designed to seek input from stakeholders to help inform and prepare for U.S. government engagement in the Health Ministers' Meeting. The G7 is an informal grouping of Canada, France, Germany, Italy, Japan, the United States, and the United Kingdom, and it also includes participation by the European Commission. Each year, a different member country serves as the presidency of the group and hosts the meetings. The presidency proposes the group's priorities for the year and hosts discussions to work towards consensus positions and actions on those priorities. This year's G7 presidency is Japan, which will be hosting the Health Ministers' Meeting on May 13 and 14, 2023.

Matters to be Discussed: The listening session will cover priority areas expected to be addressed at the G7 Health Ministers' Meeting. Provisional agenda items for the Health Ministers' Meeting include to:

1. Develop and strengthen global health architecture for public health emergencies;
2. Contribute to achieving more resilient, equitable and sustainable universal health coverage through strengthening health systems; and
3. Promote health innovation to address various health challenges.

More information on the 2023 G7 Health Ministers' Meeting can be found at: *https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/hokabunya/kokusai/g8/g7health2023_en.html.*

1. Participation is welcome from all stakeholder communities.

RSVP: Persons seeking to speak at the listening session *must register by Friday, April 28, 2023.* Persons seeking to attend the listening session in a listen-only capacity must register by Tuesday, May 2, 2023.

Registrants must include their full name, email address, and organization, if any, and indicate whether they are registering as a *listen-only attendee* or as a *speaker participant* to *OGA.RSVP1@hhs.gov.*

Requests to participate as a speaker must include all of the following:

1. The name and email address of the person desiring to participate
2. The organization(s) that person represents, if any
3. Identification of the primary topic of interest

Other Information: Written comments should be emailed to *OGA.RSVP1@hhs.gov with the subject line* ''*Written Comment Re: Stakeholder Listening Session for the G7 Health Ministers Meeting*'' by Friday, May 5, 2023.

We look forward to your comments on the G7 Health Ministers' Meeting.

Susan Kim,

Chief of Staff, Office of Global Affairs.

[FR Doc. 2023–07811 Filed 4–12–23; 8:45 am]

BILLING CODE 4150–38–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Global Affairs: Stakeholder Listening Session on Amendments to the International Health Regulations (2005)

ACTION: Notice of public listening session; request for comments.

DATES: The listening session will be held on Tuesday, June 20th, 2023, from 12:00 p.m. to 2:00 p.m., Eastern Daylight Time.

Place: The session will be held virtually, with online and dial-in information shared with registered participants.

Status: This meeting is open to the public but requires RSVP to *OGA.RSVP1@hhs.gov* by Friday, June 9, 2023. See RSVP section below for details.

SUPPLEMENTARY INFORMATION:

Purpose: The U.S. Department of Health and Human Services (HHS) is charged with leading U.S. participation in the Working Group on the Amendments to the International Health Regulations (2005) and will convene a Stakeholder Listening Session.

The World Health Assembly (WHA) originally adopted the International Health Regulations (IHR) in 1969. The regulations were amended multiple times, resulting in the current IHR (2005). The purpose of IHR (2005) is to prevent, protect against, control, and provide public health response to the international spread of disease. In May 2021, Member States set up a Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR) with the intent of strengthening WHO's capacities and ability to support Member States in the prevention and response of public health emergencies. The WGPR produced a report with key findings and recommendations that included amending the IHR. The United States submitted a package of targeted amendments to the IHR for consideration. These amendments seek to improve early warnings and alerts, transparency, and accountability in a manner that does not compromise national security or sovereignty. Other countries have also submitted proposals that the United States seek feedback from stakeholders on the proposed amendments. The Stakeholder Listening Session is designed to seek input from stakeholders and subject-matter experts on these proposals and to help inform and prepare the U.S. government for engagement with the Working Group on the Amendments to the International Health Regulations (2005).

Matters to be Discussed: The listening session will discuss potential amendments to the IHR (2005). Topics will include those amendments currently under consideration by the Working Group. An Article-by-Article Compilation of Proposed Amendments to the International Health Regulations (2005) can be found here: *https://apps.who.int/gb/wgihr/pdf_files/wgihr1/WGIHR_Compilation-en.pdf.*

Participation is welcome from stakeholder communities.

RSVP: Persons seeking to speak at the listening session must register by *Wednesday, June 14, 2023.* Persons seeking to attend the listening session in a listen-only capacity must RSVP by Thursday, June 13, 2023.

Registrants must include their full name, email address, and organization, if any, and indicate whether they are registering as a *listen-only attendee* or as a *speaker participant* to *OGA.RSVP1@hhs.gov.*

Requests to participate as a speaker must include all of the following:

1. The name and email address of the person desiring to participate
2. The organization(s) that person represents, if any
3. Identification of the primary article(s) of interest

Other Information: This listening session will be recorded for the benefit of the members of the US Working Group on Amendments to the IHR (2005).

Written comments should be emailed to *OGA.RSVP1@hhs.gov with the subject line ''Written Comment Re: Stakeholder Listening Session 2 for the IHR''* by Friday, June 30, 2023.

We look forward to your comments on proposed amendments to the International Health Regulations (2005).

Susan Kim,

Chief of Staff, Office of Global Affairs.

[FR Doc. 2023–07812 Filed 4–12–23; 8:45 am]

BILLING CODE 4150–38–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Global Affairs: Stakeholder Listening Session for the Intergovernmental Negotiating Body (INB) To Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response

ACTION: Notice of public listening session; request for comments.

DATES: The listening session will be held on Wednesday, June 28, 2023, from 12 p.m. to 2 p.m., Eastern Daylight Time.

Place: The session will be held virtually, with online and dial-in information shared with registered participants.

Status: This meeting is open to the public but requires RSVP to *OGA.RSVP@hhs.gov* by Friday, June 23, 2023. *See RSVP section below for details.*

SUPPLEMENTARY INFORMATION:

Purpose: The U.S. Department of Health and Human Services (HHS) and the Department of State are charged with co-leading the U.S. delegation to the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response and will convene an informal Stakeholder Listening Session.

The Stakeholder Listening Session is designed to seek input from stakeholders and subject matter experts to help inform and prepare for U.S. government engagement with the Intergovernmental Negotiating Body.

Matters to be Discussed: The listening session will discuss potential areas that could be included in a pandemic accord to promote pandemic prevention, preparedness, and response. Topics will include those found in the current draft of the Pandemic Accord. More information can be found at: *https://apps.who.int/gb/inb/index.html.* Participation is welcome from all stakeholder communities.

RSVP: Persons seeking to speak at the listening session *must register by Friday, June 23, 2023.* Persons seeking to attend the listening session in a listen-only capacity must register by Monday, June 26, 2023.

Registrants must include their full name, email address, and organization, if any, and indicate whether they are registering as a *listen-only attendee* or as a *speaker participant* to *OGA.RSVP@hhs.gov.*

Requests to participate as a speaker must include all of the following:

1. The name and email address of the person desiring to participate
2. The organization(s) that person represents, if any
3. Identification of the primary topic of interest

Other Information: This listening session will be recorded for the benefit of the members of the US Government who participate in the Intergovernmental Negotiating Body.

Written comments should be emailed to *OGA.RSVP@hhs.gov with the subject line ''Written Comment Re: Stakeholder Listening Session 2 for the INB''* by Friday, July 7, 2023.

We look forward to your comments on the Intergovernmental Negotiating Body (INB) and Draft of the WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response.

Susan Kim,

Chief of Staff, Office of Global Affairs.

[FR Doc. 2023–07810 Filed 4–12–23; 8:45 am]

BILLING CODE 4150–38–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Council of Councils.

The meeting will be held as a virtual meeting and will be open to the public as indicated below. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*).

A portion of 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: Council of Councils.

Date: May 11, 2023.

Open: 10:15 a.m. to 2:00 p.m.

Agenda: Call to Order and Introductions; Announcements; NIH Program Updates; Strategic Plans; and Other Business of the Committee.

Place: National Institutes of Health, Building 1, 1 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Closed: 2:00 p.m. to 3:00 p.m.

Agenda: Review of Grant Applications.

Place: National Institutes of Health, Building 1, 1 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Franziska Grieder, D.V.M., Ph.D., Executive Secretary, Council of Councils, Director, Office of Research Infrastructure Programs, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH, 6701 Democracy Boulevard, Room 948, Bethesda, MD 20892, *GriederF@mail.nih.gov*, 301–435–0744.

Any interested person may file written comments with the committee by forwarding

the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Council of Council's home page at *http://dpcpsi.nih.gov/council/* where an agenda will be posted before the meeting date.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: April 7, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–07757 Filed 4–12–23; 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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Biomedical Research.

Date: May 11, 2023.

Time: 10:00 a.m. to 9:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joseph D. Mosca, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5158, MSC 7808, Bethesda, MD 20892, (301) 408–9465, *moscajos@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 7, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–07754 Filed 4–12–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Project: Generic Clearance for Grant Program Monitoring Activities

To carry out OMB Circular A–102 [1] and 2 CFR part 215.51 [2], SAMHSA must collect grant program information necessary to ensure compliance with Federal and programmatic requirements. The Generic Clearance for Grant Program Monitoring Activities allows SAMHSA to collect standardized information from its grant recipients necessary to perform agency program oversight activities such as monitoring progress on recipient activities and determining and responding to recipient's training and technical assistance (T/TA) needs. SAMHSA currently manages grant programs that provide prevention, treatment, recovery support services, and T/TA for substance use treatment and mental health providers along the continuum of care including prevention, harm reduction, treatment, and recovery.

SAMHSA's grant recipients are currently required to submit various types of performance reports in accordance with their individual program requirements. The data collections will be designed to standardize program monitoring and performance reports of SAMHSA's grants. Program offices will use information collected under this generic clearance to monitor funding recipient activities and to provide support or take appropriate action, as needed.

A generic clearance would provide SAMHSA's program offices the flexibility to create and use tailored information collection templates based on current program reporting requirements. This is important to allow for SAMHSA's:

- Monitoring of compliance with federal practice, guidelines, and requirements,
- Oversight of the implementation of the scope of the grant activities with the grant recipients' proposed project,
- Assessment of the efficiency and efficacy of recipient activities,
- Quick understanding of and remediation to national, regional, and/or site-specific issues,
- Provision of additional support and technical assistance, as needed,
- Documentation of promising practices, innovative services, and program strengths, and
- Flexible and responsive oversight of federal funds.

A variety of performance reports will be used for collection. Program offices will use information collected under this generic clearance to monitor funding recipient activities and to provide support or take appropriate action, as needed.

A variety of instruments and platforms will be used to collect information from respondents. The annual burden hours requested

[1] Circular A–102: *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A102/a102.pdf.*

[2] 2 CFR part 215.51: *https://www.govinfo.gov/content/pkg/CFR-2012-title2-vol1/pdf/CFR-2012-title2-vol1-subtitleA.pdf.*

(180,000) are based on the number of collections we expect to conduct over the requested period for this clearance.

The estimated annual hour burden is as follows:

Type of respondent	Number of respondents	Responses per respondent	Total responses	Hours per response	Total annual burden hours	Hourly wage cost	Total hour cost
Progress Report Template (Annual)	4,000	1	4,000	8	32,000	$26	$832,000
Progress Report (Interim)	2,500	2	5,000	6	30,000	26	780,000
Grant Closeouts	1,000	1	1,000	10	10,000	26	260,000
Site Visit Report Template	4,000	1	4,000	6	24,000	26	624,000
Other	4,000	1	4,000	6	24,000	26	624,000
Total	20,000		28,000		180,000		3,120,000

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57–A, Rockville, Maryland 20857, *OR* email a copy to *carlos.graham@samhsa.hhs.gov.* Written comments should be received by June 12, 2023.

Alicia Broadus,

Public Health Advisor.

[FR Doc. 2023–07771 Filed 4–12–23; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Quarterly IRS Interest Rates Used in Calculating Interest on Overdue Accounts and Refunds of Customs Duties

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This notice advises the public that the quarterly Internal Revenue Service interest rates used to calculate interest on overdue accounts (underpayments) and refunds (overpayments) of customs duties will remain the same from the previous quarter. For the calendar quarter beginning April 1, 2023, the interest rates for overpayments will be 6 percent for corporations and 7 percent for non-corporations, and the interest rate for underpayments will be 7 percent for both corporations and non-corporations. This notice is published for the convenience of the importing public and U.S. Customs and Border Protection personnel.

DATES: The rates announced in this notice are applicable as of April 1, 2023.

FOR FURTHER INFORMATION CONTACT: Bruce Ingalls, Revenue Division, Collection Refunds & Analysis Branch, 6650 Telecom Drive, Suite #100, Indianapolis, Indiana 46278; telephone (317) 298–1107.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to 19 U.S.C. 1505 and Treasury Decision 85–93, published in the **Federal Register** on May 29, 1985 (50 FR 21832), the interest rate paid on applicable overpayments or underpayments of customs duties must be in accordance with the Internal Revenue Code rate established under 26 U.S.C. 6621 and 6622. Section 6621 provides different interest rates applicable to overpayments: one for corporations and one for non-corporations.

The interest rates are based on the Federal short-term rate and determined by the Internal Revenue Service (IRS) on behalf of the Secretary of the Treasury on a quarterly basis. The rates effective for a quarter are determined during the first-month period of the previous quarter.

In Revenue Ruling 2023–04, the IRS determined the rates of interest for the calendar quarter beginning April 1, 2023, and ending on June 30, 2023. The interest rate paid to the Treasury for underpayments will be the Federal short-term rate (4%) plus three percentage points (3%) for a total of seven percent (7%) for both corporations and non-corporations. For corporate overpayments, the rate is the Federal short-term rate (4%) plus two percentage points (2%) for a total of six percent (6%). For overpayments made by non-corporations, the rate is the Federal short-term rate (4%) plus three percentage points (3%) for a total of seven percent (7%). These interest rates used to calculate interest on overdue accounts (underpayments) and refunds (overpayments) of customs duties remain unchanged from the previous quarter. These interest rates are subject to change for the calendar quarter beginning July 1, 2023, and ending on September 30, 2023.

For the convenience of the importing public and U.S. Customs and Border Protection personnel, the following list of IRS interest rates used, covering the period from July of 1974 to date, to calculate interest on overdue accounts and refunds of customs duties, is published in summary format.

Beginning date	Ending date	Underpayments (percent)	Overpayments (percent)	Corporate overpayments (Eff. 1–1–99) (percent)
070174	063075	6	6	
070175	013176	9	9	
020176	013178	7	7	
020178	013180	6	6	
020180	013182	12	12	
020182	123182	20	20	
010183	063083	16	16	
070183	123184	11	11	

Beginning date	Ending date	Underpayments (percent)	Overpayments (percent)	Corporate overpayments (Eff. 1–1–99) (percent)
010185	063085	13	13	
070185	123185	11	11	
010186	063086	10	10	
070186	123186	9	9	
010187	093087	9	8	
100187	123187	10	9	
010188	033188	11	10	
040188	093088	10	9	
100188	033189	11	10	
040189	093089	12	11	
100189	033191	11	10	
040191	123191	10	9	
010192	033192	9	8	
040192	093092	8	7	
100192	063094	7	6	
070194	093094	8	7	
100194	033195	9	8	
040195	063095	10	9	
070195	033196	9	8	
040196	063096	8	7	
070196	033198	9	8	
040198	123198	8	7	
010199	033199	7	7	6
040199	033100	8	8	7
040100	033101	9	9	8
040101	063001	8	8	7
070101	123101	7	7	6
010102	123102	6	6	5
010103	093003	5	5	4
100103	033104	4	4	3
040104	063004	5	5	4
070104	093004	4	4	3
100104	033105	5	5	4
040105	093005	6	6	5
100105	063006	7	7	6
070106	123107	8	8	7
010108	033108	7	7	6
040108	063008	6	6	5
070108	093008	5	5	4
100108	123108	6	6	5
010109	033109	5	5	4
040109	123110	4	4	3
010111	033111	3	3	2
040111	093011	4	4	3
100111	033116	3	3	2
040116	033118	4	4	3
040118	123118	5	5	4
010119	063019	6	6	5
070119	063020	5	5	4
070120	033122	3	3	2
040122	063022	4	4	3
070122	093022	5	5	4
100122	123122	6	6	5
010123	063023	7	7	6

Dated: April 6, 2023.

Crinley S. Hoover,

Acting Chief Financial Officer, U.S. Customs and Border Protection.

[FR Doc. 2023–07805 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4687–DR; Docket ID FEMA–2023–0001]

Rosebud Sioux Tribe; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Rosebud Sioux Tribe (FEMA–4687–DR), dated February 20, 2023, and related determinations.

DATES: The declaration was issued February 20, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency

Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated February 20, 2023, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage to the lands associated with the Rosebud Sioux Tribe resulting from severe winter storms and snowstorm during the period of December 12 to December 25, 2022, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists for the Rosebud Sioux Tribe.

In order to provide federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance and Hazard Mitigation for the Rosebud Sioux Tribe. You are further authorized to provide snow assistance under the Public Assistance program for a limited period of time during or proximate to the incident period. Consistent with the requirement that federal assistance be supplemental, any federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Alana B. Kuhn, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas have been designated as adversely affected by this major disaster:

Rosebud Sioux Tribe of the Rosebud Indian Reservation for Public Assistance.

Rosebud Sioux Tribe of the Rosebud Indian Reservation for snow assistance under the Public Assistance program for any continuous 48-hour period during or proximate to the incident period.

The Rosebud Sioux Tribe of the Rosebud Indian Reservation is eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07804 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2007–0008]

National Advisory Council

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Committee management; request for applicants for appointment to the National Advisory Council.

SUMMARY: The Federal Emergency Management Agency (FEMA) requests that qualified individuals interested in serving on the FEMA National Advisory Council (NAC) apply for appointment as identified in this notice. Pursuant to the *Post-Katrina Emergency Management Reform Act of 2006* (PKEMRA), the NAC advises the FEMA Administrator on all aspects of emergency management, incorporating input from and ensuring coordination with Tribal, State, Territorial and local governments, and the non-governmental and private sectors. The NAC consists of up to 40 members, all of whom are experts and leaders in their respective fields. FEMA seeks to appoint or reappoint individuals to seven (7) discipline-specific positions on the NAC and up to two (2) members as Administrator Selections. If other positions open during the application and selection period, FEMA may select qualified candidates from the pool of applications.

DATES: FEMA will accept applications until 11:59 p.m. Eastern Time on Sunday, May 21, 2023.

ADDRESSES: The preferred method for application package submission is by email. Application packages by U.S. Mail may not be considered. Please submit using the following method: *Email: FEMA-NAC@fema.dhs.gov.* Save materials in one file using the naming convention, ''(Last Name) (First Name)_ NAC Application'' and attach to the email. The Office of the NAC will send you an email that confirms receipt of your application and will notify you of the final status of your application once FEMA selects members.

FOR FURTHER INFORMATION CONTACT: Rob Long, Designated Federal Officer, Office of the National Advisory Council, Federal Emergency Management Agency; *FEMA-NAC@fema.dhs.gov,* 202.646.2700. For more information on the NAC, including membership application instructions, visit *https://www.fema.gov/about/offices/national-advisory-council.*

SUPPLEMENTARY INFORMATION: The NAC is an advisory committee established in accordance with the provisions of the *Federal Advisory Committee Act* (FACA), 5 U.S.C. ch. 10. As required by PKEMRA, the Secretary of Homeland Security established the NAC to ensure effective and ongoing coordination of federal preparedness, protection, response, recovery, and mitigation for natural disasters, acts of terrorism, and other man-made disasters. Appointees may be designated as a Special Government Employee (SGE) as defined in section 202(a) of title 18, U.S.C., or as a Representative (Rep.) member. SGEs speak in a personal capacity as experts in their field and Representative members speak for the stakeholder group they represent.

FEMA is requesting that individuals who are interested in and qualified to serve on the NAC apply for appointment to an open position in one of the following seven discipline areas: Disabilities, Access, and Functional Needs Rep.; Elected Tribal Government Officials Rep.; Emergency Management Rep.; Emergency Response Provider Rep.; Non-Elected Tribal Government Official Rep.; Health Scientist SGE; and Standards Setting and Accrediting Rep. The Administrator may appoint up to two (2) additional candidates to serve as FEMA Administrator Selections (as SGE appointments). Please visit *https://www.fema.gov/about/offices/national-advisory-council/membership-applications* for further information on expertise required to fill these positions. Appointments will be for 3-year terms, or for the remainder of an existing term that is open. Appointments begin in December 2023.

The NAC Charter contains more information and can be found at: *https://www.fema.gov/sites/default/files/documents/fema_nac-charter_2022.pdf.*

If you are interested, qualified, and want FEMA to consider appointing you to fill an open position on the NAC, please submit an application package to the Office of the NAC as listed in the **ADDRESSES** section of this notice. There is no application form; however, each application package MUST include the following information:

- Cover letter, addressed to the Office of the NAC, that includes current position title and employer or organization you represent, home and work mailing addresses, preferred telephone number, and email address; the discipline area position(s) for which you would like consideration; why you are interested in serving on the NAC; and how you heard about the solicitation for NAC members.
- A summary of the most important accomplishments that qualify you to serve on the NAC, in the form of three to five (3–5) bullets in less than 75 words total.
- Three (3) peer or supervisor references including full name, position title, employer or organization, preferred telephone number and email address. References must be able to attest to the qualifications and accomplishments you have listed.
- Resume or Curriculum Vitae (CV).

Your application package must be less than eight (8) total pages to be considered by FEMA. Information contained in your application package should clearly indicate your qualifications to serve on the NAC and fill one of the current open positions. FEMA will not consider incomplete applications. FEMA will review the information contained in application packages and make selections based on (1) leadership attributes; (2) emergency management experience; (3) expert knowledge in identified discipline area; and (4) ability to meet NAC member expectations. FEMA will also consider overall NAC composition, including diversity (including, but not limited to geographic, demographic, and experience) and mix of officials, emergency managers, and emergency response providers from state, local, tribal, and territorial governments, when selecting members. In order for DHS to fully leverage broad-ranging experience and education, the NAC must be diverse with regard to professional and technical expertise. DHS is committed to pursuing opportunities, consistent with applicable law, to compose a committee that reflects the diversity of the nation's people.

DHS does not discriminate based on race, color, religion, sex, national origin, sexual orientation, gender identity, marital status, political affiliation, disability and genetic information, age, membership in an employee organization, or other non-merit factor. DHS strives to achieve a widely diverse candidate pool for all its recruitment actions. Current DHS and FEMA employees, including FEMA Reservists, are not eligible for membership. Federally registered lobbyists may not apply. Candidates selected for appointment as SGEs are required to complete a new entrant Confidential Financial Disclosure Report (Office of Government Ethics (OGE) Form 450) each year. You can find this form at the Office of Government Ethics website (*http://www.oge.gov*). However, please do not submit this form with your application.

Expectations: Appointees to this volunteer service opportunity are expected to fully participate in NAC activities, work with fellow members as a team, and maintain a high degree of integrity. The NAC Bylaws contain more information and can be found at: *https://www.fema.gov/sites/default/files/documents/fema_nac-bylaws.pdf.* NAC members must serve on one of the NAC subcommittees, which meet regularly through virtual means. FEMA estimates a six (6) hour minimum time commitment per month for regular communications, special activities, and subcommittee participation. Selected NAC members serve in leadership roles and participate in additional meetings and activities. Additionally, all NAC members can meet in-person up to twice per year, typically three (3) days for each meeting. FEMA does not pay NAC members for their time, but may reimburse travel expenses such as airfare, lodging, meals, incidentals, and other transportation costs within Federal Travel Regulations when pre-approved by the Designated Federal Officer.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07796 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–48–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4689–DR; Docket ID FEMA–2023–0001]

South Dakota; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of South Dakota (FEMA–4689–DR), dated February 27, 2023, and related determinations.

DATES: The declaration was issued February 27, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated February 27, 2023, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of South Dakota resulting from severe winter storms and snowstorm during the period of December 12 to December 25, 2022, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of South Dakota.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. You are further authorized to provide snow assistance under the Public Assistance program for a limited period of time during or proximate to the incident period. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Kenneth G. Clark, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of South Dakota have been designated as adversely affected by this major disaster:

Bennett, Brookings, Clark, Day, Deuel, Hamlin, Jackson, Jones, Kingsbury, Mellette, Oglala Lakota, Potter, Roberts, Stanley, Todd, and Tripp Counties for Public Assistance.

Bennett, Jones, Mellette, Stanley, Todd, and Tripp Counties for snow assistance

under the Public Assistance program for any continuous 48-hour period during or proximate to the incident period.

All areas within the State of South Dakota are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07795 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4672–DR; Docket ID FEMA–2023–0001]

Alaska; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Alaska (FEMA–4672–DR), dated September 23, 2022, and related determinations.

DATES: This change occurred on January 26, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Yolanda J. Jackson, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Timothy B. Manner as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07799 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4396–DR; Docket ID FEMA–2023–0001]

Commonwealth of the Northern Mariana Islands; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the Commonwealth of the Northern Mariana Islands (FEMA–4396–DR), dated September 29, 2018, and related determinations.

DATES: This amendment was issued February 5, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated February 5, 2023, the President amended the cost-sharing arrangements regarding Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), in a letter to Deanne Criswell, Administrator, Federal Emergency Management Agency, Department of Homeland Security, under Executive Order 12148, as follows:

I have determined that the damage in the Commonwealth of the Northern Mariana Islands resulting from Typhoon Mangkhut during the period of September 10 to September 11, 2018, is of sufficient severity and magnitude that special cost sharing arrangements are warranted regarding Federal funds provided under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act'').

Therefore, I amend the declaration of September 29, 2018, to authorize Federal funds for all categories of Public Assistance, Hazard Mitigation, and the Other Needs Assistance portion of the Individual Assistance program at 90 percent of total eligible costs.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07785 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3592–EM; Docket ID FEMA–2023–0001]

California; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of California (FEMA–3592–EM), dated March 10, 2023, and related determinations.

DATES: The declaration was issued March 10, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency

Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated March 10, 2023, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the State of California resulting from severe winter storms, flooding, landslides, and mudslides beginning on March 9, 2023, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (''the Stafford Act''). Therefore, I declare that such an emergency exists in the State of California.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Andrew F. Grant, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the State of California have been designated as adversely affected by this declared emergency:

Amador, Butte, El Dorado, Fresno, Humboldt, Imperial, Inyo, Kern, Lake, Los Angeles, Madera, Mariposa, Mendocino, Merced, Mono, Monterey, Napa, Nevada, Placer, Plumas, Sacramento, San Bernardino, San Francisco, San Mateo, San Luis Obispo, Santa Barbara, Santa Clara, Santa Cruz, Sierra, Sonoma, Stanislaus, Tulare, Tuolumne, and Yuba Counties for emergency protective measures (Category B), limited to direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07797 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4690–DR; Docket ID FEMA–2023–0001]

Muscogee (Creek) Nation; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Muscogee (Creek) Nation (FEMA–4690–DR), dated March 3, 2023, and related determinations.

DATES: The declaration was issued March 3, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated March 3, 2023 the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage to the lands associated with the Muscogee (Creek) Nation resulting from a severe winter storm during the period of December 21 to December 25, 2022, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists for the Muscogee (Creek) Nation.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance and Hazard Mitigation for the Muscogee (Creek) Nation. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Roland W. Jackson, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas have been designated as adversely affected by this major disaster:

Muscogee (Creek) Nation for Public Assistance.

The Muscogee (Creek) Nation is eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07792 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4691–DR; Docket ID FEMA–2023–0001]

Tennessee; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Tennessee (FEMA–4691–DR), dated March 8, 2023, and related determinations.

DATES: The declaration was issued March 8, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated March 8, 2023, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Tennessee resulting from a severe winter storm during the period of December 22 to December 27, 2022, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Tennessee.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Brian F. Schiller, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Tennessee have been designated as adversely affected by this major disaster:

Cocke, Coffee, Davidson, Greene, Henderson, Knox, Maury, Perry, Putnam, Shelby, and Washington Counties for Public Assistance.

All areas within the State of Tennessee are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07802 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4691–DR; Docket ID FEMA–2023–0001]

Tennessee; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Tennessee (FEMA–4691–DR), dated March 8, 2023, and related determinations.

DATES: This change occurred on March 8, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Andrew D. Friend, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Brian F. Schiller as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07784 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4658–DR; Docket ID FEMA–2023–0001]

Minnesota; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Minnesota (FEMA–4658–DR), dated July 8, 2022, and related determinations.

DATES: This change occurred on February 10, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Joseph P. Cirone, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Brian F. Schiller as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07790 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4684–DR; Docket ID FEMA–2023–0001]

Alabama; Amendment No. 5 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Alabama (FEMA–4684–DR), dated January 15, 2023, and related determinations.

DATES: This amendment was issued February 9, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated February 9, 2023, the President amended the cost-sharing arrangements regarding Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), in a letter to Deanne Criswell, Administrator, Federal Emergency Management Agency, Department of Homeland Security, under Executive Order 12148, as follows:

I have determined that the damage in certain areas of the State of Alabama resulting from severe storms, straight-line winds, and tornadoes on January 12, 2023, is of sufficient severity and magnitude that special cost sharing arrangements are warranted regarding Federal funds provided under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act'').

Therefore, I amend my declaration of January 15, 2023, to authorize Federal funds for debris removal and emergency protective measures at 100 percent of the total eligible costs for a continuous 30-day period of the State's choosing within the first 120 days of the incident period.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07791 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4689–DR; Docket ID FEMA–2023–0001]

South Dakota; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of South Dakota (FEMA–4689–DR), dated February 27, 2023, and related determinations.

DATES: This amendment was issued March 21, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of South Dakota is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of February 27, 2023.

Ziebach County for Public Assistance.

Jackson and Oglala Lakota Counties for snow assistance under the Public Assistance program for any continuous 48-hour period during or proximate to the incident period (already designated for Public Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07787 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4692–DR; Docket ID FEMA–2023–0001]

Bear River Band of the Rohnerville Rancheria; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Bear River Band of the Rohnerville Rancheria (FEMA–4692–DR), dated March 8, 2023, and related determinations.

DATES: The declaration was issued March 8, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated March 8, 2023, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage to the lands associated with the Bear River Band of the Rohnerville Rancheria resulting from an earthquake during the period of December 20, 2022 to January 1, 2023, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists for the Bear River Band of the Rohnerville Rancheria.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance and Hazard Mitigation for the Bear River Band of the Rohnerville Rancheria. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Benigno Bern Ruiz, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas have been designated as adversely affected by this major disaster:

Bear River Band of the Rohnerville Rancheria for Public Assistance.

The Bear River Band of the Rohnerville Rancheria is eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07788 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4683–DR; Docket ID FEMA–2023–0001]

California; Amendment No. 8 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of California (FEMA–4683–DR), dated January 14, 2023, and related determinations.

DATES: This amendment was issued February 14, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of California is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of January 14, 2023.

Amador, Del Norte, El Dorado, Inyo, Madera, Mariposa, Napa, Nevada, San Diego, San Francisco, Solano, Stanislaus, Sutter, Tehama, and Tuolumne Counties for Public Assistance.

Contra Costa and San Mateo Counties for Public Assistance (already designated for Individual Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07794 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4683–DR; Docket ID FEMA–2023–0001]

California; Amendment No. 9 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of California (FEMA–4683–DR), dated January 14, 2023, and related determinations.

DATES: This amendment was issued February 22, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of California is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of January 14, 2023.

Amador County for Individual Assistance (already designated for Public Assistance).

Alpine County for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07786 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4688–DR; Docket ID FEMA–2023–0001]

Oglala Sioux Tribe; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Oglala Sioux Tribe (FEMA–4688–DR), dated February 20, 2023, and related determinations.

DATES: The declaration was issued February 20, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated February 20, 2023, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage to the lands associated with the Oglala Sioux Tribe resulting from severe winter storms and snowstorm during the period of December 12 to December 25, 2022, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists for the Oglala Sioux Tribe.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance and Hazard Mitigation for the Oglala Sioux Tribe. You are further authorized to provide snow assistance under the Public Assistance program for a limited period of time during or proximate to the incident period. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Alana B. Kuhn, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas have been designated as adversely affected by this major disaster:

Oglala Sioux Tribe of the Pine Ridge Indian Reservation for Public Assistance.

Oglala Sioux Tribe of the Pine Ridge Indian Reservation for snow assistance under the Public Assistance program for any continuous 48-hour period during or proximate to the incident period.

The Oglala Sioux Tribe of the Pine Ridge Indian Reservation is eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07801 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4686–DR; Docket ID FEMA–2023–0001]

North Dakota; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of North Dakota (FEMA–4686–DR), dated February 5, 2023, and related determinations.

DATES: The declaration was issued February 5, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated February 5, 2023, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of North Dakota resulting from a severe winter storm, snowstorm, and straight-line winds during the period of November 9 to November 11, 2022, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of North Dakota.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. You are further authorized to provide snow assistance under the Public Assistance program for a limited period of time during or proximate to the incident period. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Kenneth G. Clark, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of North Dakota have been designated as adversely affected by this major disaster:

Dickey, Kidder, Mercer, Nelson, Ransom, Sargent, and Wells Counties for Public Assistance.

Kidder, Mercer, Nelson, and Wells Counties for snow assistance under the Public Assistance program for any continuous 48-hour period during or proximate to the incident period.

All areas within the State of North Dakota are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07783 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4685–DR; Docket ID FEMA–2023–0001]

Georgia; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Georgia (FEMA–4685–DR), dated January 16, 2023, and related determinations.

DATES: This change occurred on March 28, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Manny J. Toro, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of John F. Boyle as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07800 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3592–EM; Docket ID FEMA–2023–0001]

California; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of California (FEMA–3592–EM), dated March 10, 2023, and related determinations.

DATES: This amendment was issued March 16, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of an emergency declaration for the State of California is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared an emergency by the President in his declaration of March 10, 2023.

Alpine, Calaveras, Del Norte, Glenn, Kings, San Benito, San Joaquin, Orange, and Trinity Counties for emergency protective measures (Category B), limited to direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07793 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4660–DR; Docket ID FEMA–2023–0001]

North Dakota; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of North Dakota (FEMA–4660–DR), dated July 13, 2022, and related determinations.

DATES: This change occurred on January 27, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Kenneth G. Clark, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Alana B. Kuhn as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049,

Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07782 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4697–DR; Docket ID FEMA–2023–0001]

Mississippi; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Mississippi (FEMA–4697–DR), dated March 26, 2023, and related determinations.

DATES: This amendment was issued March 30, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Mississippi is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of March 26, 2023.

Carroll, Humphreys, Monroe, and Sharkey Counties for permanent work [Categories C–G] (already designated for Individual Assistance and assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program).

Montgomery and Panola Counties for Individual Assistance.

Montgomery and Panola Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07789 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4659–DR; Docket ID FEMA–2023–0001]

Minnesota; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Minnesota (FEMA–4659–DR), dated July 13, 2022, and related determinations.

DATES: This change occurred on February 10, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Joseph P. Cirone, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Brian F. Schiller as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07798 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4666–DR; Docket ID FEMA–2023–0001]

Minnesota; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Minnesota (FEMA–4666–DR), dated August 9, 2022, and related determinations.

DATES: This change occurred on February 10, 2023.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Joseph P. Cirone, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Brian F. Schiller as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2023–07803 Filed 4–12–23; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R4–ES–2023–0044; FXES11130400000–223–FF04EF4000]

Receipt of Incidental Take Permit Application and Proposed Habitat Conservation Plan for the Florida Scrub-Jay; Indian River County, FL; Categorical Exclusion

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment.

SUMMARY: We, the Fish and Wildlife Service (Service), announce receipt of an application from Remington Stewart, LLP (applicant) for an incidental take permit (ITP) under the Endangered Species Act. The applicant requests the ITP to take the federally threatened Florida scrub-jay (*Aphelocoma coerulescens*) incidental to the construction and operation of a commercial development in Indian River County, Florida. We request public comment on the application, which includes the applicant's proposed habitat conservation plan (HCP), and on the Service's preliminary determination that the proposed permitting action may be eligible for a categorical exclusion pursuant to the Council on Environmental Quality's National Environmental Policy Act (NEPA) regulations, the Department of the Interior's (DOI) NEPA regulations, and the DOI Departmental Manual. To make this preliminary determination, we prepared a draft environmental action statement and low-effect screening form, both of which are also available for public review. We invite comment from the public and local, State, Tribal, and Federal agencies.

DATES: We must receive your written comments on or before May 15, 2023.

ADDRESSES: *Obtaining Documents:* You may obtain copies of the documents online in Docket No. FWS–R4–ES–2023–0044, at *https://www.regulations.gov.*

Submitting Comments: If you wish to submit comments on any of the documents, you may do so in writing by one of the following methods:

- *Online: https://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R4–ES–2023–0044.
- *U.S. mail:* Public Comments Processing; Attn: Docket No. FWS–R4–ES–2023–0044; U.S. Fish and Wildlife Service; MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Alfredo Begazo, by U.S. mail (see **ADDRESSES**), by telephone at 772–469–4234 or via email at *alfredo_begazo@fws.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the Fish and Wildlife Service (Service), announce receipt of an application from Remington Stewart, LLP (applicant) for an incidental take permit (ITP) under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The applicant requests the ITP to take the federally listed Florida scrub-jay (*Aphelocoma coerulescens*) (scrub-jay) incidental to the construction and operation of a commercial development in Indian River County, Florida. We request public comment on the application, which includes the applicant's habitat conservation plan (HCP), and on the Service's preliminary determination that this proposed ITP qualifies as ''low effect,'' and may qualify for a categorical exclusion pursuant to the Council on Environmental Quality's National Environmental Policy Act (NEPA) regulations (40 CFR 1501.4), the Department of the Interior's (DOI) NEPA regulations (43 CFR 46), and the DOI's Departmental Manual (516 DM 8.5(C)(2)). To make this preliminary determination, we prepared a draft environmental action statement and low-effect screening form, both of which are also available for public review.

Proposed Project

The applicant requests a 5-year ITP to take scrub-jays via the conversion of approximately 0.93 acre (ac) of occupied nesting, foraging, and sheltering scrub-jay habitat incidental to the construction of a commercial development on a 3.11-ac parcel in Section 30; Township 38 South; Range 30 East; Indian River County, Florida. The applicant proposes to mitigate for take of the scrub-jays by purchasing credits equivalent to 1.86 ac of scrub-jay-occupied habitat from a Service-approved conservation bank. The Service would require the applicant to purchase the credits prior to engaging in any construction phase of the project.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, be aware that your entire comment, including your personal identifying information, may be made available to the public. While you may request that we withhold your personal identifying information, we cannot guarantee that we will be able to do so.

Our Preliminary Determination

The Service has made a preliminary determination that the applicant's project—including the construction of a commercial building, driveway, parking space, green areas, stormwater pond, and associated infrastructure (*e.g.,* electric, water, and sewer lines)—would individually and cumulatively have a minor effect on the scrub-jay and the human environment. Therefore, we have preliminarily determined that the proposed ESA section 10(a)(1)(B) permit would be a ''low-effect'' ITP that individually or cumulatively would have a minor effect on the scrub-jay and may qualify for application of a categorical exclusion pursuant to the Council on Environmental Quality's NEPA regulations, DOI's NEPA regulations, and the DOI Departmental Manual. A ''low-effect'' ITP is one that would result in (1) minor or nonsignificant effects on species covered in the HCP; (2) nonsignificant effects on the human environment; and (3) impacts that, when added together with the impacts of other past, present, and reasonable foreseeable actions, would not result in significant cumulative effects to the human environment.

Next Steps

The Service will evaluate the application and the comments to determine whether to issue the requested ITP. We will also conduct an intra-Service consultation pursuant to section 7 of the ESA to evaluate the effects of the proposed take. After considering the preceding and other matters, we will determine whether the permit issuance criteria of section 10(a)(1)(B) of the ESA have been met. If met, the Service will issue ITP number PER0563271 to Remington Stewart, LLP.

Authority

The Service provides this notice under section 10(c) of the ESA (16

U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.32), and NEPA (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1500–1508 and 43 CFR 46).

Robert L. Carey,

Division Manager, Environmental Review, Florida Ecological Services Office.

[FR Doc. 2023–07764 Filed 4–12–23; 8:45 am]

BILLING CODE 4333–15–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1304]

Certain Wet Dry Surface Cleaning Devices; Notice of Request for Submissions on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that on March 24, 2023, the presiding administrative law judge (''ALJ'') issued an Initial Determination on Violation of Section 337. On April 7, 2023, the ALJ issued a Recommended Determination on Remedy and Bond should a violation be found in the above-captioned investigation. The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation. This notice is soliciting comments from the public only.

FOR FURTHER INFORMATION CONTACT: Lynde Herzbach, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3228. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that, if the Commission finds a violation, it shall exclude the articles concerned from the United States unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry. (19 U.S.C. 1337(d)(1)). A similar provision applies to cease and desist orders. (19 U.S.C. 1337(f)(1)).

The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation, specifically: a limited exclusion order directed to certain wet dry surface cleaning devices imported, sold for importation, and/or sold after importation by respondents Tineco Intelligent Technology Co., Ltd. of Suzhou City, China; TEK (Hong Kong) Science & Technology Ltd. of Hong Kong; and Tineco Intelligent, Inc. of Seattle, Washington (collectively, ''Respondents''); and cease and desist orders directed to Respondents. Parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4).

The Commission is interested in further development of the record on the public interest in this investigation. Accordingly, members of the public are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the ALJ's Recommended Determination on Remedy and Bonding issued in this investigation on April 7, 2023. Comments should address whether issuance of the recommended remedial orders in this investigation, should the Commission find a violation, 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 recommended remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended 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 recommended orders within a commercially reasonable time; and

(v) explain how the recommended orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on May 8, 2023.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (Mar. 19, 2020). Submissions should refer to the investigation number (''Inv. No. 337–TA–1304'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing and must be served in accordance with Commission Rule 210.4(f)(7)(ii)(A) (19 CFR 210.4(f)(7)(ii)(A)). All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for 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, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written

submissions will be available for public inspection on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: April 10, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–07844 Filed 4–12–23; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 22–53]

Matthew S. Katz, M.D.; Decision and Order

I. Introduction

On August 16, 2022, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Matthew S. Katz, M.D. (Respondent), of Nashville, Tennessee, the state where Respondent is registered with the DEA.[1] OSC, at 1. The OSC proposes the revocation of Respondent's DEA Certificate of Registration (registration), FK7432278, and the denial of any applications for renewal or modification of it, alleging that Respondent was convicted of a Tennessee felony relating to controlled substances.[2] *Id.,* citing 21 U.S.C. 824(a)(2).[3]

The hearing Respondent requested was held on December 20, 2022. Tr. 1. Concluding that Respondent's acceptance of responsibility was short of unequivocal, and that his misconduct was egregious, the Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (RD) recommends that Respondent's registration be revoked. RD, at 22–23. Given the egregiousness of the uncontested facts and the facts based on substantial record evidence, the Agency agrees with the RD that revocation is the appropriate sanction.

II. Findings

A. Background Findings

Having thoroughly analyzed the certified record, the Agency finds substantial record evidence that: (1) Respondent prescribed Schedule II controlled substances without a legitimate medical purpose, (2) Respondent then instructed the patients to bring him the filled prescriptions, and (3) Respondent took most of the controlled substances for his own use after, he testified, making sure that the patient did not need them to relieve pain. Stipulation No. 6; Resp Posthearing, at 13. There is no record evidence that Respondent complied with Tennessee's legal requirements for issuing controlled substances. The Agency finds no record evidence that Respondent took steps to make sure he did not over-prescribe opiates to individuals who were already opioid-addicted, who were addicted to another substance, or who were at a particular risk of becoming opioid-addicted.

B. Undisputed Matters of Fact and Law

The Agency finds, to Respondent's credit, that he advised the Chief Administrative Law Judge and the Government that the Consent Order of the Tennessee Board of Medical Examiners (TMB) restricts him from prescribing Schedule II controlled substances in Tennessee for twelve (12) months beginning on the date of the Consent Order's entry.[4] TMB Consent Order (entered September 27, 2022), RX 7, at 6, citing Tenn. Comp. R. & Regs. 0880–02–.25 (2019). Indeed, the Agency finds that, according to the Consent Order, Respondent's loss of authority in Tennessee to prescribe Schedule II controlled substances predates the Consent Order. RX 7, at 3 (''Due to the allegations in the indictment . . ., the Respondent lost his authorization to prescribe Schedule II controlled substances in this state until the criminal cases against him reach final disposition.''). Accordingly, the Agency finds uncontroverted record evidence that Respondent presently lacks authority in Tennessee to prescribe Schedule II controlled substances.

Additionally, the parties agree to the following factual and legal matters.

1. Respondent pled *nolo contendere* to three counts of obtaining possession of oxycodone by misrepresentation, fraud, forgery, deception or subterfuge, a Class D Tennessee felony. Tenn. Code Ann. section 53–11–402(a)(3) and (b)(1); *see, e.g.,* OSC, at 2; Stipulation No. 6; Resp Posthearing, at 2, 13.

2. Prior Agency decisions state that a *nolo contendere* plea is a ''conviction'' for purposes of 21 U.S.C. 824(a)(2). *See, e.g., Erica N. Grant, M.D.,* 86 FR 40641, 40646–48 (2021) (collecting cases); Resp Posthearing, at 13; *but cf.* Transcript of Guilty Plea Proceedings, *State of Tennessee* v. *Matthew S. J. Katz,* No. 2021–B–794 (Criminal Court for Davidson County, Tennessee, Division III, June 30, 2022), GX 3b, at 4 (The Court: ''So do you understand that this is a special probation, that is . . . you're not going to be convicted, and it will be removed from your record if you follow the conditions.'').

3. Respondent is not eligible for a Schedule II registration because he lacks authority in Tennessee to dispense Schedule II controlled substances. Resp Posthearing, at 16–17; Government's Post-Hearing Brief (dated January 20, 2023) (Govt Posthearing), at 10.

III. Discussion

According to the Controlled Substances Act (CSA), the Attorney General ''shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(g)(1). The CSA defines ''practitioner'' as a ''physician . . . licensed, registered, or otherwise permitted, by the . . . jurisdiction in which he practices . . ., to distribute, dispense . . . [, or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). The Agency has long interpreted these two CSA provisions to mean that state authority to dispense controlled substances is a prerequisite to the Agency's issuance of a registration. *See, e.g., Valerie Augustus, M.D.,* 88 FR 1098, 1099 (2023).

Further, the Attorney General is authorized to suspend or revoke a registration ''upon a finding that the registrant . . . has been convicted of a felony . . . of any State . . . relating to any substance defined in this subchapter as a controlled substance . . . .'' 21 U.S.C. 824(a)(2).

[1] Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Public Law 117–215, 136 Stat. 2257 (2022) (MRA), amended the Controlled Substances Act (CSA) and other statutes. Relevant to this matter, the MRA redesignated 21 U.S.C. 823(f), cited in the OSC, as 21 U.S.C. 823(g)(1). Accordingly, this Decision cites to the current designation, 21 U.S.C. 823(g)(1), and to the MRA-amended CSA throughout.

[2] The OSC also seeks denial of ''any applications for any other DEA registrations.'' OSC, at 1.

[3] The OSC alleges that Respondent ''pled guilty'' to the Class D felony, Tenn. Code Ann. section 53–11–402. OSC, at 2. The Government acknowledges that Respondent pled ''*nolo contendere.*'' *See, e.g.,* Government's Prehearing Statement (September 30, 2022), at 2. The parties agree that Respondent's plea is subject to an Order of Deferral. *See, e.g. id.;* Request for Hearing (September 22, 2022), at 1. The parties also agree that the Agency considers Respondent's *nolo contendere* plea to be a ''conviction'' for purposes of 21 U.S.C. 824(a)(4). Respondent's Post-Hearing Brief (January 20, 2023) (Resp Posthearing), at 13.

[4] The Consent Order also places Respondent's medical license on probation for three years. RX 7, at 5.

The Government has the burden of proof in this proceeding. 21 CFR 1301.44.

Based on undisputed factual and legal matters, the Agency finds conclusive record evidence that: (1) Respondent lacks authority in Tennessee to dispense Schedule II controlled substances, and (2) the Government presented a *prima facie* case that Respondent is a felon convicted of an offense relating to a controlled substance. *Supra* section II.A. Accordingly, the Agency finds that: (1) Respondent is not eligible for a registration to dispense Schedule II controlled substances, and that (2) Respondent's registration, as to Schedules III through V, is subject to revocation due to his felony conviction relating to controlled substances. 21 U.S.C. 802(21), 823(g)(1); *see, e.g., Valerie Augustus, M.D.,* 88 FR 1099 (as to Schedule II eligibility); 21 U.S.C. 824(a)(2); *see, e.g., Johnny C. Benjamin, Jr., M.D.,* 86 FR 32280, 32282 (2021) (as to felony conviction).

IV. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that one or more grounds for revocation exists, the burden shifts to the Respondent to show why he can be entrusted with a registration.[5] *Garrett Howard Smith, M.D.,* 83 FR 18882 (2018). Moreover, as past performance is the best predictor of future performance, the Agency has required that a respondent must unequivocally accept responsibility for the unlawful acts for which he was convicted, and demonstrate that he will not engage in future misconduct.[6] *Id.* In addition, the Agency has found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* The Agency has also considered the need to deter similar acts by applicants and by the community of registrants. *Id.*

The OSC that initiated this adjudication alleges that the registration of Respondent, who has been convicted of a felony relating to a controlled substance, should be revoked. *Supra* section I. As already discussed, the Agency is without authority to allow Respondent to maintain his registration to dispense Schedule II controlled substances. *Supra* section III. Accordingly, at a minimum, Respondent's authorization to dispense Schedule II controlled substances must now be revoked.

It is the Administrator's CSA-mandated exercise of discretion, however, that determines whether Respondent will continue to hold a registration to dispense Schedules III through V. 21 U.S.C. 824(a). The parties disagree about whether Respondent unequivocally accepted responsibility. *See, e.g.,* Resp Posthearing, at 13–14; Govt Posthearing at 6–9. The certified record in this matter is not sufficiently developed to determine whether Respondent unequivocally accepted responsibility. However, based on the facts in the certified record that are well-developed and undisputed, the Agency concludes that whether Respondent unequivocally accepted responsibility would not impact a finding as to the appropriate sanction given the egregiousness of Respondent's conduct.

In this matter, the Agency found substantial record evidence that, regardless of the resulting harm his patients could suffer, Respondent prescribed controlled substances so that he could divert at least a portion of them to himself. *See, e.g.,* Resp Posthearing, at 4–6, 13–14. These most egregious facts must result in the revocation of Respondent's registration. To allow Respondent to maintain any controlled substance prescribing authority in the face of the egregiousness of the found facts, the danger of his disregard for the CSA, and the safety of his patients would send a message to the current and prospective registrant community that compliance with the CSA is not a condition precedent to the issuance and retention of a registration. *Garrett Howard Smith, M.D.,* 83 FR 18910. Accordingly, the Agency shall order the sanction the Government requested, without restricting Respondent from applying for a registration in the future.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1) and 824(a)(2), I hereby revoke DEA Certificate of Registration FK7432278 issued to Matthew S. Katz, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending application of Matthew S. Katz, M.D., to renew or modify this registration, as well as for any other pending application(s) of Matthew S. Katz, M.D., for registration in Tennessee. This Order is effective May 15, 2023.

Signing Authority

This document of the Drug Enforcement Administration was signed on April 10, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–07834 Filed 4–12–23; 8:45 am]

BILLING CODE 4410–09–P

[5] Respondent describes himself as a ''highly trained vitreoretinal surgeon'' who ''credibly explained'' that ''he developed an addiction to opioid pain killers'' after a back injury that ''he attempted to manage himself.'' Resp Posthearing, at 3. Although ''it felt appropriate to him'' at the time to manage himself, ''he now acknowledges that behavior sounds 'crazy' to him.'' *Id.* Respondent's brief also states that he ''candidly acknowledged he engaged in dishonest, inappropriate, and unlawful behaviors in pursuit of substances to sustain the addiction.'' *Id.; infra.* Respondent was not asked to address his listing of ''cocaine'' in the ''drug(s) of choice'' section of the Tennessee Medical Foundation contract. RX 5, at 8.

[6] Respondent argues that his ability to continue his medical work requires his maintenance of a registration. *See, e.g.,* Resp Posthearing, at 11–12. After carefully reviewing his argument and the bases he posits for it, including RX 4 and RX 6, the Agency finds that the evidence Respondent, himself, offered belies this argument. Indeed, the record includes evidence that Respondent's skill, commitment to his sobriety, willingness to undergo extensive monitoring, and the apparent good will he has engendered have been sufficient for him to obtain and/or retain his current professional employment. *See, e.g.,* Resp Posthearing, at 7–12, 14–15.

The Agency notes that Respondent's argument, even if proven, is irrelevant to whether Respondent may be entrusted with a registration, the salient issue in this adjudication.

DEPARTMENT OF JUSTICE

Notice of Proposed Settlement Agreement Under The Federal Debt Collection Procedures Act, The Comprehensive Environmental Response, Compensation, and Liability Act, and The Resource Conservation and Recovery Act

On April 7, 2023, the Maxus Liquidating Trust (''Trust'') filed a motion with the United States Bankruptcy Court for the District of Delaware seeking approval of a Settlement and Release (the ''Main Agreement'') entered into by the Trust and YPF S.A., YPF International S.A. (f/k/a YPF International Ltd.), YPF Holdings, Inc., and YCLH Holdings, Inc. (f/k/a CLH Holdings, Inc.), Repsol, S.A., Repsol Exploración, S.A., Repsol USA Holdings LLC, Repsol E&P USA LLC,

Repsol Offshore E&P USA Inc., Perenco Trinidad & Tobago (Holdings) ETVE SLU (f/k/a Repsol E&P T&T Limited), and Repsol Services Company (the ''Private Parties''). The motion was filed as document number 883 in *Maxus Liquidating Trust* v. *YPF S.A. et al.,* Adv. Pro. No. 18–50489(CTG) (Bankr. D. Del.) (the ''Adversary Proceeding''), which is part of the bankruptcy case of Maxus Energy Corporation and certain of its affiliates (collectively ''Debtors''), *In re Maxus Energy Corporation, et al.,* No. 16–11501(CTG) (Bankr. D. Del.), in the same court (the ''Bankruptcy Case''). The Main Agreement is Exhibit B of the Motion, document number 883–2. Attached as Exhibit 2 at to the Main Agreement, at page 93 of 161, is a proposed Settlement and Covenant Not to Sue (the ''Government Agreement''), which has been agreed to, subject to public comment, by the United States, on behalf of the U.S. Environmental Protection Agency (''EPA''), the U.S. Department of the Interior (''DOI''), the U.S. National Oceanic and Atmospheric Administration (''NOAA''), the State of Ohio, the State of Wisconsin, and the Private Parties.

Under the Amended Plan of Liquidation (''Plan'') in the Bankruptcy Case, approved by the Delaware Bankruptcy Court on May 22, 2017, the Trust was established to pursue claims, on behalf of the Debtors, against the Private Parties, who were direct or indirect parents of the Debtors, asserting alter ego liability, fraudulent transfer claims, and related claims. Bankruptcy Case Doc. No. 1460–1. Under the Plan, any monies recovered by the Trust are to be distributed to various creditors and the Environmental Response/Restoration Trust (''ERRT''), pursuant to a distribution formula set forth in the Plan. The ERRT was established to fund remedial and restoration activities at the Diamond Alkali Superfund Site in Newark, New Jersey (''Diamond Alkali Site''). On June 14, 2018, the Trust filed its complaint. The Main Agreement, agreed to by the Trust and the Private Parties, is a settlement of the Trust's claims. The Main Agreement requires the YPF Private Parties to make a payment to the Trust in the amount of $287,500,000 (less certain deductions of $2,000,000), plus interest, and the Repsol Private Parties to make a payment to the Trust in the amount of $287,500,000, plus interest, for a total of $573,000,000, plus interest. With respect to the United States, approximately $80 million of this recovery will be distributed by the Trust to EPA in connection with the Diamond Alkali Site, approximately $80 million will be distributed to DOI and NOAA related to their natural resource damages claims in connection with the Diamond Alkali Site, and approximately $470,000 will be distributed to EPA in connection with the Milwaukee Solvay Coke & Gas Superfund Site, located in Milwaukee, Wisconsin. In addition, approximately $25 million will be distributed to the ERRT.

The Government Agreement provides that, in consideration of the payments that the Private Parties will make to the Trust under the Main Agreement, approximately $160 million of which will in turn be paid to the United States and approximately $25 million of which will be paid to the ERRT, the United States, on behalf of EPA, DOI, and NOAA, covenants not to sue the Private Parties and certain of their affiliates/employees (''Related Private Parties'') for: (a) any common law civil claims or causes of action that are Trust Derivative Claims, as defined in the Government Agreement, related to (i) the Covered Sites, including response actions and natural resource damages at the Covered Sites, (ii) the United States' proofs of claim filed in the Bankruptcy Case on behalf of EPA, DOI and NOAA, (iii) the Bankruptcy Case, or (iv) the Adversary Action; (b) any claim or cause of action under Subchapter D of the Federal Debt Collection Procedures Act (28 U.S.C. 3301–3308) to recover on a debt that is an environmental liability at a Covered Site where such claim or cause of action arises from the transactions at issue in the Adversary Proceeding; and (c) any civil claims or causes of action pursuant to Sections 106 or 107 of CERCLA (42 U.S.C. 9606 and 9607) or Section 7003 of RCRA (42 U.S.C. 6973) with respect to the Covered Sites. Trust Derivative Claims are defined in the Government Agreement as claims that were or could have been asserted by the Debtors and/or the Trust against the Related Private Parties seeking relief or recovery arising from harm to any Debtor or any Debtor's estate based on any legal theory including, for example, that such party was the corporate alter ego of any Debtor or wrongfully took or otherwise appropriated assets of any Debtor. Covered Sites are defined in the Government Agreement to include: (a) the Diamond Alkali Superfund Site; (b) the Milwaukee Solvay Superfund Site; (c) the Diamond Shamrock Kearny Plant Site at 1015 Belleville Turnpike, Kearny, New Jersey; (d) the St. Johnsbury Trucking Site at Obrien St. and Sellers St. in Kearny, New Jersey; (e) certain real property related to the former Diamond Shamrock Painesville Works Site in Painesville, Ohio; and (f) the Maxus Agricultural Chemicals facility at 5421 Reichhold Rd., Tuscaloosa, Alabama. The covenants provided by the United States are subject to a reservation of rights that reserves the right of the United States to bring certain claims, including claims for any liability that a Related Private Party might have that does not arise from or through a liability of a Debtor.

The publication of this notice opens a period for public comment on the Government Agreement. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *Maxus Liquidating Trust* v. *YPF S.A. et al.,* Adv. Pro. No. 18–50489(CTG) (Bankr. D. Del.), D.J. Ref. No. 90–11–3–07683/11. All comments must be submitted no later than 30 days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Under section 7003(d) of the RCRA, a member of the public may request, during the 30-day public comment period, a public meeting concerning the proposed Agreement.

During the public comment period, the Government Agreement may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* The Department of Justice will provide a paper copy of the Government Agreement upon written request. Please email your request to *pubcomment-ees.enrd@usdoj.gov* or mail your request to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Henry Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2023–07759 Filed 4–12–23; 8:45 am]

BILLING CODE 4410–15–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 23–031]

Notice of Information Collections

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collections.

SUMMARY: The National Aeronautics and Space Administration, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections.

DATES: Comments are due by June 13, 2023.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 60 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under 60-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Bill Edwards-Bodmer, NASA Clearance Officer, NASA Headquarters, 300 E Street SW, JF0000, Washington, DC 20546, 757–864–3292, or *b.edwards-bodmer@nasa.gov*.

SUPPLEMENTARY INFORMATION FOR 2700–0135:

I. Abstract

The NASA Kennedy Space Center (KSC) manages and facilitates the center-specific Job Shadowing Program (JSP). The program targets high school and undergraduate students and offers an opportunity to experience the practical application of STEM, business, and other disciplines aligned to NASA's long-term workforce needs, in a NASA-unique workplace setting. Program participants receive insight into NASA and KSC's history, current activities, and other student opportunities through briefings, tours, and career panels. Each participant is then matched with a subject matter expert to gain direct exposure to the implementation of their respective fields of interest and related career paths.

II. Methods of Collection

Electronic.

III. Data

Title: Job Shadowing Program.

OMB Number: 2700–0135.

Type of Review: Reinstatement.

Affected Public: High school and college students, and faculty.

Estimated Annual Number of Activities: 4.

Estimated Number of Respondents per Activity: 20.

Annual Responses: 80.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 40.

Estimated Total Annual Cost: $784.

SUPPLEMENTARY INFORMATION FOR 2700–0150:

I. Abstract

NASA's founding legislation, the Space Act of 1958, as amended, directs the Agency to expand human knowledge of Earth and space phenomena and to preserve the role of the United States as a leader in aeronautics, space science, and technology. The NASA Office of Education has three primary goals (1) strengthen NASA and the Nation's future workforce, (2) attract and retain students in science, technology, engineering and mathematics, or STEM, disciplines, and (3) engage Americans in NASA's mission. This notice informs the public of NASA's intent to revise a currently approved information collection for a project formerly known as the NASA Summer of Innovation Project. The request for renewal pertains to the administration of surveys to youth in support of the agency's STEM challenge activities for middle school youth. The information collection was revised to collect the minimum amount of data required to (1) evaluate the activity for improvement opportunities, and (2) collect outcome data to assess the activity model's effectiveness in meeting its intended objectives. Youth surveys have been retained in this information collection, but the parent survey and teacher focus groups have been eliminated to reduce burden. The number of youths participating in this information collection has been reduced to reflect the estimated number of participants who will be engaged in this activity in the future. The cost of the information collection, to participating members of the public, has also been reduced as a result of these and other changes to the information collection.

II. Methods of Collection

Electronic.

III. Data

Title: NASA Office of Education STEM Challenges.

OMB Number: 2700–0150.

Type of Review: Reinstatement.

Affected Public: Individuals.

Estimated Annual Number of Activities: 810.

Estimated Number of Respondents per Activity: 1.

Annual Responses: 1,620.

Estimated Time per Response: 6 minutes.

Estimated Total Annual Burden Hours: 162.

Estimated Total Annual Cost: $1,175.

SUPPLEMENTARY INFORMATION FOR 2700–0157:

I. Abstract

The National Aeronautics and Space Administration seeks to collect information from members of the public to plan, conduct, and register participants and volunteers for the NASA Human Exploration Rover Challenge, which supports science, technology, engineering, or mathematics (STEM) education. This engineering design challenge focuses on NASA's current plans to explore planets, moons, asteroids, and comets—all members of the solar system family. The challenge will focus on designing, constructing, and testing technologies for mobility devices to perform in these different environments, and it will provide valuable experiences that engage students in the technologies and concepts that will be needed in future exploration missions. NASA collects the minimum information necessary from teams, participants, and volunteers to plan and conduct the event.

II. Methods of Collection

Electronic.

III. Data

Title: NASA Human Exploration Rover Challenge.

OMB Number: 2700–0157.

Type of Review: Reinstatement.

Affected Public: Individuals.

Estimated Annual Number of Activities: 1,185.

Estimated Number of Respondents per Activity: 1.

Annual Responses: 1,185.

Estimated Time per Response: 71.5.

Estimated Total Annual Burden Hours: 1,415.

Estimated Total Annual Cost: $7,425.

SUPPLEMENTARY INFORMATION FOR 2700–0184:

I. Abstract

The NASA Universal Registration and Data Management System is a comprehensive tool designed to allow learners (*i.e.,* students, educators, and awardee principal investigators) to apply to NASA STEM engagement

opportunities (*e.g.,* internships, fellowships, challenges, educator professional development, experiential learning activities, etc.) in a single location. NASA personnel manage the selection of applicants and implementation of engagement opportunities within the Universal Registration and Data Management System. The information collected will be used by the NASA Office of STEM Engagement (OSTEM) in order to review applications for participation in NASA engagement opportunities. The information is reviewed by OSTEM project and activity managers, as well as NASA mentors who would be hosting students. This information collection will consist of student-level data such as demographic information submitted as part of the application. In addition to supporting student selection, student-level data will enable NASA OSTEM to fulfill federally mandated reporting on its STEM engagement activities and report relevant demographic information as needed for Agency performance goals and success criteria (annual performance indicators).

II. Methods of Collection

Electronic.

III. Data

Title: NASA Universal Registration and Data Management System.

OMB Number: 2700–0184.

Type of Review: Reinstatement.

Affected Public: Eligible students or educators, and/or awardee principal investigators may voluntarily apply for an internship or fellowship experience at a NASA facility, or register for a STEM engagement opportunity (*e.g.,* challenges, educator professional development, experiential learning activities, etc.). Parents/caregivers of eligible student applicants (at least 16 years of age but under the age of 18) may voluntarily provide consent for their eligible student applicants to apply.

Estimated Annual Number of Activities: 40.

Estimated Number of Respondents per Activity: 4,125.

Annual Responses: 165,000.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 82,500.

Estimated Total Annual Cost: $1,015,207.

IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) 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 automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

William Edwards-Bodmer,

NASA PRA Clearance Officer.

[FR Doc. 2023–07848 Filed 4–12–23; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL CREDIT UNION ADMINISTRATION

Privacy Act of 1974: Systems of Records

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice of a new system of records.

SUMMARY: Pursuant to the Privacy Act of 1974, the National Credit Union Administration (NCUA) gives notice of a new Privacy Act system of records. The new system is NCUA–27, NCUA General Support System Records. This system consists of information collected to provide authorized individuals with access to NCUA information technology resources.

DATES: Submit comments on or before May 15, 2023. This system will be effective immediately, and routine uses will be effective on May 15, 2023.

ADDRESSES: You may submit comments by any of the following methods, but please send comments by one method only:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- NCUA website: *http://www.ncua.gov/RegulationsOpinionsLaws/proposed_regs/proposed_regs.html.* Follow the instructions for submitting comments.
- *Fax:* (703) 518–6319. Use the subject line described above for email.
- *Mail:* Address to Melane Conyers-Ausbrooks, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.
- *Hand Delivery/Courier:* Same as mail address.

FOR FURTHER INFORMATION CONTACT: Jennifer Chemel, Attorney-Advisor, Office of General Counsel, the National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314.

SUPPLEMENTARY INFORMATION: This notice informs the public of the NCUA's proposal to establish and maintain a new system of records in accordance with the Privacy Act of 1974. The information collected in the NCUA–27 system of records consists of information collected for the purpose of providing authorized individuals with access to NCUA information technology resources.

The format of NCUA–27 aligns with the guidance set forth in Office of Management and Budget Circular A–108.

By the National Credit Union Administration Board on April 10, 2023.

Melane Conyers-Ausbrooks,

Secretary of the Board.

SYSTEM NAME AND NUMBER:

NCUA–27, NCUA General Support System Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428.

SYSTEM MANAGER(S):

Chief Information Officer, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

12 U.S.C. 1751 *et seq.* and 40 U.S.C. 11331.

PURPOSE(S) OF THE SYSTEM:

The information in the system is being collected to enable the NCUA to provide authorized individuals access to NCUA information technology resources. The system enables the NCUA to maintain account information required for approved access to information technology, lists of individuals seeking or receiving access to NCUA information technology or equipment, and lists of individuals who are appropriate organizational points of contact. The information will also be used for administrative purposes to ensure quality control, performance, and improving management processes.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include all persons who are authorized to access NCUA information technology resources, including: (1) Employees, contractors, and any lawfully designated representatives of federal, state, territorial, tribal, or local government agencies or entities, in furtherance of the NCUA's mission; (2) individuals who have business with the NCUA and who have provided personal information in order to facilitate access to NCUA information technology resources; and (3) individuals who are points of contact provided for government business, operations, or programs.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records in this system may contain data relating to individuals, including but not limited to: name; telephone numbers, including business, cellular, and home numbers; level of access; home or other provided address for the receipt of issued IT equipment or resources; email addresses of senders and recipients; records of access to NCUA computers and networks including equipment issued, user ID and passwords, date(s) and time(s) of access, IP address of access, logs of internet activity and records on the authentication of the access request; records of identity management related to individual user's request including universal resource locator of individual's chosen identity assurance certificate provider and response from certificate provider of positive or negative authentication; and positions or titles of contacts, their business or organizational affiliations, and other contact information provided to the NCUA that is derived from other sources to facilitate authorized access to NCUA Information Technology resources. The information in this system includes information relating to system access and does not include the data held within the systems or information technology resources to which access or interaction is sought.

RECORD SOURCE CATEGORIES:

Information in this system is obtained from individuals and entities associated with or granted access to NCUA information technology resources.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the NCUA as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. If a record in a system of records indicates a violation or potential violation of civil or criminal law or a regulation, and whether arising by general statute or particular program statute, or by regulation, rule, or order, the relevant records in the system or records may be disclosed as a routine use to the appropriate agency, whether federal, state, local, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, rule, regulation, or order issued pursuant thereto.

2. A record from a system of records may be disclosed as a routine use to a member of Congress or to a congressional staff member in response to an inquiry from the congressional office made at the request of the individual about whom the record is maintained;

3. Records in a system of records may be disclosed as a routine use to the Department of Justice, when: (a) NCUA, or any of its components or employees acting in their official capacities, is a party to litigation; or (b) Any employee of NCUA in his or her individual capacity is a party to litigation and where the Department of Justice has agreed to represent the employee; or (c) The United States is a party in litigation, where NCUA determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and NCUA determines that use of such records is relevant and necessary to the litigation, provided, however, that in each case, NCUA determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

4. Records in a system of records may be disclosed as a routine use in a proceeding before a court or adjudicative body before which NCUA is authorized to appear (a) when NCUA or any of its components or employees are acting in their official capacities; (b) where NCUA or any employee of NCUA in his or her individual capacity has agreed to represent the employee; or (c) where NCUA determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and NCUA determines that use of such records is relevant and necessary to the litigation, provided, however, NCUA determines that disclosure of the records is compatible with the purpose for which the records were collected.

5. A record from a system of records may be disclosed to contractors, experts, consultants, and the agents thereof, and others performing or working on a contract, service, cooperative agreement, or other assignment for NCUA when necessary to accomplish an agency function. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to NCUA employees.

6. Records may be disclosed to the Department of Homeland Security (DHS) if captured in an intrusion detection system used by NCUA and DHS pursuant to a DHS cybersecurity program that monitors internet traffic to and from federal government computer networks to prevent cybersecurity incidents;

7. A record from a system of records may be disclosed to appropriate agencies, entities, and persons when (1) NCUA suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (2) NCUA has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by NCUA or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with NCUA's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

8. To another Federal agency or Federal entity, when the NCUA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Electronic records and backups are stored on secure servers, approved by NCUA's Office of the Chief Information Officer (OCIO), and accessed only by authorized personnel.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrievable by a variety of fields including the individual's name or username.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are maintained and disposed in accordance with the General Records Retention Schedules issued by the National Archives and Records Administration (NARA).

ADMINISTRATIVE, TECHNICAL AND PHYSICAL SAFEGUARDS:

NCUA has implemented the appropriate administrative, technical, and physical controls in accordance with the Federal Information Security Modernization Act of 2014, Public Law 113–283, S. 2521, and NCUA's information security policies to protect the confidentiality, integrity, and availability of the information system and the information contained therein. Access is limited only to individuals authorized through NIST-compliant Identity, Credential, and Access Management policies and procedures. The records are maintained behind a layered defensive posture consistent with all applicable federal laws and regulations, including Office of Management and Budget Circular A–130 and NIST Special Publication 800–37.

RECORD ACCESS PROCEDURES:

Individuals wishing access to their records should submit a written request to the Senior Agency Official for Privacy, NCUA, 1775 Duke Street, Alexandria, VA 22314, and provide the following information:

1. Full name.
2. Any available information regarding the type of record involved.
3. The address to which the record information should be sent.
4. You must sign your request.

Attorneys or other persons acting on behalf of an individual must provide written authorization from that individual for the representative to act on their behalf. Individuals requesting access must also comply with NCUA's Privacy Act regulations regarding verification of identity and access to records (12 CFR 792.55).

CONTESTING RECORD PROCEDURES:

Individuals wishing to request an amendment to their records should submit a written request to the Senior Agency Official for Privacy, NCUA, 1775 Duke Street, Alexandria, VA 22314, and provide the following information:

1. Full name.
2. Any available information regarding the type of record involved.
3. A statement specifying the changes to be made in the records and the justification therefore.
4. The address to which the response should be sent.
5. You must sign your request.

Attorneys or other persons acting on behalf of an individual must provide written authorization from that individual for the representative to act on their behalf.

NOTIFICATION PROCEDURES:

Individuals wishing to learn whether this system of records contains information about them should submit a written request to the Senior Agency Official for Privacy, NCUA, 1775 Duke Street, Alexandria, VA 22314, and provide the following information:

1. Full name.
2. Any available information regarding the type of record involved.
3. The address to which the record information should be sent.
4. You must sign your request.

Attorneys or other persons acting on behalf of an individual must provide written authorization from that individual for the representative to act on their behalf. Individuals requesting access must also comply with NCUA's Privacy Act regulations regarding verification of identity and access to records (12 CFR 792.55).

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This is a new system.

[FR Doc. 2023–07847 Filed 4–12–23; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Privacy Act of 1974: Systems of Records

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice of a new system of records.

SUMMARY: Pursuant to the Privacy Act of 1974, the National Credit Union Administration (NCUA) gives notice of a new Privacy Act system of records. The new system is NCUA–26, Prospective Official Application Records. The Federal Credit Union Act requires that the NCUA investigate the general character and fitness of the management and officials of a proposed federal credit union or proposed federally insured state-chartered credit union. This system will include information that the NCUA collects and maintains to meet these requirements of the Federal Credit Union Act. Information is collected directly from the individual with their consent.

DATES: Submit comments on or before May 15, 2023. This system will be effective immediately, and routine uses will be effective on May 15, 2023.

ADDRESSES: You may submit comments by any of the following methods, but please send comments by one method only:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *NCUA Website: http://www.ncua.gov/RegulationsOpinionsLaws/proposed_regs/proposed_regs.html.* Follow the instructions for submitting comments.
- *Fax:* (703) 518–6319. Use the subject line described above for email.
- *Mail:* Address to Melane Conyers-Ausbrooks, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.
- *Hand Delivery/Courier:* Same as mail address.

FOR FURTHER INFORMATION CONTACT: Jennifer Chemel, Attorney-Advisor, Office of General Counsel, the National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314.

SUPPLEMENTARY INFORMATION: This notice informs the public of the NCUA's proposal to establish and maintain a new system of records in accordance with the Privacy Act of 1974. The proposed system of records covers the NCUA's collection and maintenance of records on applications for proposed federal and federally insured state-chartered credit union officials and employees. The Federal Credit Union Act requires that the NCUA investigate the general character and fitness of officials and senior management of proposed federal credit unions and proposed federally insured state-chartered credit unions. The Federal Credit Union Act defines management of a federal credit union as the proposed credit union's board of directors, credit committee, and supervisory committee. Senior management official is defined as a chief executive officer, an assistant chief executive officer, a chief financial officer, and any other senior executive officer. NCUA's Office of Credit Union Resources and Expansion (CURE) manages the credit union charter process and performs these general investigations with the assistance of the NCUA's Office of Continuity and Security Management.

The format of NCUA–26 aligns with the guidance set forth in Office of

Management and Budget (OMB) Circular A–108.

By the National Credit Union Administration Board on April 10, 2023.

Melane Conyers-Ausbrooks,

Secretary of the Board.

SYSTEM NAME AND NUMBER:

NCUA–26, Prospective Official Application Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428.

SYSTEM MANAGER(S):

Director, Office of Credit Union Resources and Expansion, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

12 U.S.C. 1754 and 12 CFR part 701.

PURPOSE(S) OF THE SYSTEM:

The NCUA uses information maintained in this system to carry out its statutory and other regulatory responsibilities, including evaluating the general character and fitness of prospective officials and employees of proposed federal credit unions and proposed federally insured state-chartered credit unions, and evaluating that applicants have requisite skills and commitment to dedicate time and effort to operate a successful credit union.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals, such as prospective officials and employees, or other persons who are subject to background checks designed to evaluate the general character and fitness bearing on the individual's fitness to be an official or employee of a proposed federal credit union or a proposed federally insured state-chartered credit union.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records in the system include name, contact information, date of birth, and Social Security numbers of individuals proposed as either officials or management employees of proposed federal credit unions or proposed federally insured state-chartered credit unions. Records may also include interagency or intra-agency correspondence or memoranda; suspicious activity reports; federal, state, or local criminal law enforcement agency investigatory reports, indictments and/or arrest and conviction information; reporting agency credit reports; adverse credit records (*e.g.,* bankruptcies, liens, judgments); administrative enforcement orders or agreements. Records also include actions taken by the NCUA in connection with these proposals.

RECORD SOURCE CATEGORIES:

The information in the system is obtained from individuals named in notices filed pursuant to 12 CFR 701 Appendix B, federal or state financial regulatory agencies, criminal law enforcement authorities, credit bureaus, and NCUA personnel.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the NCUA as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. A record from a system of records may be disclosed as a routine use to third parties to the extent necessary to obtain information that is relevant to an investigation of an individual's general character and fitness;

2. If a record in a system of records indicates a violation or potential violation of civil or criminal law or a regulation, and whether arising by general statute or particular program statute, or by regulation, rule, or order, the relevant records in the system or records may be disclosed as a routine use to the appropriate agency, whether federal, state, local, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, rule, regulation, or order issued pursuant thereto;

3. A record from a system of records may be disclosed as a routine use to a member of Congress or to a congressional staff member in response to an inquiry from the congressional office made at the request of the individual about whom the record is maintained;

4. Records in a system of records may be disclosed as a routine use to the Department of Justice, when: (a) NCUA, or any of its components or employees acting in their official capacities, is a party to litigation; or (b) Any employee of NCUA in his or her individual capacity is a party to litigation and where the Department of Justice has agreed to represent the employee; or (c) The United States is a party in litigation, where NCUA determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and NCUA determines that use of such records is relevant and necessary to the litigation;

5. Records in a system of records may be disclosed as a routine use in a proceeding before a court or adjudicative body before which NCUA is authorized to appear (a) when NCUA or any of its components or employees are acting in their official capacities; (b) where NCUA or any employee of NCUA in his or her individual capacity has agreed to represent the employee; or (c) where NCUA determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and NCUA determines that use of such records is relevant and necessary to the litigation;

6. A record from a system of records may be disclosed as a routine use to contractors, experts, consultants, and the agents thereof, and others performing or working on a contract, service, cooperative agreement, or other assignment for NCUA when necessary to accomplish an agency function or administer an employee benefit program. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to NCUA employees;

7. A record from a system of records may be disclosed to appropriate agencies, entities, and persons when (1) NCUA suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (2) NCUA has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by NCUA or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with NCUA's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm; and

8. To another Federal agency or Federal entity, when the NCUA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the

recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Electronic records and backups are stored on secure servers, approved by NCUA's Office of the Chief Information Officer (OCIO), within a FedRAMP-authorized commercial Cloud Service Provider's (CSP) Software-as-a-Service solution hosting environment and accessed only by authorized personnel.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by the name of an individual covered by the system.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are maintained and disposed in accordance with the General Records Retention Schedules issued by the National Archives and Records Administration (NARA) or an NCUA records disposition schedule approved by NARA.

ADMINISTRATIVE, TECHNICAL AND PHYSICAL SAFEGUARDS:

NCUA has implemented the appropriate administrative, technical, and physical controls in accordance with the Federal Information Security Modernization Act of 2014, Public Law 113–283, S. 2521, and NCUA's information security policies to protect the confidentiality, integrity, and availability of the information system and the information contained therein. Access is limited only to individuals authorized through NIST-compliant Identity, Credential, and Access Management policies and procedures. The records are maintained behind a layered defensive posture consistent with all applicable federal laws and regulations, including OMB Circular A–130 and NIST Special Publication 800–37.

RECORD ACCESS PROCEDURES:

Individuals wishing access to their records should submit a written request to the Senior Agency Official for Privacy, NCUA, 1775 Duke Street, Alexandria, VA 22314, and provide the following information:

1. Full name.

2. Any available information regarding the type of record involved.

3. The address to which the record information should be sent.

4. You must sign your request.

Attorneys or other persons acting on behalf of an individual must provide written authorization from that individual for the representative to act on their behalf. Individuals requesting access must also comply with NCUA's Privacy Act regulations regarding verification of identity and access to records (12 CFR 792.55).

CONTESTING RECORD PROCEDURES:

Individuals wishing to request an amendment to their records should submit a written request to the Senior Agency Official for Privacy, NCUA, 1775 Duke Street, Alexandria, VA 22314, and provide the following information:

1. Full name.

2. Any available information regarding the type of record involved.

3. A statement specifying the changes to be made in the records and the justification therefore.

4. The address to which the response should be sent.

5. You must sign your request.

Attorneys or other persons acting on behalf of an individual must provide written authorization from that individual for the representative to act on their behalf.

NOTIFICATION PROCEDURES:

Individuals wishing to learn whether this system of records contains information about them should submit a written request to the Senior Agency Official for Privacy, NCUA, 1775 Duke Street, Alexandria, VA 22314, and provide the following information:

1. Full name.

2. Any available information regarding the type of record involved.

3. The address to which the record information should be sent.

4. You must sign your request.

Attorneys or other persons acting on behalf of an individual must provide written authorization from that individual for the representative to act on their behalf. Individuals requesting access must also comply with NCUA's Privacy Act regulations regarding verification of identity and access to records (12 CFR 792.55).

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Federal criminal law enforcement investigatory reports maintained as part of this system may be subject of exemptions imposed by the originating agency pursuant to 5 U.S.C. 552a(j)(2).

HISTORY:

This is a new system.

[FR Doc. 2023–07846 Filed 4–12–23; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; National Science Foundation Proposal/Award Information—NSF Proposal and Award Policies and Procedures Guide

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to renew this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting Office of Management and Budget (OMB) clearance of this collection for no longer than 3 years.

DATES: Written comments on this notice must be received by June 12, 2023 to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to the address below.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Suite E7400, Alexandria, Virginia 22314; telephone (703) 292–7556; or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including Federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: ''National Science Foundation Proposal/Award Information—NSF Proposal and Award Policies and Procedures Guide.''

OMB Approval Number: 3145–0058.

Expiration Date of Approval: October 31, 2025.

Type of Request: Intent to seek approval to extend with revision an information collection for three years. The primary purpose of this revision is to update the NSF Proposal and Award Policies and Procedures Guide (PAPPG) to incorporate a number of policy-related changes and clarifications of language. The draft NSF PAPPG is now available for your review and consideration on the NSF website at *http://www.nsf.gov/bfa/dias/policy/.* To facilitate review, revised text has been highlighted in yellow throughout the document to identify significant changes. A brief comment explanation of the change also is provided.

Proposed Project: The National Science Foundation Act of 1950 (Pub. L.

81–507) sets forth NSF's mission and purpose:

''To promote the progress of science; to advance the national health, prosperity, and welfare; to secure the national defense. . . .''

The Act authorized and directed NSF to initiate and support:

- Basic scientific research and research fundamental to the engineering process;
- Programs to strengthen scientific and engineering research potential;
- Science and engineering education programs at all levels and in all the various fields of science and engineering;
- Programs that provide a source of information for policy formulation; and
- Other activities to promote these ends.

NSF's core purpose resonates clearly in everything it does: promoting achievement and progress in science and engineering and enhancing the potential for research and education to contribute to the Nation. While NSF's vision of the future and the mechanisms it uses to carry out its charges have evolved significantly over the last six decades, its ultimate mission remains the same.

Use of the Information: The regular submission of proposals to the Foundation is part of the collection of information and is used to help NSF fulfill this responsibility by initiating and supporting merit-selected research and education projects in all the scientific and engineering disciplines. NSF receives more than 50,000 proposals annually for new projects, and makes approximately 11,000 new awards.

NSF funding is primarily made through issuance of grants, cooperative agreements, contracts, other transactions and other arrangements awarded to approximately 3,000 institutions of higher education, non-profit organizations, tribal nations, for-profit organizations, and state and local governments. The awards are based mainly on merit evaluations of proposals submitted to the Foundation.

The Foundation has a continuing commitment to monitor the operations of its information collection to identify and address excessive reporting burdens as well as to identify any real or apparent inequities based on gender, race, ethnicity, or disability of the proposed principal investigator(s)/project director(s) or the co-principal investigator(s)/co-project director(s).

Burden on the Public: The Foundation estimates that an average of 120 hours is expended for each proposal submitted. An estimated 50,000 proposals are expected during the course of one year for a total of 6,000,000 public burden hours annually.

Comments: Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Dated: April 10, 2023.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2023–07780 Filed 4–12–23; 8:45 am]

BILLING CODE 7555–01–P

NEIGHBORHOOD REINVESTMENT CORPORATION

Sunshine Act Meetings

TIME AND DATE: 2 p.m., Thursday, April 20, 2023.

PLACE: 1255 Union Street NE, Fifth Floor, Washington, DC 20002.

STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Regular Board of Directors meeting. The General Counsel of the Corporation has certified that in his opinion, one or more of the exemptions set forth in the Government in the Sunshine Act, 5 U.S.C. 552b (c)(2) and (4) permit closure of the following portion(s) of this meeting:

- Executive Session

Agenda

I. Call to Order
II. FY2022 External Audit Discussion with BDO Auditors
III. Sunshine Act Approval of Executive (Closed) Session
IV. Executive Session with BDO Auditors
V. Special Topic
VI. Executive Session: Report from CEO
VII. Executive Session: Report from CFO
VIII. Executive Session: General Counsel Report
IX. Executive Session: NeighborWorks Compass Update
X. Action Item Approval of Meeting Minutes
XI. Action Item Approval of FY2022 External Audit
XII. Action Item Cigna Special Delegation
XIII. Action Item NW Compass: Strategy and Contracting Authority
XIV. Discussion Item March 16 Audit Committee Report
XV. Discussion Item Report from CIO
XVI. Discussion Item IT Tech Support Contract—Request to Increase Contract Amount
XVII. Capital Corporation Update and Grant Request for June
XVIII. Discussion Item Investment Policy Review
XIX. Discussion Item Expanded Spending Authority for Large Events
XX. Management Program Background and Updates
XXI. Adjournment

PORTIONS OPEN TO THE PUBLIC: Everything except the Executive Session.

PORTIONS CLOSED TO THE PUBLIC: Executive Session.

CONTACT PERSON FOR MORE INFORMATION: Lakeyia Thompson, Special Assistant, (202) 524–9940; *Lthompson@nw.org.*

Lakeyia Thompson,

Special Assistant.

[FR Doc. 2023–07883 Filed 4–11–23; 11:15 am]

BILLING CODE 7570–02–P

POSTAL REGULATORY COMMISSION

[Docket No. PI2023–3; Order No. 6479]

Classification of First-Class Package Service Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is initiating a proceeding to explore commenters' claims that the First-Class Package Service product may not be correctly classified as a Competitive product. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 26, 2023; *Reply Comments are due:* August 23, 2023.

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:

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I. Introduction
II. Background
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IV. Ordering Paragraphs

I. Introduction

In Order No. 6384, the Commission stated it would initiate a proceeding to explore commenters' claims that the First-Class Package Service (FCPS) product [1] may not be correctly classified as a Competitive product.[2] The Commission establishes this docket to examine those claims.

II. Background

A. Statutory Framework

Under the Postal Accountability and Enhancement Act (PAEA),[3] postal products are separated into two distinct classifications: Market Dominant and Competitive. 39 U.S.C. 3621, 3631, 3642. Section 3642 of title 39 governs the addition of products to, removal of products from, or transfer of products (or components of a product) between the Market Dominant and Competitive product lists.[4] The Commission may consider a change to a product's classification upon request of the Postal Service, upon request of users of the mail, or upon its own initiative. 39 U.S.C. 3642(a). There is nothing to prevent transfer of only part of a product between product lists. 39 U.S.C. 3642(c).

The criteria for assigning a product to either the Market Dominant or Competitive product list are described in 39 U.S.C. 3642(b). These criteria include an assessment of the Postal Service's market power, whether or not the product is covered by the postal monopoly, the availability and nature of private sector competitors, the views of users of the product, and the likely impact on small businesses. *Id.* The market power criteria are specified in 39 U.S.C. 3642(b)(1), the postal monopoly criteria are specified in 39 U.S.C. 3642(b)(2), and the considerations related to private sector competitors, users of the product, and small businesses are specified in 39 U.S.C. 3642(b)(3).

B. Historical Classification of First-Class Package Service

Until April 2011, the First-Class Mail Parcels (FCMP) product appeared on the Market Dominant list and included four price categories: Commercial Plus, Commercial Base, Retail Single-Piece, and Keys and Identification Devices.[5] On February 24, 2011, the Postal Service filed a request with the Commission to transfer the Commercial Plus and Commercial Base categories to the Competitive product list and to provisionally rename them ''Lightweight Commercial Parcels.'' [6] The Lightweight Commercial Parcels product was proposed to be identical to the Commercial categories of FCMP, except that items classified as ''letters'' would be prohibited. Docket No. MC2011–22, Notice at 2. The Postal Service did not request transfer of the Retail Single-Piece or Keys and Identification Devices subcategories at that time. The transfer was unopposed. Order No. 710 at 3–5. On April 6, 2011, the Commission granted the Postal Service's transfer request.

On August 12, 2011, the Postal Service requested to change the provisional Lightweight Commercial Packages name to Commercial First-Class Package Service.[7] The Postal Service also requested to remove the letter prohibition from the Commercial Plus price category, as Commercial Plus prices were more than six times the price of a 1-ounce Single-Piece First-Class Mail Letter and thus not subject to the postal monopoly. Docket No. MC2011–28, Notice at 2. On August 31, 2011, the Commission granted the Postal Service's requests.[8]

On November 14, 2014, the Postal Service proposed to transfer the remaining two price categories of FCMP: Retail Single-Piece and Keys and Identification Devices to the Competitive product list.[9] The Postal Service noted that some large commercial mailers used both Retail Single-Piece FCMP and Commercial FCPS, suggesting that the products served a single market. Docket No. MC2015–7, Notice, Attachment B at 3. The Postal Service further stated that the new combined FCPS product would compete in the 2–3-day air and ground parcel markets and would not have a dominant share of those markets. *Id.* at 4. On August 26, 2015, the Commission denied the Postal Service's transfer request on the grounds that the Postal Service had not presented sufficient evidence for the Commission to determine the market in which Retail Single-Piece FCMP operated.[10] The Postal Service filed a petition for review of Order No. 2686 with the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit). On December 6, 2016, the D.C. Circuit granted the petition for review and remanded Order No. 2686 to the Commission for further proceedings.[11] The D.C. Circuit noted that the Postal Service had supplied the same type of market share data that the Commission previously relied upon when approving previous transfer requests. *U.S. Postal Serv.,* 842 F.3d at 1273. The D.C. Circuit explained that by rejecting that data as insufficient, the Commission had changed the nature of proof required to demonstrate a lack of market power compared to the previous transfer dockets but had neither acknowledged nor explained its change in course. *Id.* The D.C. Circuit noted that the previous transfers were not materially different from the proposed transfer and concluded that the Commission was obliged to ''forthrightly distinguish or outrightly reject'' its precedent established in the previous transfer orders when deciding to change course. *Id.* at 1274. As the Commission had not done so in Order No. 2686, the D.C. Circuit remanded the case to the Commission for further proceedings. *Id.*

Following the D.C. Circuit's remand, the Postal Service updated its original proposal and provided additional information in response to a Chairman's Information Request.[12]

Based on this data and other updates occurring in the interim between the original proposed transfer and the

[1] As defined in section 2125 of the Mail Classification Schedule (MCS), available at *https://www.prc.gov/mail-classification-schedule.*

[2] Docket No. CP2023–42, Order Approving Price Adjustments for Competitive Products, December 22, 2022, at 11 (Order No. 6384).

[3] Public Law 109–435, 120 Stat. 3198 (2006).

[4] 39 U.S.C. 3642. The implementing regulations for this section appear in 39 CFR part 3040.

[5] Docket No. MC2011–22, Order Adding Lightweight Commercial Parcels to the Competitive Product List, April 6, 2011, at 2 (Order No. 710).

[6] Docket No. MC2011–22, Request of the United States Postal Service Under Section 3642, February 24, 2011, at 1 (Docket No. MC2011–22, Notice).

[7] Docket No. MC2011–28, Notice of Minor Classification Change, August 12, 2011, at 1 (Docket No. MC2011–28, Notice).

[8] Docket No. MC2011–28, Order Regarding Commercial First-Class Package Service, August 31, 2011, at 8 (Order No. 835).

[9] Docket No. MC2015–7, Request of the United States Postal Service to Transfer First-Class Mail Parcels to the Competitive Product List, November 14, 2014, at 1 (Docket No. MC2015–7, Notice).

[10] Docket No. MC2015–7, Order Denying Transfer of First-Class Mail Parcels to the Competitive Product Category, August 26, 2015, at 1 (Order No. 2686).

[11] *U.S. Postal Serv.* v. *Postal Regul. Comm'n,* 842 F.3d 1271 (D.C. Cir. 2016) (per curiam).

[12] Docket No. MC2015–7, Order Conditionally Approving Transfer, July 20, 2017, at 2–3 (Order No. 4009); *see* Docket No. MC2015–7, Response of the United States Postal Service to Chairman's Information Request No. 2, June 26, 2017 (Docket No. MC2015–7, Response to CHIR No. 2).

updated proposal, the Commission found that the Postal Service did not possess power over the market for Retail Single-Piece FCMP or the combined FCPS product and approved the transfer. *Id.* at 32–34, 40. The Commission observed that the market share of the combined FCPS product had decreased since FY 2013, and that price increases to the Retail Single-Piece FCMP product had coincided with decreased volume. *Id.* at 31, 33. The Commission further determined that transfer of the product would not violate the postal monopoly. *Id.* at 34–35. Finally, the Commission concluded that the transfer was justified in consideration of the factors set forth in 39 U.S.C. 3642(b)(3). *Id.* at 37.

C. Recent Developments Regarding First-Class Package Service

On June 17, 2021, the Postal Service filed a request for an advisory opinion on its proposal to revise the service standards for FCPS, effective October 1, 2021.[13] Specifically, the Postal Service sought to lengthen the service standards by 1 to 2 additional days for approximately 31.2 percent of FCPS volume and to shorten the service standards by 1 day for approximately 4.8 percent of FCPS volume.[14] The Commission concluded, among other things, that the Postal Service's stated goals appeared reasonable and that the proposed changes should have a positive impact on the Postal Service's ability to meet its performance targets. Docket No. N2021–2, Advisory Opinion at 3. However, the Commission also noted certain concerns with the Postal Service's modeling of cost savings, transportation efficiencies, and network operations. *Id.* at 3–4.

On July 13, 2022, the Postal Service filed with the Commission a request to expand the FCPS product up to 70 pounds, with corresponding changes to the size (dimension) limitations and pricing tiers.[15] However, the Postal Service later informed the Commission that the changes would be postponed to such time in calendar year 2023 as management deemed appropriate.[16]

On October 28, 2022, the Commission approved the Postal Service's proposed classification changes.[17] The Commission determined that the Postal Service's request to remove USPS Retail Ground from the Competitive product list satisfied the requirements of 39 U.S.C. 3642 and the Commission's regulations. Order No. 6318 at 13. The Commission determined that the proposed changes would likely have a positive effect on users of FCPS and small businesses and would not likely have a material effect on competitors. *Id.* at 18.

On November 14, 2022, the Commission established Docket No. CP2023–42 to consider the Postal Service's notice concerning changes in rates and classifications of general applicability for Competitive products, which were scheduled to take effect on January 22, 2023.[18] In its notice, the Postal Service proposed a 6.9 percent average price increase for Retail FCPS and an 8.0 percent average price increase for Commercial FCPS. Order No. 6327 at 3.

On December 22, 2022, the Commission approved the Postal Service's proposed rate changes. Order No. 6384 at 1. In so doing, the Commission concluded that the commenters' claims that the Commission erred in transferring FCPS to the Competitive product list were beyond the scope of the proceeding. *Id.* at 10. The Commission further noted that the increase in FCPS prices and recent changes to FCPS service standards cited by the commenters did not, on their own, establish that the Postal Service took such actions without risk of losing significant business to competitors. *Id.* (citing 39 U.S.C. 3642(b)(1)). The Commission stated that it would ''explore commenters' claims that FCPS may not be correctly classified as a Competitive product'' in a separate proceeding. *Id.* at 11.

On February 10, 2023, the Postal Service filed a notice of rate adjustment for Competitive products in which it proposed rates of general applicability for the expanded FCPS product, up to 70 pounds, effective July 9, 2023.[19] In addition, the Postal Service proposed renaming the enhanced and expanded product ''USPS Ground Advantage.'' Docket No. CP2023–113, Notice at 1. The Postal Service also stated that Certificate of Mailing and Certified Mail would be removed from the list of optional features for USPS Ground Advantage, and that it was submitting two additional minor corrections to the MCS. *Id.* at 4. Those proposed changes are currently pending before the Commission in Docket Nos. CP2023–113 and CP2023–114.

III. Invitation for Comments

The Commission invites interested persons to comment on whether FCPS, as currently defined, is properly classified as a Competitive product. Specifically, the Commission invites comments, as well as supporting evidence and analysis, regarding the relevant market(s) in which FCPS operates and the Postal Service's market power in such market(s), that could either call into question or support the Commission's previous determination that the Postal Service could not effectively set the price of FCPS substantially above costs, raise prices significantly, decrease quality, or decrease output, without risk of losing a significant level of business to other firms offering similar products.[20] In addition, in light of the Postal Service's proposed expansion and enhancement of FCPS and its proposed renaming to USPS Ground Advantage, commenters questioning the Competitive classification of FCPS should also discuss whether any portion of the proposed USPS Ground Advantage product should be classified as Market Dominant and provide supporting analysis addressing the criteria set out in 39 U.S.C. 3642(b) and prior Commission decisions applying section 3642(b).

Comments are due on July 26, 2023. Any reply comments are due on August 23, 2023. Materials filed in this docket will be available for review on the Commission's website at *http://www.prc.gov.* Pursuant to 39 U.S.C. 505, Kenneth R. Moeller will serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

[13] Docket No. N2021–2, United States Postal Service Request for an Advisory Opinion on Changes in the Nature of Postal Services, June 17, 2021, at 1 (Docket No. N2021–2, Request).

[14] Docket No. N2021–2, Advisory Opinion on the Service Standard Changes Associated with First-Class Package Service, September 29, 2021, at 1–2 (Docket No. N2021–2, Advisory Opinion).

[15] Docket No. MC2022–82, USPS Notice of Changes in Classifications of General Applicability for Competitive Products, July 13, 2022, at 1–2 (Docket No. MC2022–82, Notice).

[16] Docket Nos. MC2022–81 and MC2022–82, USPS Notice of Revised Effective Date, Pursuant to Governors' Decision 22–4, August 16, 2022, at 1–2.

[17] Docket Nos. MC2022–81 and MC 2022–82, Order Removing USPS Retail Ground from the Competitive Product List and Approving Competitive Classification Changes to First-Class Package Service and Parcel Select, October 28, 2022, at 1 (Order No. 6318).

[18] Docket No. CP2023–42, Notice and Order Concerning Changes in Rates and Classifications of General Applicability for Competitive Products, November 14, 2022, at 1 (Order No. 6327).

[19] Docket No. CP2023–113, USPS Notice of Changes in Rates and Classifications of General Applicability for First-Class Package Service, February 10, 2023, at 2–3 (Docket No. CP2023–113, Notice).

[20] Order No. 4009 at 33 (citing 39 U.S.C. 3642(b)(1)).

By the Commission.

Mallory Richards,

Attorney-Advisor.

[FR Doc. 2023–07722 Filed 4–12–23; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service 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:* April 13, 2023.

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 April 3, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 111 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–129, CP2023–132.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2023–07825 Filed 4–12–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service 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:* April 13, 2023.

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 March 28, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 108 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–126, CP2023–129.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2023–07813 Filed 4–12–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service 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:* April 13, 2023.

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 March 28, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 109 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–127, CP2023–130.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2023–07821 Filed 4–12–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service 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:* April 13, 2023.

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 April 4, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 113 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–131, CP2023–134.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2023–07817 Filed 4–12–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service 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:* April 13, 2023.

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 April 4, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 112 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–130, CP2023–133.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2023–07816 Filed 4–12–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service 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:* April 13, 2023.

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 March 29, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 110 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–128, CP2023–131.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2023–07820 Filed 4–12–23; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97267; File No. SR–NYSEARCA–2023–30]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Amending the Rule Governing the Listing and Trading of Shares of the Gabelli Equity Income ETF

April 7, 2023.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 5, 2023, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to reflect a change in the name of the Gabelli Equity Income ETF (the ''Fund'') and an updated description of the investment strategy for the Fund, shares of which are currently listed and traded on the Exchange pursuant to NYSE Arca Rule 8.900–E. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this rule filing is to reflect a change to the name of the Fund and an updated description of the Fund's investment strategy. The Commission previously approved the listing and trading of Shares of the Fund on the Exchange pursuant to NYSE Arca Rule 8.900–E.[3] NYSE Arca Rule 8.900–E governs the listing and trading of Managed Portfolio Shares, which are securities issued by an actively managed open-end investment management company.[4] The Shares of the Fund are issued by the Gabelli ETFs Trust (the ''Trust''), a statutory trust organized under the laws of the State of Delaware and registered with the Commission as an open-end management investment company.[5]

The Approval Order stated that the Fund's name would be the Gabelli Equity Income ETF. The Exchange now proposes to update the name of the Fund to the Gabelli Commercial Aerospace and Defense ETF, which name is reflected in the Registration Statement and is consistent with the updated description of the Fund discussed below.

The Approval Order stated that the Fund seeks a high level of total return on its assets with an emphasis on income and intends to invest in income producing equity securities including U.S. exchange-listed common stock and preferred stock. The Exchange proposes to update the description of the Fund to provide that, as set forth in the Registration Statement, the Fund will seek to achieve its investment objective

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 89663 (August 25, 2020), 85 FR 53868 (August 31, 2020) (SR–NYSEArca–2020–48) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of Gabelli ETFs Under Rule 8.900–E, Managed Portfolio Shares) (the ''Approval Order'').

[4] *See* Securities Exchange Act Release No. 88648 (April 15, 2020), 85 FR 22200 (April 21, 2020). Rule 8.900–E(c)(1) provides that the term ''Managed Portfolio Share'' means a security that (a) represents an interest in an investment company (''Investment Company'') registered under the Investment Company Act of 1940 (the ''1940 Act'') organized as an open-end management investment company that invests in a portfolio of securities selected by the Investment Company's investment adviser consistent with the Investment Company's investment objectives and policies; (b) is issued in a Creation Unit, or multiples thereof, in return for a designated portfolio of instruments (and/or an amount of cash) with a value equal to the next determined net asset value and delivered to the Authorized Participant (as defined in the Investment Company's Form N–1A filed with the Commission) through a Confidential Account; (c) when aggregated into a Redemption Unit, or multiples thereof, may be redeemed for a designated portfolio of instruments (and/or an amount of cash) with a value equal to the next determined net asset value delivered to the Confidential Account for the benefit of the Authorized Participant; and (d) the portfolio holdings for which are disclosed within at least 60 days following the end of every fiscal quarter.

[5] The Trust is registered under the 1940 Act. The Commission issued an order granting exemptive relief to the Trust (''Exemptive Order'') under the 1940 Act on December 3, 2019 (Investment Company Act Release No. 33708). The Exemptive Order was granted in response to the Trust's application for exemptive relief (the ''Exemptive Application'') (File No. 812–15036). The Trust has filed a registration statement on Form N–1A under the Securities Act of 1933 (the ''1933 Act'') and the 1940 Act for the Fund (File No. 812–15036) (''Registration Statement''). The Trust subsequently filed Post-Effective Amendment No. 6 to the Registration Statement reflecting the new name of the Fund and the updated description of the Fund's investment strategy. *See* Post-Effective Amendment No. 6 to Registration Statement on Form N–1A for the Trust, dated March 11, 2023 (File Nos. 333–238109 and 811–23568). Investments made by the Fund will comply with the conditions set forth in the Exemptive Application and the Exemptive Order. *See* Approval Order, 85 FR at 53869 & n. 9. The description of the Fund and the changes to the Fund proposed herein are based, in part, on information in the Registration Statement, as amended. Shares of the Fund have been listed and traded on the Exchange since January 4, 2023. The Adviser (as defined in the Approval Order) represents that it will not implement the changes described herein until the instant proposed rule change is operative.

by investing, under normal market conditions, at least 80% of its net assets (including any assets purchased using borrowings for investment purposes) in securities in the aerospace and defense sectors. According to the Registration Statement, the Fund defines an ''aerospace and defense'' company as a company that derives at least 50% of its revenues from, or devotes 50% of its assets to, aerospace and/or defense related activities. Aerospace companies include manufacturers, assemblers and distributors of aircraft and aircraft parts; defense companies include producers of components and equipment for the defense industry, such as military aircraft, radar equipment and weapons.

Except for the changes noted above, all other representations made in the Exchange's previous rule filing to list and trade Shares of the Fund remain unchanged and will continue to constitute continuing listing requirements for the Fund. As set forth in the Approval Order, the Fund's holdings will continue to conform to the permissible investments as set forth in the Exemptive Application and Exemptive Order, and the holdings will be consistent with the Registration Statement and all requirements in the Exemptive Application and Exemptive Order.[6] The Fund will also continue to comply with the requirements of Rule 8.900–E.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes the proposed rule change is designed to remove impediments to and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest because it would reflect the change in the Fund's name and description, as set forth in the Registration Statement. Specifically, the proposed rule change would reflect a change in the Fund's name from the Gabelli Equity Income ETF to the Gabelli Commercial Aerospace and Defense ETF and reflect the Fund's updated strategy, through which the Fund will seek to achieve its investment objectives by investing, under normal market conditions, at least 80% of its net assets (including any assets purchased using borrowings for investment purposes) in securities in the aerospace and defense sectors. The proposed change is also designed to remove impediments to and perfect the mechanism of a free and open market, promote just and equitable principles of trade, and protect investors and the public interest because the Fund's investments will be consistent with the Registration Statement and continue to comply with all conditions set forth in the Exemptive Application and Exemptive Order. Except for the changes noted above, all other representations made in the Exchange's original rule filing remain unchanged and will continue to constitute continuing listing requirements for the Fund.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. As noted above, the proposed rule change would reflect only a change in the name and description of the Fund and would thus facilitate the continued listing and trading of Shares of the Fund on the Exchange, thereby promoting competition among various ETF products, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[9] and subparagraph (f)(6) of Rule 19b–4 thereunder.[10]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[11] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange asserts that waiver of the operative delay would be consistent with the protection of investors and the public interest because it would promptly reflect the updated name and description of the Fund and facilitate the continued listing and trading of the shares of the Fund. In addition, the Commission notes that all types and quantities of proposed permitted investments are presently permitted. For these reasons, and because the proposal raises no novel legal or regulatory issues, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[12]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[6] *See* note 3, *supra.*

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[11] 17 CFR 240.19b–4(f)(6)(iii).

[12] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEARCA–2023–30 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2023–30. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2023–30 and should be submitted on or before May 4, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–07735 Filed 4–12–23; 8:45 am]

BILLING CODE 8011–01–P

[13] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97268; File No. SR–MEMX–2023–07]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Fee Schedule

April 7, 2023.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on March 31, 2023, MEMX LLC (''MEMX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to amend the Exchange's fee schedule applicable to Members [4] (the ''Fee Schedule'') pursuant to Exchange Rules 15.1(a) and (c). The Exchange proposes to implement the changes to the Fee Schedule pursuant to this proposal on April 3, 2023. The text of the proposed rule change is provided in Exhibit 5.

II. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Exchange Rule 1.5(p).

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Fee Schedule to modify the required criteria under NBBO Setter/Joiner Tier 1.

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues, to which market participants may direct their order flow. Based on publicly available information, no single registered equities exchange currently has more than approximately 16% of the total market share of executed volume of equities trading.[5] Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow, and the Exchange currently represents approximately 3% of the overall market share.[6] The Exchange in particular operates a ''Maker-Taker'' model whereby it provides rebates to Members that add liquidity to the Exchange and charges fees to Members that remove liquidity from the Exchange. The Fee Schedule sets forth the standard rebates and fees applied per share for orders that add and remove liquidity, respectively. Additionally, in response to the competitive environment, the Exchange also offers tiered pricing, which provides Members with opportunities to qualify for higher rebates or lower fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

The Exchange currently offers NBBO Setter/Joiner Tiers 1–2 under which a Member may receive an additive rebate for a qualifying Member's executions of Added Displayed Volume (other than Retail Orders) that establish the NBBO (such orders, ''Setter Volume'') and executions of Added Displayed Volume

[5] Market share percentage calculated as of March 30, 2023. The Exchange receives and processes data made available through consolidated data feeds (*i.e.,* CTS and UTDF).

[6] *Id.*

(other than Retail Orders) that establish a new best bid or offer on the Exchange that matches the NBBO first established on an away market (such orders, ''Joiner Volume''). With respect to NBBO Setter/Joiner Tier 1, the Exchange currently provides an additive rebate of $0.0004 per share for executions of Setter Volume and Joiner Volume for Members that qualify for such tier by achieving: (1) an ADAV [7] with respect to orders with Fee Code B [8] that is equal to or greater than 0.10% of the TCV; [9] or (2) an ADAV with respect to orders with Fee Code B that is equal to or greater than 10,000,000 shares.[10] The Exchange now proposes to modify the required criteria such that a Member would now qualify for such tier by achieving an ADAV with respect to orders with Fee Code B that is equal to or greater than 0.10% of the TCV. Thus, such proposed change would keep the first of such two alternative criteria intact and eliminate the second of such criteria. The Exchange notes that no Members are presently achieving the second of such criteria, and as such, the Exchange does not believe that the proposed elimination of such criteria will have a significant impact on any Member's trading behavior on the Exchange. The Exchange therefore no longer wishes to, nor is it required to, maintain such criteria. The Exchange believes that the additive rebate for executions of Setter Volume and Joiner Volume provided under NBBO Setter/Joiner Tier 1, which the Exchange is not proposing to change with this proposal, remains commensurate with the required criteria under such tier, as modified, and is reasonably related to the market quality benefits that such tier is designed to achieve.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[11] in general, and with Sections 6(b)(4) and 6(b)(5) of the Act,[12] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As discussed above, the Exchange operates in a highly fragmented and competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient, and the Exchange represents only a small percentage of the overall market. The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [13]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange believes that the proposed change to modify NBBO Setter/Joiner Tier 1 to remove the alternative criteria based on an ADAV threshold that is expressed as a number of shares is reasonable because it would simply remove one of two alternative criteria applicable to such Tier. The Exchange believes that the additive rebate for executions of Setter Volume and Joiner Volume provided under NBBO Setter/Joiner Tier 1, which the Exchange is not proposing to change with this proposal, remains commensurate with the required criteria under such tier, as modified, and is reasonably related to the market quality benefits that such tier is designed to achieve. The Exchange also believes the additive rebate for executions of Setter Volume and Joiner Volume provided under NBBO Setter/Joiner Tier 1 remains equitable and not unfairly discriminatory, as such additive rebate will continue to apply equally to all qualifying Members.

The Exchange notes that volume-based incentives and discounts (such as tiers) have been widely adopted by exchanges (including the Exchange), and are reasonable, equitable and not unfairly discriminatory because they are open to all members on an equal basis and provide additional benefits or discounts that are reasonably related to the value to an exchange's market quality associated with higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns, and the introduction of higher volumes of orders into the price and volume discovery process. The Exchange believes that NBBO Setter/Joiner Tier 1, as modified by the change proposed herein, is reasonable, equitable and not unfairly discriminatory for these same reasons, as such tier would continue to provide Members with an incentive to achieve certain volume thresholds on the Exchange, is available to all Members on an equal basis, and, as described above, is reasonably designed to encourage Members to maintain or increase their order flow, including in the form of liquidity-adding volume under the required criteria to the Exchange, which the Exchange believes would promote price discovery, enhance liquidity and market quality, and contribute to a more robust and well-balanced market ecosystem on the Exchange to the benefit of all Members and market participants.

For the reasons discussed above, the Exchange submits that the proposal satisfies the requirements of Sections 6(b)(4) and 6(b)(5) of the Act [14] in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to unfairly discriminate between customers, issuers, brokers, or dealers. As described more fully below in the Exchange's statement regarding the burden on competition, the Exchange believes that its transaction pricing is subject to significant competitive forces, and that the proposed fees and rebates described herein are appropriate to address such forces.

[7] As set forth on the Fee Schedule, ''ADAV'' means the average daily added volume calculated as the number of shares added per day, which is calculated on a monthly basis.

[8] The Exchange notes that orders with Fee Code B include orders, other than Retail Orders, that establish the NBBO.

[9] As set forth on the Fee Schedule, ''TCV'' means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply.

[10] The pricing for NBBO Setter/Joiner Tier 1 is referred to by the Exchange on the Fee Schedule under the existing description ''NBBO Setter/Joiner Tier 1'' with a Fee Code of S1 to be appended to the otherwise applicable Fee Code assigned by the Exchange on the monthly invoices for qualifying executions.

[11] 15 U.S.C. 78f.

[12] 15 U.S.C. 78f(b)(4) and (5).

[13] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[14] 15 U.S.C. 78f(b)(4) and (5).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposal will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the proposal is intended to make a minor modification to the criteria applicable to an existing tier that is intended to incentivize market participants to direct additional order flow to the Exchange, which the Exchange believes would promote price discovery and enhance liquidity and market quality on the Exchange to the benefit of all Members and market participants. The Exchange further believes that the proposal furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [15]

Intramarket Competition

As discussed above, the proposal would make a minor modification to the criteria applicable to an existing tier in a manner that is still consistent with the Exchange's overall pricing philosophy of encouraging displayed liquidity, thereby enhancing liquidity and market quality on the Exchange to the benefit of all Members, as well as enhancing the attractiveness of the Exchange as a trading venue, which the Exchange believes, in turn, would continue to encourage market participants to continue to direct order flow, or direct additional order flow, to the Exchange. Greater liquidity benefits all Members by providing more trading opportunities and encourages Members to send additional orders to the Exchange, thereby contributing to robust levels of liquidity, which benefits all market participants.

The Exchange does not believe that the proposed changes to modify the criteria applicable to NBBO Setter/Joiner Tier 1 would impose any burden on intramarket competition because such change will apply to all Members uniformly, in that the proposed rebate for such executions would remain unchanged and applicable to all qualifying Members, and the opportunity to qualify for the enhanced rebate is available to all Members. As noted above, no Members are presently achieving the criteria that is proposed to be deleted, and as such, the Exchange does not believe that the proposed elimination of such criteria will have a significant impact on any Member's trading behavior on the Exchange. As described above, the Exchange believes that the required criteria under NBBO Setter/Joiner Tier 1, as modified, remains commensurate with the corresponding rebate under such tier and are reasonably related to the enhanced liquidity and market quality that such tier is designed to promote. For the foregoing reasons, the Exchange believes the proposed changes would not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intermarket Competition

As noted above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. Members have numerous alternative venues that they may participate on and direct their order flow to, including 15 other equities exchanges and numerous alternative trading systems and other off-exchange venues. As noted above, no single registered equities exchange currently has more than approximately 16% of the total market share of executed volume of equities trading. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. Moreover, the Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates and market participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. As described above, the proposed change represents a minor modification to the criteria applicable to an existing tier that is intended to incentivize market participants to direct order flow to the Exchange through a volume-based tier, which have been widely adopted by exchanges, including the Exchange.

Additionally, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [16] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *SEC,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[17] Accordingly, the Exchange does not believe its proposed pricing change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act [18] and Rule 19b–4(f)(2) [19] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

[15] *See supra* note 12.

[16] *See supra* note 12.

[17] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSE–2006–21)).

[18] 15 U.S.C. 78s(b)(3)(A)(ii).

[19] 17 CFR 240.19b–4(f)(2).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MEMX–2023–07 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MEMX–2023–07. This file number should be included in the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Section, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MEMX–2023–07 and should be submitted on or before May 4, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–07736 Filed 4–12–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97260; File No. SR-Phlx–2023–07]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Make Permanent Certain P.M.-Settled Pilots

April 7, 2023.

On February 23, 2023, Nasdaq PHLX LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to make permanent the pilot to permit the listing and trading of options based on 1/100 the value of the Nasdaq-100 Index and the Exchange's nonstandard expirations pilot program. The proposed rule change was published for comment in the **Federal Register** on March 2, 2023.[3]

Section 19(b)(2) of the Act[4] provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is April 16, 2023.

The Commission is extending this 45-day time period. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates May 31, 2023, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR-Phlx–2023–07).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–07730 Filed 4–12–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97263; File No. SR–NASDAQ–2022–079]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Amendment No. 1 and Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 1, To Amend Rules 4702(b)(14) and (b)(15) Concerning Dynamic M–ELO Holding Periods

April 7, 2023.

On December 21, 2022, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to replace the static holding period requirements for Midpoint Extended Life Orders and Midpoint Extended Life Orders Plus Continuous Book with dynamic holding periods. The proposed rule change was published for comment in the **Federal Register** on January 10, 2023.[3] On February 22, 2023, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On March 9, 2023, the Exchange filed Amendment No.1 to the proposed rule change, which amended and superseded the proposed rule change as originally filed.[6] The

[20] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 96980 (February 24, 2023), 88 FR 13161.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 92844 (January 4, 2023), 88 FR 1438.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 96963, 88 FR 12710 (February 28, 2023).

[6] In Amendment No. 1, the Exchange (i) included additional information regarding the data used by its model, including a list of the 142 categories of

Commission received two comments on the proposal, and the Exchange submitted a response to comments when it filed Amendment No. 1.[7] The Commission is publishing this notice and order to solicit comments on the proposed rule change, as modified by Amendment No. 1, from interested persons and to institute proceedings pursuant to Section 19(b)(2)(B) of the Act[8] to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rules 4702(b)(14) and (b)(15) of the Exchange's Rulebook to replace the static holding period requirements for Midpoint Extended Life Orders and Midpoint Extended Life Orders Plus Continuous Book with dynamic holding periods. Amendment No. 1 supersedes the original filing in its entirety.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rules 4702(b)(14) and (15) of the Exchange's Rulebook to replace the static 10 millisecond holding period requirements for its Midpoint Extended Life Order (''M–ELO'') and Midpoint Extended Life Order Plus Continuous Book (''M–ELO+CB'') Order Types with dynamic holding periods (''Dynamic M–ELO and M–ELO+CB'' or collectively, ''Dynamic M–ELO'').

Background

In 2018, the Exchange introduced the M–ELO, which is a Non-Displayed Order priced at the Midpoint between the National Best Bid and Offer (''NBBO'') and which is eligible for execution only against other eligible M–ELOs and only after a minimum of one-half second passes from the time that the System accepts the order (the ''Holding Period'').[9] In 2019, the Exchange introduced the M–ELO+CB, which closely resembles the M–ELO, except that a M–ELO+CB may execute at the midpoint of the NBBO, not only against other eligible M–ELOs (and M–ELO+CBs), but also against Non-Displayed Orders with Midpoint Pegging and Midpoint Peg Post-Only Orders (''Midpoint Orders'') that rest on the Continuous Book for at least one-half second and have Trade Now enabled.[10]

When the Exchange designed M–ELO, it originally set the length of the Holding Period at one-half second because it determined that this time period would be sufficient to ensure that likeminded investors would interact only with each other, and with minimal market impacts. The Exchange believed that the longer length of the M–ELO Holding Period and its simplicity in design would provide greater protection for participants than they could achieve through competing delay mechanisms.

In 2020, however, the Exchange shortened the length of the Holding Period to 10 milliseconds.[11] The Exchange did so after studying two years of actual use and performance of M–ELOs, as well as customer feedback. That is, the Exchange came to understand that, while users of M–ELO and M–ELO+CB are less concerned with achieving rapid executions of their Orders than are other participants, they are not indifferent about the length of time in which their M–ELOs and M–ELO+CBs must wait before they are eligible for execution. Indeed, participants informed the Exchange that in certain circumstances, such as when they sought to trade symbols that on average had a lower time-to-execution than a half-second, they were reticent to enter M–ELOs or M–ELO+CBs. They indicated that the associated Holding Periods for these Order Types were longer than necessary to achieve the desired protections and that, during the residual portion of the Holding Periods, they risked losing out on favorable execution opportunities that would otherwise be available to them had they placed a non-MELO order.

Based upon this feedback, the Exchange studied the potential effects of reducing the length of the Holding Periods for both M–ELOs and M–ELO+CBs (as well as for Midpoint Orders that would execute against M–ELO+CBs). Ultimately, the Exchange determined that it could reduce the Holding Periods to 10 milliseconds without compromising the protective power that M–ELO and M–ELO+CB are intended to provide to participants and investors.[12] Thus, the Exchange determined that shortening the Holding Periods to 10 milliseconds for M–ELOs and M–ELO+CBs would increase the efficacy of the mechanism while not undermining the power of those Order Types to fulfill their underlying purpose of minimizing market impacts. At the same time, the Exchange determined

data points; (ii) described its model retraining process; (iii) added information regarding the types of modifications for which it would request Commission approval; (iv) indicated it would regularly publish data regarding M–ELO and M–ELO+CB performance and holding period changes; and (v) stated its model would constitute an established, non-discriminatory method and would operate according to pre-disclosed rules and objectives without the exercise of discretion. When it submitted Amendment No. 1, the Exchange also submitted it as a comment letter to the filing, available at: *https://www.sec.gov/comments/sr-nasdaq-2022-079/srnasdaq2022079-20159016-327215.pdf.*

[7] Comments and the Exchange's response to comments are available at: *https://www.sec.gov/comments/sr-nasdaq-2022-079/srnasdaq2022079.htm.*

[8] 15 U.S.C. 78s(b)(2)(B).

[9] *See* Securities Exchange Act Release No. 34–82825 (March 7, 2018), 83 FR 10937 (March 13, 2018) (SR–NASDAQ–2017–074) (''M–ELO Approval Order'').

[10] *See* Securities Exchange Act Release No. 34–86938 (September 11, 2019), 84 FR 48978 (September 17, 2019) (SR–NASDAQ–2019–048) (''M–ELO+CB Approval Order'').

[11] *See* Securities Exchange Act Release No. 34–88743 (April 24, 2020), 85 FR 24068 (April 30, 2020) (SR–NASDAQ–2020–011) (''M–ELO Timer Approval Order'').

[12] The Exchange examined each of its historical M–ELO executions to determine at what Midpoints of the NBBO the M–ELOs would have executed if their Holding Periods had been shorter than one-half second (500 milliseconds). After examining the historical effects of shorter Holding Periods of between 10 milliseconds and 400 milliseconds, the Exchange determined that a reduction of the M–ELO Holding Period to as short as 10 milliseconds would have caused an average impact on mark-outs of only 0.10 basis points (across all symbols). In other words, compared to the execution price of an average M–ELO with a one-half second Holding Period, the Exchange found that a M–ELO with a 10 millisecond Holding Period would have had an average post-execution impact that was only a tenth of a basis point per share—a difference in protective effect that is immaterial. *See* Nasdaq, ''The Midpoint Extended Life Order (M–ELO); M–ELO Holding Period,'' available at *https://www.nasdaq.com/articles/the-midpoint-extended-life-order-m-elo%3A-m-elo-holding-period-2020-02-13* (analyzing effects of shortened Holding Periods on M–ELO performance).

that a reduction in the Holding Periods to 10 milliseconds would dramatically add to the circumstances in which M–ELOs and M–ELO+CBs would be useful to participants. In its M–ELO Timer Approval Order, the Commission agreed with the Exchange:

The Commission notes that, with the proposed ten-millisecond Holding Period and Resting Period, M–ELOs and M–ELO+CBs would continue to be optional order types that are available to investors with longer investment time horizons, including institutional investors. The Commission also believes that the proposal could make M–ELOs and M–ELO+CBs more attractive for securities that on average have a time-to-execution of less than one-half second and, for investors who currently do not use M–ELOs and M–ELO+CBs for these securities, provide optional order types that could enhance their ability to participate effectively on the Exchange. The Commission notes that, if market participants determine that the proposal would make M–ELOs and M–ELO+CBs less attractive for their particular investment objectives, such market participants may elect to reduce or eliminate their use of these optional order types. Moreover, as noted above, the Exchange will continue to conduct real-time surveillance to monitor the use of M–ELOs and M–ELO+CBs to ensure that such usage remains appropriately tied to the intent of the order types. If, as a result of such surveillance, the Exchange determines that the shortened Holding Period does not serve its intended purpose or adversely impacts market quality, the Exchange would seek to make further recalibrations.[13]

For similar reasons and with even better potential results for participants, the Exchange now proposes to further refine the length of the Holding Periods for M–ELOs and M–ELO+CBs, this time through the application of innovative and patent pending machine learning technology.

Dynamic M–ELO

After receiving feedback from participants that even 10 millisecond Holding Periods for M–ELO and M–ELO+CB may, at times, exceed what is necessary to accomplish the underlying intent of these Order Types, the Exchange began to experiment with making further refinements to the duration of the Holding Periods. Ultimately, the Exchange concluded that shorter Holding Periods could achieve the same, if not better results for participants in terms of mark-outs, but not in all circumstances. That is, where prices of the underlying securities are stable, and not subject to imminent unfavorable changes, M–ELOs and M–ELO+CBs face lower risks of confronting spread-crossing orders, such that shorter Holding Periods could suffice to protect M–ELOs and M–ELO+CB from such orders. In periods of heightened price volatility, however, M–ELOs and M–ELO+CBs also face heightened risks, such that longer Holding Periods would continue to be beneficial in protecting M–ELOs and M–ELO+CBs from such risks. Thus, the Exchange determined that another across-the-board reduction of the static 10 millisecond Holding Periods would be sub-optimal because it could impact the performance of the M–ELO and M–ELO+CB Order Types during periods of heightened volatility.

In light of these observations, the Exchange tasked its artificial intelligence and machine learning laboratory (the ''AI Core Development Group'') to explore whether it could employ these innovative technologies to optimize the length of M–ELO and M–ELO+CB Holding Periods during various states of price volatility, and then to vary the lengths of the Holding Periods dynamically during the lifecycles of M–ELOs and M–ELO+CBs, with the objectives of improving the performance of these Order Types while also further reducing opportunity costs.

As the Exchange explains in greater depth in the attached [sic] white paper,[14] the AI Core Development Group proceeded to develop an artificial intelligence-based timer control system that will achieve these objectives.[15] The AI Core Development Group did so by using reinforcement learning techniques—machine learning paradigms which develop optimal solutions to problems over time by taking actions to solve them, generating feedback on the results of such actions, applying that feedback to direct and improve the next round of solutions, and then repeating the feedback loop until the paradigm achieves optimized solutions.

In this instance, the AI Core Development Group applied reinforcement learning techniques to a simulation of the M–ELO Book that it constructed using a representative data set from the first quarter of 2022 (the ''Training Period''). The Training Period data consisted of 380 out of the 6,257 symbols on the M–ELO Book (accounting for approximately 67 percent of M–ELO volume). The symbols chosen reflect both actively-traded and thinly-traded securities, and both low-priced and high-priced securities.

The AI Core Development Group then developed a machine learning model and applied it to the Training Period data. The Group programmed the model to value the achievement of higher fill rates or lower mark-outs than that which occurred in a historical simulation of M–ELOs and M–ELO+CBs involving the Training Period data.[16] The Group then programmed the model to seek to achieve its goals by taking one of five possible actions with respect to the duration of the Holding Periods at 30 second intervals [17] for each symbol during each trading day of the Training Period. That is, at each 30 second internal, the model evaluated market conditions for each symbol over the prior 30 second period and either kept the Holding Periods the same, increased/decreased them by 0.25 milliseconds, or increased/decreased them by 0.50 milliseconds.[18] After each decision-making round, the model utilized the results to inform its actions at the next 30 second increment.

In making its decisions, the model (again, drawing upon a combination of historical SIP and M–ELO-specific data) considered 142 categories of data points.[19] A confluence of data points

[13] M–ELO Timer Approval Order, *supra,* at 85 FR 24069.

[14] *See* Diana Kafkes et al., ''Applying Artificial Intelligence & Reinforcement Learning Methods Towards Improving Execution Outcomes,'' SSRN, October 19, 2022, available at *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4243985* (attached hereto [sic] as Exhibit 3(a)) (the ''White Paper'').

[15] Although the AI Core Development Group acknowledges that an optimal Holding Period would update with every incoming order, it determined that training a reinforcement learning model on every order would be too difficult to program and too difficult to implement given the nanosecond latency requirements of the Exchange. The Group then investigated more feasible update cadences and determined the point at which optimal outcomes were best balanced with the level of programming and implementation difficulty to be between 15 and 30 second updates. Ultimately, the Group chose a 30 second update cadence to give the model the greatest opportunity to learn between potential actions.

[16] As the White Paper explains, the Group developed a model to simulate activity on the Exchange involving M–ELOs and M–ELO+CBs during the Training Period. *See* White Paper, *supra,* at 10.

[17] *See id.*

[18] The AI Core Development Group experimented with a range of permissible Holding Period durations. Ultimately, it concluded that it could produce better outcomes for M–ELO and M–ELO+CB participants than the existing approach using Holding Periods as low as 0.25 milliseconds and as high as 2.5 milliseconds, under normal market conditions.

[19] Nasdaq attaches [sic] a full list of these data elements (attached hereto [sic] as ''*Exhibit 3(b)*''), along with an observation of the strength of the correlations that currently exist between changes to those data values and decisions the system makes to set the duration of Holding Periods at any given time. *See also* White Paper, *supra,* at 31, for a description of these features.

that correlated with an increase in volatility tended to cause the model to increase the durations of Holding Periods, including increases in the standard deviation of NBBO prices, the number of unique participants placing sell orders on M–ELO and M–ELO+CB, and the volume-weighted average of the NBBO spread. Conversely, a confluence of data points that correlated with greater price stability tended to cause the model to decrease the durations of Holding periods, such as an increase in the median and max number of shares per trade and the number of resting bids left in the M–ELO and M–ELO+CB Book.

The AI Core Development Team produced variations of its model that prioritized achievement of the lowest mark-outs, the highest fill rates, and a blend of these two objectives.[20] Through a process of learning and experimentation involving a combination of historical and simulated data, the AI Core Development Group settled on a Dynamic M–ELO model that achieved substantial simulated performance improvements for users of M–ELO and M–ELO+CB—both in terms of mark-outs and fill rates—as compared to the static 10 millisecond Holding Periods. As the White Paper explains in greater detail, Dynamic M–ELO yielded an average combined volume-weighted (simulated) improvement of 31.7 percent, including a 20.3 percent increase in fill rates and a 11.4 percent reduction in mark-outs.[21] The White Paper provides a more fulsome explanation of these improvements.[22]

Based upon these exciting results, the Exchange now proposes to amend Rule 4702(b)(14) and (15) to replace the static 10 millisecond timers applicable to M–ELO and M–ELO+CB with Dynamic M–ELO Holding Periods. Using the Exchange's proprietary and patent pending technology, the Dynamic M–ELO system will evaluate and, as it deems necessary, adjust the length of the Holding Periods for each symbol comprising M–ELOs and M–ELO+CBs (and Midpoint Orders on the Continuous Book that opt to interact with M–ELO+CBs after resting on the Book) every 30 seconds throughout the Market Hours (each such 30 second interval, a ''Change Event''). In so doing, Dynamic M–ELO will help participants to achieve a more optimized blend of the underlying purposes of the M–ELO and M–ELO+CB Order Types: protection against adverse selection (low mark-outs) without sacrificing opportunities to achieve high-quality executions (high fill rates).

A proposed M–ELO or M–ELO+CB with a Dynamic Holding Period will operate as follows. At the outset of Market Hours (approximately 9:30:00 a.m.), the Exchange will impose initial Holding Periods of 1.25 milliseconds for M–ELOs and M–ELO+CBs in all symbols. Thereafter, Holding Periods for a given symbol will become eligible to change dynamically from the initial duration beginning at 9:30:30 a.m. and then at 30 second intervals thereafter during Market Hours. The Exchange will then apply to the M–ELO or M–ELO+CB Order a Holding Period that is of the duration that prevailed at the time of entry. For example, if participant A enters a M–ELO for symbol XYZ at 9:30:25 a.m., then Holding Period for that M–ELO will be 1.25 milliseconds. If at 9:30:30:00 a.m., the System decides to lower the duration of the Holding Period by 0.50 milliseconds, and then participant B enters a M–ELO for symbol XYZ at 9:30:45 a.m., then the System will assign a 0.75 millisecond Holding Period to participant B's M–ELO. To be clear, the System will determine Dynamic M–ELO Holding Periods independently for M–ELOs and M–ELO+CBs in each symbol.

During normal market conditions, the range of potential Holding Period durations for M–ELOs and M–ELO+CBs will be between 0.25–2.50 milliseconds, with the Holding Period duration being eligible to change by increments of either 0.25 or 0.50 milliseconds at each Change Event. Thus, if the Holding Period for a M–ELO in symbol XYZ is set at 0.75 milliseconds at 2:22:11 p.m., and at 2:22:41 p.m., the System determines to increase the duration of the Holding Period, it may do so only by 0.25 or 0.50 milliseconds during that event.

When a Change Event occurs, and the System determines to adjust the duration of a Holding Period for a symbol, that adjustment will apply, not only to all M–ELOs and M–ELO+CBs for that symbol entered within the 30 second period after the Change Event occurs, but also to M–ELOs and M–ELO+CBs entered prior to the Change Event with unexpired Holding Periods (with applicability retroactive to the time of Order acceptance). Thus, if a participant enters a M–ELO in symbol XYZ at 1:14:299 p.m., and the prevailing Holding Period applicable to that M–ELO is 2 milliseconds, and at 1:14:30 p.m., the System modifies the Holding Period to be 1.5 milliseconds, then the M–ELO will become eligible to execute at 1:14:3005 p.m. This is the case because the M–ELO will have already expended 1 millisecond of its Holding Period as of the time of the Change Event; thereafter, the M–ELO will need to rest only another 0.5 milliseconds to become eligible to execute under the new 1.5 millisecond Holding Period (as measured from 1:14:299 p.m.). This last feature ensures that the M–ELO Book maintains time priority among M–ELOs and M–ELO+CBs in a dynamic environment. That is, it ensures that no M–ELO or M–ELO+CB with an unexpired Holding Period at the time of a Change Event will end up becoming eligible to execute later than a M–ELO entered after the Change Event which has a shorter Holding Period applicable to it.

If at any time, the System detects extraordinary instability in a symbol, then the System will activate a ''stability protection mechanism'' to provide an extra layer of protection to M–ELO and M–ELO users from the heightened risks of adverse selection that exists during such periods of instability.[23] The stability protection mechanism will override the prevailing Holding Periods for M–ELOs and M–ELO+CBs in a symbol experiencing extraordinary instability and immediately increase the duration of those Holding Periods to 12 milliseconds for a period of 750 milliseconds. The System may activate the stability protection mechanism even between Change Events. The System will evaluate, at each NBBO update, whether market conditions remain extraordinarily unstable and, if so, it will restart the 750 millisecond Stability Protected Period and maintain the 12

[20] The AI Core Development Group also applied to the model a paradigm called ''retraining'' to combat the degradation of model performance that can otherwise occur as the reference data it uses for initial comparison becomes stale. Finally, the AI Core Development group added a stability protection mechanism to the model to provide maximum production to participants in the event that the model observes extraordinary levels of instability in the National Best Bid and Offer during the prior three seconds as compared to reference data. When the model detects such instability, it is programmed to increase the length of the Holding Period to 12 milliseconds for a period of 750 milliseconds.

[21] *See* White Paper, *supra,* at 22.

[22] *See id.*

[23] For purposes of this Rule, the System determines that ''extraordinary instability'' for a symbol exists through observations it makes following every change in the NBBO for that symbol that occurs during the trading day. When the NBBO changes, the System looks back at the prior three seconds of trading and measures the difference between the highest and the lowest NBBO midpoint values that occurred during that period, and then it compares that measurement to a threshold value for the symbol. The System concludes that extraordinary instability exists for a symbol if the measurement exceeds the threshold value. The threshold value for a symbol, in turn, is the difference between the highest and the lowest NBBO midpoint values for the symbol that, if applied to its trading activity during the prior trading day, would have caused the System to deem trading in the symbol to be extraordinarily unstable for as close to one percent of that day as possible.

millisecond Holding Period until conditions stabilize. Once the System determines that market conditions have stabilized (*i.e.,* all measurements for the symbol are at or below the threshold value throughout the duration of the prevailing Stability Protected Period), the System will revert the duration of the Holding Periods to that which prevailed as of the Change Event that occurred immediately prior to the activation of the stability protection mechanism or, if the stability protection mechanism was active when a Change Event occurred, to the duration selected at the immediately preceding Change Event. The System will then proceed to reevaluate the duration of the Holding Periods as per the regular schedule of Change Events.

The following is an illustration of the operation of the stability protection mechanism. At 11:10:04 a.m., the prevailing Holding Period for M–ELOs in symbol XYZ is 1.5 milliseconds. At the same time, the NBBO for symbol XYZ updates. The System looks back at the prior three seconds of trading in symbol XYZ and finds that during that period, the highest observed NBBO midpoint was $10.05, and the lowest was $10.00, such that the difference between these two values is a range of $0.05. The System then looks back at trading behavior for symbol XYZ during the immediately preceding trading day. In doing so, the System calculates the value of the threshold that would have caused the symbol to be deemed extraordinarily unstable for one percent of the trading day; the System determines that this threshold value is a range of $0.03. The System then compares the $0.03 threshold to its measurement of the prior three seconds of NBBO changes ($0.05), and concludes that over these past three seconds, the symbol is extraordinarily unstable. Accordingly, the System activates the stability protection mechanism and the Holding Period for M–ELOs in symbol XYZ immediately increases to 12 milliseconds for a period of 750 milliseconds. However, 5 milliseconds after the Stability Protection Period commences, the NBBO updates again, thus prompting the System to repeat its assessment of the stability of the symbol in light of the update. This reassessment reveals that the symbol remains unstable, such that a new Stability Protection Period of 750 milliseconds begins at that time (overriding the pre-existing Period). Over the course of this new Stability Protection Period, the NBBO shifts two more times, but each of the ensuing reassessments indicate that the NBBO ranges for the symbol have fallen below the $0.03 threshold. The Stability Protection Period elapses 750 milliseconds after it began with the symbol remaining stable. Thus, the Holding Period reverts to 1.5 milliseconds.

If the Exchange halts trading in a symbol, then upon resumption of trading, any new M–ELO or M–ELO+CB in that symbol and any pending M–ELO or M–ELO+CB in that symbol with an unexpired Holding Period will be subject to a new 12 milliseconds Holding Period (running from the time when trading resumes) until the next scheduled Change Event, at which point the System may determine to adjust that Holding Period to a duration within the range applicable under normal market conditions.[24] If, however, the System determines that extraordinary instability in the symbol exists, it will instead determine to activate the stability protection mechanism and maintain the duration of the Holding Period at 12 milliseconds for another 750 milliseconds. This design will help to ensure that M–ELOs and M–ELO+CBs receive added protection coming out of halt conditions.[25]

The Exchange notes that same dynamic process described above will also apply to and govern the time periods during which Midpoint Orders on the Continuous Book must rest before they will become eligible to interact with M–ELO+CBs (provided that participants have opted for their Midpoint Orders to interact with M–ELO+CBs). Thus, the same Holding Period duration that the System sets for a M–ELO+CB in a symbol during Regular Market Hours will also be the length of time that a Midpoint Order must rest on the Continuous Book must rest before it may interact with a M–ELO+CB.

Apart from these impacts of Dynamic Holding Periods, M–ELOs and M–ELO+CBs will continue to behave as they do now in all respects, and as set forth in Rules 4702(b)(14) and (15).

It is important to note that within the parameters discussed herein and in the White Paper, the Exchange will continue to re-train Dynamic M–ELO and M–ELO+CB on a weekly basis (outside of market hours) so that the model will continue to learn from and act upon the basis of more recent SIP and M–ELO book data sets, and further improve its performance over time. The retraining process should not result in dramatic or unpredictable changes to the behavior of Dynamic M–ELO. The retraining process will not retrain the model from scratch each week; rather, it will retain the model's existing data inputs, knowledge base, and objectives—all without alteration. Retraining will result in new behaviors only as needed to address new scenarios that the model did not confront previously, and even then, only in a manner designed to further optimize outcomes, *i.e.,* reduce mark-outs or increase fill rates. If the System assesses that a retrained model would be worse than the existing model in achieving its objectives, then the System will continue to use the existing model and discard the retrained model. This retraining process is a standard and accepted practice for use of deep learning models; it helps to ensure that deep learning models not only work well, but that they continue to work well in dynamic circumstances.[26]

The Exchange will not modify the underlying structure of Dynamic M–ELO and M–ELO+CB without first obtaining the Commission's approval to do so, including modifications to the data elements the model considers in making decisions about Holding Period durations, the conditions under which the model may adjust the duration of Holding Periods, the frequency with which the model my adjust the Holding Periods, the range of Holding Period durations available to M–ELOs and M–ELO+CBs, the increments by which Holding Periods may change at any given Change Event, and the procedures for triggering, maintaining, and ending 12 millisecond Holding Periods during times of extraordinary instability.[27]

[24] Prior to commencement of a new 12 millisecond Holding Period for a new or pending M–ELO or M–ELO+CB following a Halt, the System will first determine whether the M–ELO or M–ELO+CB is or remains eligible for execution. That is, the Holding Period will commence only if, upon commencement of trading following the Halt, the midpoint price for the Order is within the limit set by the participant. If not, the System will hold the Order until the midpoint falls within the limit set by the participant, at which time the 12 millisecond Holding Period will commence.

[25] Also as a safeguard, the System will apply a default Holding Period of 12 milliseconds to a M–ELO or M–ELO+CB if ever it fails to receive a signal during a Change Event as to whether the System should adjust or maintain the duration of the prevailing Holding Period. The System will continue to apply the default 12 millisecond Holding Period until the next Change Event where the signal is restored and the System is able to act dynamically again.

[26] During periods where the model is not undergoing retraining, the System will behave predictably from day to day, such that its decisions when presented with given set of facts and circumstances in a given security on day 1 should be the same as they would be on day 2.

[27] In addition to the proposed changes described above, the Exchange proposes to delete an extraneous reference in Rule 4702(b)(15) to M–ELO+CB being eligible to execute against a Midpoint Order on the Continuous Book if the Continuous Book order has the ''Midpoint'' Trade Now Attribute enabled. In a prior filing, the

Although the Exchange will seek Commission approval prior to changing any of the data elements that the model considers, the Exchange will not seek Commission approval prior to retraining the model to adjust the weighting it applies to those data elements.

To aid investors in understanding and evaluating Dynamic M–ELO, Nasdaq will continue to publish weekly and monthly transparency statistics on Nasdaqtrader.com, as it does now, about the performance of its M–ELOs and M–ELO+CBs, including statistics listing the weekly numbers of shares and trades in M–ELOs by symbol, weekly aggregated M–ELO share and trade data, and monthly aggregated block data.[28] Nasdaq also will continue to disclose monthly data on Nasdaq.com, as it does now (the M–ELO Monthly Report), about M–ELO and M–ELO+CB mark-outs (quote stability by time horizon) and fill rates.[29] Moreover, Nasdaq will add statistics to the M–ELO Monthly Report about how frequently, on average, the System changes Holding Period durations for the top decile, median, and bottom decile of symbols, as measured by monthly M–ELO and M–ELO+CB trading volumes. Nasdaq will retain copies of each historical iteration of its models as part of its books and records, and make them available to the Commission upon request, should it wish to examine them to understand how the model changes over time. Furthermore, Nasdaq will publish an equity trader alert in advance of deploying a retrained version of Dynamic M–ELO whenever Nasdaq has reason to anticipate that the retrained version will produce results that differ materially from the prior version, *i.e.,* a projected change in mark-outs or fill-rates of 10% or more in either direction.

Implementation

The Exchange intends to make the proposed change effective for M–ELOs and M–ELO+CBs in the Second or Third Quarter of 2023, but that time frame is subject to change. The Exchange will publish a Trader Alert in advance of making the proposed change effective.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[30] in general, and furthers the objectives of Section 6(b)(5) of the Act,[31] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by allowing for more widespread use of M–ELOs and M–ELO+CBs.

When the Commission approved the M–ELO and the M–ELO+CB, it determined that these Order Types are consistent with the Act because they ''could create additional and more efficient trading opportunities on the Exchange for investors with longer investment time horizons, including institutional investors, and could provide these investors with an ability to limit the information leakage and the market impact that could result from their orders.'' [32] Nothing about the Exchange's proposal should cause the Commission to revisit or rethink this determination. Indeed, the proposal will not alter the fundamental design of these Order Types, the manner in which they operate, or their effects.

Even with Dynamic M–ELO Holding Periods, M–ELOs and M–ELO+CBs will continue to provide their users with protection against information leakage and adverse selection—and they will do so at levels which are substantially undiminished from that which they provide now.[33]

At the same time, however, the proposal will benefit market participants and investors by reducing the opportunity costs of utilizing M–ELOs and M–ELO+CBs. The proposal, in other words, will re-calibrate the lengths of the Holding Periods so that M–ELOs and M–ELO+CBs will operate in the ''Goldilocks'' zone—their Holding Periods will not be so short as to render them unable to provide meaningful protections against information leakage and adverse selection, but the Holding Periods also will not be too long so as to cause participants and investors to miss out on favorable execution opportunities. Nasdaq believes the proposal will render M–ELOs and M–ELO+CBs more useful and attractive to market participants and investors, and this increased utility and attractiveness, in turn, will spur an increase in M–ELO and M–ELO+CB use cases on the Exchange, both from new and existing users of M–ELOs and M–ELO+CBs. Ultimately, the proposal should enhance market quality by increasing opportunities for midpoint executions on the Exchange.

As Nasdaq explained above, the proposal will operate within strict, well-defined, and transparent parameters. Although it will undergo weekly retraining (outside of market hours), such retraining will aim to improve the performance of the model in achieving its twin objectives; retraining will not alter the inputs, objectives, or basic design parameters of Dynamic M–ELO without prior Commission approval.[34] Moreover, the Exchange will not deploy a retrained model if it fails to achieve performance improvements. To aid investors in evaluating Dynamic M–ELO, the Exchange will publish statistics about its performance, including as to mark-outs and fill rates, as well as statistics about how frequently the System changes Holding Period durations. To further facilitate accountability, the Exchange will retain each historical iteration of its model as part of its books and records, and make such information available to the Commission, upon request. The Exchange will also publish equity trader alerts whenever retraining will result in a performance change of 10% or more.

Nasdaq notes that the twin objectives it prescribes for the model involve the absolute values of mark-outs and fill rates; they are not designed to further the performance of any participant or any category of participant. Thus, Nasdaq believes the model is objective and designed to avoid bias and discrimination.

The Exchange notes that use of Dynamic M–ELOs and M–ELO+CBs remains voluntary for all market participants. Accordingly, if any market participant feels that the dynamic Holding Periods are still too long or too short or because competing venues offer more attractive delay mechanisms, then

Exchange folded the concept of ''Midpoint Trade Now'' into the general ''Trade Now'' Attribute. *See* Securities Exchange Act Release No. 34–92180 (June 15, 2021), 86 FR 33420 (June 24, 2021)(SR–NASDAQ–2021–044).

[28] *See http://www.nasdaqtrader.com/Trader.aspx?id=MELOSymbolData.*

[29] *See, e.g., https://www.nasdaq.com/docs/M-ELO-Monthly-Report.* Nasdaq understands that current users of M–ELO and M–ELO independently monitor the performance of these Order Types. Nasdaq often receives feedback from such users about M–ELO and M–ELO+CB performance, which Nasdaq then factors into decisions about improvements and enhancements. Nasdaq expects that this feedback loop will continue after implementation of Dynamic M–ELO.

[30] 15 U.S.C. 78f(b).

[31] 15 U.S.C. 78f(b)(5).

[32] M–ELO Approval Order, *supra* 83 FR at 10938–39; M–ELO+CB Approval Order, *supra,* 84 FR at 48980.

[33] *See* note 12, *supra.*

[34] As discussed above, Nasdaq will not seek Commission approval prior to allowing the model, as part of its re-training process, to vary the weighting of the data elements it ingests. Nasdaq believes this is appropriate because such variance will only occur to the extent that it will improve the model's performance with respect to pre-defined objectives. Nasdaq will alert traders if the retraining process would result in substantial performance changes, and it will also publish statistics to help participants to assess performance themselves. Moreover, Nasdaq will retain historical iterations of its models for the Commission's review, should it wish to examine how these models have changed over time.

the participants are free to pursue other trading strategies or utilize other trading venues. They need not utilize Dynamic M–ELOs or M–ELO+CBs.

Furthermore, the design of Dynamic-MELO would constitute an ''established, non-discretionary'' method that is consistent with the definition of an exchange, as set forth in SEC Rule 3b–16.[35] The Commission stated as follows when it adopted Rule 3b–16:

> A system uses established non-discretionary methods either by providing a trading facility or by setting rules governing trading among subscribers. The Commission intends for ''established, non-discretionary methods'' to include any methods that dictate the terms of trading among the multiple buyers and sellers entering orders into the system. Such methods include those that set procedures or priorities under which open terms of a trade may be determined. For example, traditional exchanges' rules of priority, parity, and precedence are ''established non-discretionary methods,'' as are the trading algorithms of electronic systems. Similarly, systems that determine the trading price at some designated future date on the basis of pre-established criteria (such as the weighted average trading price for the security on the specified date in a specified market or markets) are using established, non-discretionary methods.[36]

Nothing in the Reg. ATS Adopting Release or in any of its illustrative examples suggests that Dynamic M–ELO would constitute an exercise of discretionary behavior. Dynamic M–ELO will handle and execute Orders according to published, pre-determined rules that are disclosed to the public and which provide reasonable notice of how the Order Type will behave.[37] To the extent that the design of the System permits variation in the Holding Periods for such Orders, it does so by design. The range of potential variations, the objectives that such variations are intended to achieve, and the factors that determine when such variations may occur are also predetermined and set forth in the Exchange's Rules or otherwise disclosed to the public. The mere fact that the System may apply different weights over time to the factors it uses to determine whether and by how much to vary a Holding Period does not mean that the System will act with discretion in the same sense that a human being could be said to be exercise independent judgment when deciding whether and how to handle an order.[38] Even when the System makes decisions about changing the Holding Periods, the System will operate pursuant to a mathematical algorithm from which it cannot deviate—an algorithm that is programmed to achieve pre-defined and pre-disclosed objectives.[39]

Finally, the Exchange notes that it will continue to conduct real-time surveillance to monitor the use of M–ELOs and M–ELO+CBs to ensure that such usage remains appropriately tied to the intent of the Order Types. If, as a result of such surveillance, the Exchange determines that the Dynamic M–ELO Holding Periods do not serve their intended purposes, or adversely impact market quality, then the Exchange will seek to make further re-calibrations.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes that this proposal will promote the competitiveness of the Exchange by rendering its M–ELO and M–ELO+CB Order Types more attractive to participants.

The Exchange adopted the M–ELO and M–ELO+CB as pro-competitive measures intended to increase participation on the Exchange by allowing certain market participants that may currently be underserved on regulated exchanges to compete based on elements other than speed. The proposed change continues to achieve this purpose. With Dynamic M–ELO Holding Periods, both M–ELOs and M–ELO+CBs will afford their users with a level of protection from information leakage and adverse selection that is better from what is achievable at present.[40] At the same time, the Dynamic Holding Periods will increase opportunities to interact with other like-minded investors with longer time horizons while also lowering the opportunity costs for participants that utilize M–ELOs and M–ELO+CBs, particularly for securities that trade within the ''Goldilocks'' zone. In sum, the proposed changes will not burden competition, but instead may promote competition for liquidity in M–ELOs and M–ELO+CBs by broadening the circumstances in which market participants may find such Orders to be useful. With the proposed changes, market participants will be more likely to determine that the benefits of entering M–ELOs and M–ELO+CBs outweigh the risks of doing so.

The proposed change will not place a burden on competition among market

[35] *See* 17 CFR 240.3b–16(a)(2) (''(a) An organization, association, or group of persons shall be considered to constitute, maintain, or provide 'a market place or facilities for bringing together purchasers and sellers of securities or for otherwise performing with respect to securities the functions commonly performed by a stock exchange,' as those terms are used in section 3(a)(1) of the Act, (15 U.S.C. 78c(a)(1)), if such organization, association, or group of persons: (1) Brings together the orders for securities of multiple buyers and sellers; and (2) Uses established, non-discretionary methods (whether by providing a trading facility or by setting rules) under which such orders interact with each other, and the buyers and sellers entering such orders agree to the terms of a trade.'').

[36] *See* Securities Exchange Act Release No. 40760 (December 8, 1998), 63 FR 70844, 70850 (December 22, 1998).

[37] *See id*. at 70900 (''an essential indication of the non-discretionary status of rules and procedures is that those rules and procedures are communicated to the systems users'' and ''[t]hus, participants have an expectation regarding the manner of execution—that is, if an order is entered, it will be executed in accordance with those procedures and not at the discretion of a counterparty or intermediary.'').

[38] *Cf. id*. at 70851 (explaining that a traditional block trading desk is an example of a system that does not use established, non-discretionary methods because the operators of such desks do not act according to fixed procedures known to their customers, but instead shop orders around for potential counterparties and make their own determinations as to whether and how to execute block orders, including by sometimes deciding to take a proprietary position in part of the block order).

[39] *See id*. at 80755 (describing an example of a system that would be non-discretionary in nature: ''System I permits participants to enter a range of ranked contingent buy and sell orders at which they are willing to trade securities. These orders are matched based on a mathematical algorithm whose priorities are designed to achieve the participants' objectives. System I does not display orders to any participants. System I is included under Rule 3b–16.''); *see also* Securities Exchange Act Release No. 34–89686 (August 20, 2020), 85 FR 54438, at 54445, n.92 (September 1, 2020) (Order approving SR–IEX–2019–15) (rejecting argument that IEX's D-Limit order time is an exercise of discretion because ''D-Limit orders will not allow IEX to exercise any discretion on any particular order by deviating from the CQI and D-Limit functionality, which is hardcoded in the IEX rulebook.''; Securities Exchange Act Release No. 34–78101 (June 17, 2016), 81 FR 41141, at 41153(June 17, 2016) (Order approving IEX Form 1 and D-Peg Order Type) (''the Commission does not believe that the hardcoded conditionality of the IEX proposed ''discretionary'' peg order type provides IEX with actual discretion or the ability to exercise individualized judgment when executing an order. Rather, if IEX's fixed formula determines the quote to be stable, the discretionary peg order can execute up to the midpoint; if it does not deem the quote to be stable, then it will hold the order to its pegged price. As such, IEX would not exercise discretion over the routing and execution of a resting order''). Nasdaq does not believe that it is necessary to codify its mathematical formula for Dynamic M–ELO in its Rules because Nasdaq has disclosed sufficient information in its Rules and in its filing to inform the public as to the possible and expected behaviors associated with Dynamic M–ELO, as well as a means for the Commission and/or investors to verify whether Dynamic M–ELO is performing appropriately. Much as the Commission does not require an exchange to codify the source code it uses to effectuate other behaviors or actions that it explains in its Rules, including the behaviors of other complex Order Types, there is no basis to require codification of the Dynamic M–ELO formula in this instance.

[40] *See* White Paper, *supra*.

venues, as any market may adopt an order type that operates similarly to a M–ELO or a M–ELO+CB with Dynamic M–ELO Holding Periods.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Proceedings To Determine Whether To Approve or Disapprove SR–NASDAQ–2022–079, as Modified by Amendment No. 1, and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act [41] to determine whether the proposed rule change, as modified by Amendment No.1, should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change and the comments received thereon. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, the Commission seeks and encourages interested persons to provide additional comment on the proposed rule change to inform the Commission's analysis of whether to approve or disapprove the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,[42] the Commission is providing notice of the grounds for possible disapproval under consideration. As noted above, the Commission received two comments on the proposal and the Exchange simultaneously filed a response to comments along with Amendment No. 1.[43] Of note, both commenters assert that the Exchange must provide additional information about how it determines the Dynamic Holding Periods proposed herein.[44] One of these commenters states that ''as a threshold question, how can the public 'provide meaningful comment on the proposal' without knowing what all the categories and parameters are.'' [45] This commenter also states that it is unclear under what circumstances the Exchange believes it would need to file a proposed rule change should the machine learning model alter its methods or functionalities, specifically citing the proposed retraining of the artificial intelligence based timer control system.[46] This commenter also questions whether the proposed rule change provides sufficient information to determine whether (i) it is not unfairly discriminatory and (ii) will not place a burden on competition among market venues.[47]

Nasdaq replied to these comments with its own comment letter and by filing Amendment No. 1. Nasdaq states, among other things, that it is not necessary to describe precisely how its system will react in each and every circumstance it will confront in the market as long as the choices that the system can make are bounded and its range of behaviors are understood and reasonably predictable, which it asserts is ''indeed the case for Dynamic M–ELO.'' [48] Nasdaq also submitted the full list of these data elements as both an Appendix A to its response to comments and new Exhibit 3B to the proposal in Amendment No. 1. Nasdaq also states that:

> Nasdaq is clear that it will seek approval prior to altering the data inputs that the system ingests for decision-making purposes, but not for changes to the relative weighting that the system applies to these data elements. Nasdaq also will seek Commission approval prior to altering the twin objectives of Dynamic M–ELO or making changes to its fundamental operating parameters, such as changes to the permissible range of Holding Periods, to the permissible change increments for a Holding Period at any given Change Event, to the frequency with which Change Events may occur, to the procedures for triggering, maintaining, and ending 12 millisecond Holding Periods during times of extraordinary instability.[49]

The Commission is instituting proceedings to allow for additional analysis of, and input from commenters with respect to, the consistency of the proposal, as modified by Amendment No. 1, with Sections 6(b)(5) [50] and 6(b)(8) of the Act.[51] Section 6(b)(5) of the Act requires that the rules of a national securities exchange be designed, among other things, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. Section 6(b)(8) of the Act requires that the rules of a national securities exchange not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal, as modified by Amendment No. 1. In particular, the Commission invites the written views of interested persons concerning whether the proposal, as modified by Amendment No. 1, is consistent with Sections 6(b)(5) and 6(b)(8), or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request for an opportunity to make an oral presentation.[52]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal, as modified by Amendment No. 1, should be approved or disapproved by May 4, 2023. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by May 18, 2023.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or

[41] 15 U.S.C. 78s(b)(2)(B).

[42] *Id.*

[43] *See* supra note 6.

[44] *See* Letters from Joseph Saluzzi, Partner, Themis Trading LLC, to Vanessa Countryman, Secretary, Commission, dated January 25, 2023, at 2 (''Nasdaq should be required to reveal all of the specifics behind their dynamic holding period formula so others can evaluate how it works and decide if they would like to have Nasdaq apply the logic to their orders.''); and R. T. Leuchtkafer to Vanessa Countryman, Secretary, Commission, dated January 31, 2023, at 1–2 (''Leuchtkafer Letter'').

[45] *See* Leuchtkafter Letter, at 1.

[46] *See* id., at 2 (stating that ''it's not at all clear under exactly what circumstances Nasdaq will seek approval for a change.'').

[47] *See id.,* at 2–3.

[48] *See* Letter from Brett Kitt, Associate Vice President and Principal Associate General Counsel, Nasdaq, Inc., to Vanessa Countryman, Secretary, Commission, dated March 9, 2023, at 2 (''Nasdaq Letter'').

[49] *See* Nasdaq Letter at 3.

[50] 15 U.S.C. 78f(b)(5).

[51] 15 U.S.C. 78f(b)(8).

[52] Section 19(b)(2) of the Act, as amended by the Securities Act Amendments of 1975, Public Law 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

• Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2022–079 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Numbers SR–NASDAQ–2022–079. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of these filings also will be available for inspection and copying at the principal office of the Exchange.

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2022–079 and should be submitted on or before May 4, 2023. Rebuttal comments should be submitted by May 18, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[53]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–07733 Filed 4–12–23; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97266; File No. SR–BOX–2023–10]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule on the BOX Options Market LLC Facility To Establish a New Qualified Contingent Cross (''QCC'') Growth Rebate

April 7, 2023.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 31, 2023, BOX Exchange LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A)(ii) of the Act,[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend the Fee Schedule to establish a new Qualified Contingent Cross (''QCC'') Growth Rebate on the BOX Options Market LLC (''BOX'') options facility. While changes to the fee schedule pursuant to this proposal will be effective upon filing, the changes will become operative on April 3, 2023. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at *https://rules.boxexchange.com/rulefilings.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule for trading on BOX to establish a new Qualified Contingent Cross (''QCC'') Growth Rebate.

Currently, BOX assesses $0.20 per contract to Broker Dealers and Market Makers for both the Agency Order and contra order of a QCC transaction. Public Customers and Professional Customers are not assessed a QCC Transaction Fee. Further, rebates are paid on all qualifying orders pursuant to Section IV.D.1 of the BOX Fee Schedule. Specifically, a QCC Rebate is paid to the Participant that entered the order into the BOX system when at least one party to the QCC transaction is a Broker Dealer or Market Maker. The Participant receives a per contract rebate on QCC transactions according to the tier achieved. Volume thresholds will be calculated on a monthly basis by totaling the Participant's QCC Agency Order volume on BOX. The Exchange notes that the QCC Rebate is intended to incentivize the sending of more QCC Orders to BOX.

The QCC Rebate tier structure is as follows:

Tier	QCC Agency order volume on BOX (per month)	Rebate 1 (per contract)	Rebate 2 (per contract)
1	0 to 1,499,999 contracts	($0.14)	($0.22)
2	1,500,000 to 2,499,999 contracts	(0.16)	(0.24)
3	2,500,000 to 3,499,999 contracts	(0.16)	(0.25)

[53] 17 CFR 200.30–3(a)(12), (57).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

Tier	QCC Agency order volume on BOX (per month)	Rebate 1 (per contract)	Rebate 2 (per contract)
4	3,500,000+ contracts	(0.17)	(0.27)

The Exchange now proposes to establish Section IV.D.1.b., QCC Growth Rebate.[5] Specifically, the Exchange proposes that if a Participant's QCC Agency Order volume on BOX achieves Tier 3 of the QCC Rebate in the month AND the Participant's total QCC volume combined with total QOO volume exceeds 11 million contracts per month, then the Participant will qualify for the rebates in Tier 4 of the QCC Rebate (''QCC Growth Rebate qualifications''). Strategy QOO Orders and Strategy QCC Orders will not be counted toward the QCC Growth rebate volume. Further, the Exchange proposes that Participants are entitled to one QCC Rebate in a given month, which would be the greater of the QCC Rebate in Section (a) or the QCC Growth Rebate detailed in Section (b), but not both.

The Exchange notes that the proposed change is a competitive response as a similar QCC Growth Rebate currently exists at another options exchange.[6] Further, the Exchange believes that the proposal will encourage Participants to send increased QCC and QOO order flow to BOX in order to achieve a higher rebate.

Lastly, the Exchange is proposing to amend Section IV.D.2 to make changes that reflect the addition of Section IV.D.1.a. and Section IV.D.1.b. to the BOX Fee Schedule.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act, in general, and Section 6(b)(4) and 6(b)(5) of the Act,[7] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among BOX Participants and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange's proposal to establish a new QCC Growth Rebate is reasonable because this rebate will provide additional incentives for BOX Participants to engage in substantial amounts of trading activity which would serve to bring additional open outcry liquidity to the Trading Floor and additional QCC order flow to BOX. This incentive may also encourage Participants to begin sending such order flow to BOX for the opportunity to earn this rebate.

As discussed above, the Exchange notes that a similar QCC Growth Rebate currently exists at another exchange. At Phlx, in order to qualify for the QCC Growth Tier Rebate, a member's or member organization's total floor transaction, and electronic QCC Orders and Floor QCC Orders volume must exceed 12,500,000 contracts in a given month. In addition to the aforementioned criteria, the member's or member organization's respective Phlx House Account must execute QCC transaction volume of 250,000 or more contracts in excess of the member's or member organization's QCC transaction volume in January 2023. For members or member organizations with no QCC transaction volume in January 2023, the QCC transaction volume, in their respective Phlx House Account, must be 250,000 or more contracts in a given month. Additionally, Phlx offers an alternative to qualify for the QCC Growth Tier Rebate. Specifically, if a member's or member organization's Open Outcry Floor Transaction volume in a given month exceeds 500,000 contracts and a member's or member organization's respective Phlx House Account executes QCC transaction volume of 2,500,000 or more contracts in excess of the member's or member organization's QCC transaction volume in January 2023, the member or member organization will qualify for the QCC Growth Tier Rebate. BOX is proposing a similar structure in that a BOX Participant will qualify for the QCC Growth Rebate if the Participant achieves Tier 3 of the current QCC Rebate structure (QCC Agency Order volume on BOX is 2,500,000 to 3,499,999 contracts in a given month) AND the Participant's QCC and QOO volume exceeds 11 million contracts in the given month. The Exchange believes that the proposed QCC Growth Rebate qualifications are reasonable because they offer Participants an additional opportunity to achieve a higher QCC rebate. Additionally, the Exchange's proposal to establish a new QCC Growth Rebate is equitable and not unfairly discriminatory because any Participant may qualify for this rebate.[8] All BOX Participants may enter order flow to obtain a QCC Growth Rebate.

The Exchange believes the proposal will create an incentive for Participants to bring liquidity to BOX—both electronically and on the Trading Floor. The Exchange believes that if the proposed incentive is effective, then an ensuing increase in trading activity on BOX will improve the quality of the market overall to the benefit of all market participants. Further, to the extent this proposal attracts new Participant volume to BOX, all market participants should benefit through increased liquidity and more trading opportunities. The Exchange believes this proposal is designed to increase participation on BOX and reward those Participants for the unique role they play in ensuring a robust market.

The Exchange believes that combining a Participant's total QCC and QOO volume to count toward the QCC Growth Rebate is not a novel idea. On NYSE American LLC (''NYSE American''), Floor Brokers qualify for rebates by achieving billable manual volume of combined manual transactions and QCC transactions.[9] Similarly, the Exchange proposes to combine a Participant's QOO and QCC volume in order to qualify for the proposed QCC Growth Rebate. As discussed herein, the Exchange believes this structure will incentivize Participants to direct order flow to BOX—both electronically and on the BOX Trading Floor—in order to take advantage of the proposed rebate, thus resulting in increased liquidity and trading opportunities to the benefit of all market participants.

The Exchange's exclusion of QCC and QOO strategy transactions is reasonable as Strategy QCC transactions are not currently assessed a fee and Strategy QOO transactions are subject to the fee cap and rebates detailed in Section V.D of the BOX Fee Schedule. The Exchange

[5] Additionally, the Exchange proposes to retitle the current QCC Rebate as Section IV.D.1.a.

[6] *See* Nasdaq Phlx LLC (''Phlx'') Pricing Schedule *and* Securities Exchange Act Release No. 96990 (February 27, 2023), 88 FR 13477 (March 3, 2023)(SR–PHLX–2023–06).

[7] 15 U.S.C. 78f(b)(4) and (5).

[8] The Exchange notes that all BOX Participants may transact an options business electronically or on the BOX Trading Floor with a registered Trading Permit. BOX Participants may transact business on the Trading Floor through a Floor Broker.

[9] *See* NYSE American Fee Schedule. The Exchange notes that while the concept of combining electronic and floor volume is not novel, the details of NYSE American's Floor Broker rebate program differ from what BOX is proposing herein. Specifically, the volume qualifications and the per contract rebates on NYSE American are different from BOX's proposal.

also notes that another exchange excludes strategy transactions from their respective QCC Growth Rebate.[10] Further, the exclusion of strategy transactions from the QCC Growth Rebate is equitable and not unfairly discriminatory as this exclusion will be uniformly applied to all Participant types.

The Exchange believes this proposal to pay Participants the greater of the QCC Rebate in proposed Section IV.D.1.a or the QCC Growth Rebate in proposed Section IV.D.1.b in a given month, but not both QCC Rebates, is reasonable, equitable, and not unfairly discriminatory because BOX is simply offering another way for Participants to qualify for rebates that already exist today and BOX would uniformly only pay the greater of the two QCC Rebates.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The proposal does not impose an undue burden on inter-market competition. The Exchange believes its proposal remains competitive with other options markets and will offer market participants with another choice of where to transact its business. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges. Because competitors are free to modify their own fees and rebates in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

The proposed changes do not impose an undue burden on intra-market competition. In terms of intra-market competition, the Exchange does not believe that its proposals will place any category of market participant at a competitive disadvantage. The Exchange believes that the proposed QCC Growth Rebate will encourage market participants to send a greater amount of QCC orders and QOO Orders to BOX for execution in order to obtain greater rebates and lower their costs. Further, the proposed QCC Growth Rebate should incentivize a greater amount of floor transactions on BOX, thereby allowing BOX to compete more effectively with other options floor models. The Exchange again notes that any market participant may send an order to a BOX Floor Broker for execution on BOX's Trading Floor. The Exchange believes that the additional liquidity will enhance the quality of BOX's market and increase certain trading opportunities on BOX's Trading Floor.

The Exchange's proposal to establish the QCC Growth Rebate does not impose an undue burden on competition, rather is it pro-competitive in that would serve to increase liquidity on BOX, thus rendering BOX a more attractive and vibrant venue to market participants. The QCC Growth Rebate Qualifications do not impose an undue burden on competition because, as discussed above, all Participants may qualify for the QCC Growth Rebate. Further, the QCC Growth Rebate Qualifications do not impose an undue burden on competition because the proposal is designed to increase participation on BOX and reward those Participants for providing increased order flow to BOX to the benefit of all market participants.

The Exchange's exclusion of strategy transactions does not impose an undue burden on competition as the exclusion will be uniformly applied to all Participant types. Lastly, the Exchange's proposal to pay Participants the greater of the QCC Rebate in Section IV.D.1.a or the QCC Growth Rebate in Section IV.D.1.b in a given month, but not both QCC Rebates, does not impose an undue burden on competition because BOX is simply offering another way for Participants to qualify for rebates that already exist today and BOX would uniformly only pay the greater of the two QCC Rebates.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Exchange Act[11] and Rule 19b–4(f)(2) thereunder,[12] because it establishes or changes a due, or fee.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BOX–2023–10 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–BOX–2023–10. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change.

[10] *See* Phlx Pricing Schedule.

[11] 15 U.S.C. 78s(b)(3)(A)(ii).

[12] 17 CFR 240.19b–4(f)(2).

Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BOX–2023–10, and should be submitted on or before May 4, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–07734 Filed 4–12–23; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97261; File No. SR–ISE–2023–08]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Make Permanent Certain P.M.-Settled Pilots

April 7, 2023.

On February 23, 2023, Nasdaq ISE, LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to make permanent the pilot to permit the listing and trading of options based on ⅕ the value of the Nasdaq-100 Index and the Exchange's nonstandard expirations pilot program. The proposed rule change was published for comment in the **Federal Register** on March 2, 2023.[3]

Section 19(b)(2) of the Act[4] provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is April 16, 2023.

The Commission is extending this 45-day time period. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates May 31, 2023, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–ISE–2023–08).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–07731 Filed 4–12–23; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97262; File No. SR–CboeEDGX–2023–023]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Concerning Order-to-Trade Ratio Fees for Market Makers

April 7, 2023.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on March 29, 2023, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX Options'') proposes to amend its Fee Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule to adopt Order-to-Trade Ratio Fees.[4]

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 options venues to which market participants may direct their order flow. Based on publicly available information, no single options exchange has more than 16% of the market share and currently the Exchange represents only approximately 6% of the market share.[5] Thus, in such a low-concentrated and highly competitive market, no single options exchange, including the Exchange, possesses significant pricing power in the execution of option order flow. The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces

[13] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 96979 (February 24, 2023), 88 FR 13182.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange initially filed the proposed rule change on February 1, 2023 (SR–CboeEDGX–2023–009). On March 29, 2023, the Exchange withdrew that filing and submitted this proposal.

[5] *See* Cboe Global Markets U.S. Options Market Monthly Volume Summary (March 24, 2023), available at *https://markets.cboe.com/us/options/market_statistics/.*

constrain the Exchange's transaction fees, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange proposes to adopt Order-to-Trade Ratio Fees. The proposed fees will be charged to market participants registered as Market Makers on EDGX Options based on the number of orders (including modification messages) entered compared to the number of orders traded in a calendar month. The calculation of the ratio will not include quotes or trades resulting from such quotes.[6] A Market Maker's order flow will be aggregated together with any affiliated Member sharing at least 75% common ownership. The proposed fees are as follows:

Tier	Order-to-trade ratio	Fee
Tier 1	0 to 999	$0
Tier 2	1,000 to 1,999	2,500
Tier 3	2,000 to 4,999	5,000
Tier 4	5,000 to 9,999	10,500
Tier 5	10,000 to 14,999 ...	35,000
Tier 6	15,000 to 19,999 ...	100,000
Tier 7	20,000 and above	150,000

The Exchange notes that Market Makers with incrementally higher order-to-trade ratios have the potential residual effect of exhausting system resources, bandwidth, and capacity. Higher order-to-trade ratios may, in turn, create latency and impact other Members' ability to receive timely executions. Recognizing Market Maker quoting activity is an important source of liquidity on exchanges, and that orders and executions often occur in large numbers, the purpose of this proposal is to focus on activity that is truly disproportionate while fairly allocating costs. The proposed fee structure has multiple thresholds, and the proposed fees are incrementally greater at higher order-to-trade ratios because the potential impact on exchange systems, bandwidth and capacity becomes greater with increased order-to-trade ratios. The proposal contemplates that a Market Maker would have to exceed the high order to trade ratio of 999 before that Market Maker would be charged a fee under the proposed tiers. The Exchange believes that it is in the interests of all Members and market participants who access the Exchange to not allow other market participants to exhaust System resources, but to encourage efficient usage of network capacity. The Exchange also believes this proposal (and in particular the proposed high fee amounts associated with higher order-to-trade ratios) will reduce the incentive for Market Makers to engage in excessive order and trade activity that may require the Exchange to otherwise increase its storage capacity and will encourage such activity to be submitted in good faith for legitimate purposes.

The Exchange also represents that the proposed fees are not intended to raise revenue; rather, as noted above, it is intended to encourage efficient behavior so that market participants do not exhaust System resources. The Exchange also notes that it intends to provide Market Makers with daily reports, free of charge, which will detail their order and trade activity in order for those firms to be fully aware of all order and trade activity they (and their affiliates) are sending to the Exchange. This will allow Market Maker firms to monitor their behavior and determine whether it is approaching any of the order-to-trade thresholds that trigger the proposed fees.

The Exchange lastly notes that other exchanges have adopted various fee programs that assess incrementally higher fees to Members that have incrementally higher order-to-trade ratios for similar reasons.[7] There is also an exchange that adopted a fee applicable to Market Makers that exceed a prescribed high threshold of quote messages.[8]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[9] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[10] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[11] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4) of the Act,[12] which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities.

First, the Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The Exchange is only one of 16 options exchanges which market participants may direct their order flow and/or participate on as a Market-Maker, and it represents a small percentage of the overall market. Competing options exchanges similarly assess fees to deter Members, including in some cases only Market-Makers, from over utilizing the exchange's System by sending excessive messages.[13]

The Exchange believes the proposed fees are reasonable as Market Makers that do not exceed the high order to trade ratio of 999 will not be charged any fee under the proposed tiers. Quoting activity (and trades resulting from quotes) are also not included in the order-to-trade ratio, thereby ensuring Market Makers quoting activity, which acts as important source of liquidity, is not impeded by the proposal.[14] The Exchange believes it's reasonable, equitable and not unfairly discriminatory to assess higher fees for

[6] The term ''quote'' refers to bids and offers submitted in bulk messages. A bulk message means a single electronic message a user submits with an M (Market-Maker) capacity to the Exchange in which the User may enter, modify, or cancel up to an Exchange-specified number of bids and offers. A User may submit a bulk message through a bulk port as set forth in Exchange Rule 21.1(j)(3). *See* Rule 16.1 (definition of bulk message).

[7] *See e.g.,* Securities Exchange Act Release No. 60102 (June 11, 2009), 74 FR 29251 (June 19, 2009) (SR–NYSEArca–2009–50) (adopting fees applicable to Members (albeit not just Market Makers) based on the number of orders entered compared to the number of executions received in a calendar month). It appears that Nasdaq similarly assesses a penalty charge to its members that exceed certain ''weighted order-to-trade ratios''. *See Price List—Trading Connectivity,* NASDAQ, *available at https://www.nasdaqtrader.com/trader.aspx?id=pricelisttrading2.*

[8] *See* Securities Exchange Act Release No. 91406 (March 25, 2021), 86 FR 16795 (March 31, 2023) (SR–EMERALD–2021–10) (adopting an ''Excessive Quoting Fee'' to ensure that Market Makers do not over utilize the exchange's System by sending messages (albeit quotes instead of orders) to the MIAX Emerald, to the detriment of all other Members of the exchange).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Id.*

[12] 15 U.S.C. 78f(b)(4).

[13] See supra note 6.

[14] The Exchange is able to identify quoting activity versus other message activity because quotes come into the system via bulk messages.

greater higher order-to-trade ratios because the potential impact on exchange systems, bandwidth and capacity becomes greater with increased order-to-trade ratios. This impact may also require the Exchange to purchase additional hardware to increase its storage capacity. The Exchange believes the proposed high fee amounts are reasonable as the Exchange believes them to commensurate with the proposed thresholds. Particularly, the proposed fee amounts that correspond to high order-to-trade ratios are designed to incentivize Market Makers to reduce excessive order and trade activity that the Exchange believes can be detrimental to all market participants at those levels and encourage such activity to be made in good faith and for legitimate purposes. Indeed, the Exchange believes that it is in the interests of all Members and market participants who access the Exchange to not allow Market Markets to exhaust System resources, but to encourage efficient usage of network capacity. The Exchange therefore also believes that the proposed order-to-trade ratio fees appropriately reflect the benefits to different firms of being able to send orders into the Exchange's System and also believes the proposed fee is one method of facilitating the Commission's goal of ensuring that critical market infrastructure has ''levels of capacity, integrity, resiliency, availability, and security adequate to maintain their operational capability and promote the maintenance of fair and orderly markets.'' [15]

The Exchange also believes adopting order-to-trade ratio fees is reasonable as unfettered usage of System capacity and network resource consumption can have a detrimental effect on all market participants who access and use the Exchange. As discussed, high order-to-trade ratios may adversely impact system resources, bandwidth, and capacity which may, in turn, create latency and impact other Members' ability to receive timely executions. The Exchange believes the proposed fees are therefore reasonable as they are designed to focus on activity that is truly disproportionate while fairly allocating costs.

The Exchange believes the proposed change is also equitable and not unfairly discriminatory because it applies uniformly to all Market Makers registered on EDGX Options. While the Exchange has no way of predicting with certainty how the proposed changes will impact Market Maker activity, based on trading activity from the prior months the Exchange would expect that, absent any changes to Member behavior, the vast majority of Members would fall within proposed Tier 1 (and thus not be subject to any new fees). With respect to Market Makers that exceed this threshold, the Exchange anticipates, absent any change in behavior, approximately two Members to fall within Tier 2, one Member to fall within Tier 3, no Members to fall within Tiers 4, 5 or 6 one Member to fall within Tier 7. Since the implementation of the proposed fee on February 1, 2023, the Exchange notes that it has observed a decrease in order-to-trade ratios by Market Makers, which the Exchange believes demonstrates that the proposed fee is working as designed. Particularly, in February 2023, only two Market Makers were assessed the proposed order-to-trade ratio fees; particularly one Market Maker fell within Tier 2 and one Market-Maker fell within Tier 4 (down from anticipated Tier 7). Additionally, as discussed above, the Exchange believes it's equitable and not unfairly discriminatory to assess incrementally higher fees for Market Makers that have higher order-to-trade ratios because the potential impact on exchange systems, bandwidth and capacity becomes greater with increased order-to-trade ratios. In addition, the Exchange believes that excluding quoting activity from the calculation of the ratio for the proposed fees is not unfairly discriminatory because it will ensure Market Makers are able to continue providing important liquidity to the Exchange and meet their quoting obligations. The Exchange also believes its equitable and not unfairly discriminatory to only assess the proposed fees to Market Makers because Market Makers on the Exchange are the only market participants that are exceeding proposed Tier 1, which is the only tier in which no fee is assessed (said another way, no other market participant has an order-to-trade ratio high enough to trigger a fee). For example, most market participants that route customer orders to the Exchange currently have order-to-trade ratios lower than 10. The Exchange also believes it's equitable and not unfairly discriminatory to aggregate a Market Maker's order flow with any affiliated Member sharing at least 75% common ownership even if such affiliated Member is not a Market Maker in order to prevent Market Makers from shifting their order flow and trading activity to their non-Market Maker affiliate in order to circumvent the proposed fees.

The Exchange lastly believes that its proposal is reasonable, equitably allocated and not unfairly discriminatory because it is not intended to raise revenue for the Exchange; rather, it is intended to encourage efficient behavior so that Market Makers do not exhaust System resources, while balancing the increase in order-to-trade ratio has seen from some market participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In particular, the Exchange believes the proposed rule change does not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed fees applies uniformly to all Market Makers registered on EDGX Options. Further, any Market Maker who exceeds the order-to-trade ratio of 999 will be subject to a fee under the proposed tiers. As noted above, the Exchange also believes its not unfairly discriminatory to only assess the proposed fees to Market Makers because Market Makers on the Exchange are the only market participants that are exceeding an order-to-trade ratio of 999(*i.e.,* Tier 1). The Exchange believes it's equitable and not unfairly discriminatory to aggregate a Market Maker's order flow with any affiliated Member sharing at least 75% common ownership even if such affiliated Member is not a Market Maker in order to prevent Market Makers from shifting their order flow and trading activity to their non-Market Maker affiliate in order to circumvent the proposed fees. As such, the Exchange believes that the proposed change neither favors nor penalizes one or more categories of market participants in a manner that would impose an undue burden on competition. Rather, the proposal seeks to benefit all market participants by encouraging the efficient utilization of the Exchange's network while taking into account the important liquidity provided by Market Makers. As discussed above potential impact on exchange systems, bandwidth and capacity becomes greater with increased order-to-trade ratios. The Exchange also anticipates that the vast majority of Market Makers on the Exchange will not be subject to any fees under the proposed tiers. Accordingly, the Exchange believes that the proposed

[15] *See* Securities Exchange Act Release No. 73639 (November 19, 2014), 79 FR 72251 (December 5, 2014) (File No. S7–01–13) (Regulation SCI Adopting Release).

Order-to-Trade Ratio Fees does not favor certain categories of market participants in a manner that would impose a burden on competition.

The Exchange also believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues they may participate on and direct their order flow, including 15 other options exchanges. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single options exchange has more than 16% of the market share. Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchanges if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' The fact that this market is competitive has also long been recognized by the courts. In NetCoalition v. Securities and Exchange Commission, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . .''. Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [16] of the Act and subparagraph (f)(2) of Rule 19b–4 [17] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [18] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeEDGX–2023–023 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeEDGX–2023–023. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeEDGX–2023–023, and should be submitted on or before May 4, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–07732 Filed 4–12–23; 8:45 am]

BILLING CODE 8011–01–P

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b 4(f)(2).

[18] 15 U.S.C. 78s(b)(2)(B).

[19] 17 CFR 200.30–3(a)(12).

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36688]

Green Mountain Railroad Corporation—Trackage Rights Exemption—New England Central Railroad, Inc.

Green Mountain Railroad Corporation (GMRC) has filed a verified notice of exemption under 49 CFR 1180.2(d)(7) for acquisition of overhead trackage rights over approximately 61.4 miles of rail line owned by New England Central Railroad, Inc. (NECR), between milepost 14.46 at White River Junction, Vt., and milepost 99.0 at Millers Falls, Mass. (the Line).[1]

[1] GMRC notes that, due to the Line's history, the mileposts are not indicative of the Line's total route miles and the stated distance is accurate although the mileposts could suggest otherwise.

GMRC and NECR have entered into a written trackage rights agreement [2] that grants GMRC overhead trackage rights over the Line. Those rights allow GMRC to enter and exit the Line at certain intermediate points as well as its terminal points, as described in the verified notice. GMRC states that the trackage rights are among settlement terms that the Board imposed ''as a condition of the Board's approval'' in *CSX Corp.—Control & Merger—Pan Am Systems, Inc.,* FD 36472 et al., (STB served Apr. 14, 2022).

The transaction may be consummated on or after April 27, 2023, the effective date of the exemption.

As a condition to this exemption, any employees affected by the acquisition of the trackage rights will be protected by the conditions imposed in *Norfolk & Western Railway—Trackage Rights—Burlington Northern, Inc.,* 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Railway—Lease & Operate—California Western Railroad,* 360 I.C.C. 653 (1980).

If the notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than April 20, 2023 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36688, must be filed with the Surface Transportation Board via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on GMRC's representative, Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606.

According to GMRC, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: April 7, 2023.

[2] A redacted version of the trackage rights agreement between GMRC and NECR was filed with the verified notice. An unredacted version of the agreement was submitted to the Board under seal concurrently with a motion for protective order, which is addressed in a separate decision.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2023–07721 Filed 4–12–23; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 1329X]

Elkhart & Western Railroad Co. LLC—Discontinuance of Trackage Rights Exemption—in Marshall and Fulton Counties, Ind.

On March 24, 2023, Elkhart & Western Railroad Co. LLC (E&W), a Class III rail carrier, filed a petition under 49 U.S.C. 10502 for exemption from the prior approval requirements of 49 U.S.C. 10903 to discontinue trackage rights over approximately 11.7 miles of rail line owned by Fulton County, L.L.C. (FC), extending from milepost I–108.6 near Argos, Ind., to milepost I–96.9 at Rochester, Ind., in Marshall and Fulton Counties, Ind. (the Line). The Line traverses United States Postal Services Zip Codes 46501 and 46975.

According to E&W, until recently, it was the exclusive service provider on the Line, pursuant to a trackage rights agreement (Agreement) with FC. E&W states that the Agreement expired on March 15, 2023, and, on the same day, Patriot Rail Company, LLC, which indirectly controls E&W, embargoed the Line due to unsafe track conditions. E&W notes that FC has a common carrier obligation on the Line as well as a plan for a corporate affiliate, Rochester & Erie Railway, LLC (RERY), to operate the Line, *see* RERY, Notice of Exemption, *Rochester & Erie Ry.—Operation Exemption—Fulton Cnty., LLC,* FD 36671. Therefore, according to E&W, RERY will be affiliated with the Line as its operator, and shippers will have access to common carrier service, should FC and RERY determine that operations can be resumed safely.

E&W states that it does not believe that the Lines contain federally granted rights-of-way. E&W also states that any documentation in its possession will be made available promptly to those requesting it.

As a condition to this exemption, any employee adversely affected by the discontinuance of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by July 12, 2023.

Because this is a discontinuance proceeding and not an abandonment, interim trail use/rail banking and public use conditions are not appropriate. Because there will be environmental review during any subsequent abandonment, this discontinuance does not require an environmental review. *See* 49 CFR 1105.6(c)(5), 1105.8(b).

Any offer of financial assistance (OFA) for subsidy under 49 CFR 1152.27(b)(2) will be due no later than 120 days after the filing of the petition for exemption, or 10 days after service of a decision granting the petition for exemption, whichever occurs sooner.[1] Persons interested in submitting an OFA must first file a formal expression of intent to file an offer by April 24, 2023, indicating the intent to file an OFA for subsidy and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(1)(i).

All filings in response to this notice must refer to Docket No. AB 1329X and must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on E&W's representative, Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606–3208. Replies to the petition are due on or before May 3, 2023.

Persons seeking further information concerning discontinuance procedures may contact the Board's Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238 or refer to the full abandonment and discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Office of Environmental Analysis at (202) 245–0294. If you require accommodation under the Americans with Disabilities Act, please call (202) 245–0245.

Board decisions and notices are available at *www.stb.gov.*

Decided: April 7, 2023.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Raina White,

Clearance Clerk.

[FR Doc. 2023–07832 Filed 4–12–23; 8:45 am]

BILLING CODE 4915–01–P

[1] The filing fee for OFAs can be found at 49 CFR 1002.2(f)(25).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2023–0930]

Notice of Intent To Designate as Abandoned Blue Aviation, LLC, Supplemental Type Certificate No. SA02238AT

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Notice of intent to designate Blue Aviation, LLC, Supplemental Type Certificate as abandoned; request for comments.

SUMMARY: This notice announces the FAA's intent to designate Blue Aviation, LLC, Supplemental Type Certificate (STC) No. SA02238AT as abandoned and make the related engineering data available upon request. The FAA has received a request to provide engineering data concerning this STC. The FAA has been unsuccessful in contacting Blue Aviation, LLC, concerning the STC. This action is intended to enhance-aviation safety.

DATES: The FAA must receive all comments by October 10, 2023.

ADDRESSES: You may send comments on this notice by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Gary Wechsler, AIR–755, FAA, Atlanta ACO Branch, 1701 Columbia Avenue, College Park, Georgia 30337.
- *Email: Gary.Wechsler@faa.gov.* Include ''Docket No. FAA–2023–0930'' in the subject line of the message.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Gary Wechsler, Aerospace Engineer, AIR–755, FAA, Atlanta ACO Branch, 1701 Columbia Avenue, College Park, Georgia 30337; telephone 404–474–5575; email *Gary.Wechsler@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites interested parties to provide comments, written data, views, or arguments relating to this notice. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2023–0930'' at the beginning of your comments. The FAA will consider all comments received on or before the closing date. All comments received will be available in the docket for examination by interested persons.

Background

The FAA is posting this notice to inform the public of the intent to designate Blue Aviation, LLC, STC No. SA02238AT, for the installation of Pratt & Whitney PT6A–34 and –35 engines in Textron Aviation (Beech, Raytheon) Model 65–A90, 65–C90, C90, C90A, and E90 airplanes, as abandoned, and subsequently release the related engineering data.

The FAA has received a third-party request for the release of the aforementioned engineering data under the provisions of the Freedom of Information Act (FOIA), 5 U.S.C. 552. The FAA cannot release commercial or financial information under FOIA without the permission of the data owner. However, in accordance with title 49 of the United States Code § 44704(a)(5), the FAA can provide STC ''engineering data'' it possesses for STC maintenance or improvement, upon request, if the following conditions are met:

1. The FAA determines the STC has been inactive for three or more years;
2. Using due diligence, the FAA is unable to locate the owner of record or the owner of record's heir; and
3. The availability of such data will enhance aviation safety.

There has been no activity on this STC for more than three years.

On November 7, 2022, the FAA sent a registered letter to Blue Aviation, LLC, at its last known address, 2282 Airport Road, Selmer, TN 38375. The letter informed Blue Aviation, LLC, that the FAA had received a request for engineering data related to STC No. SA02238AT and was conducting a due diligence search to determine whether the STC was inactive and may be considered abandoned. The letter further requested Blue Aviation, LLC, to respond in writing within 60 days and state whether it is the holder of the STC. The FAA also attempted to make contact with Blue Aviation, LLC, by other means, including telephone communication and emails, without success.

Information Requested

If you are the owner or heir or a transferee of STC No. SA02238AT or have any knowledge regarding who may now hold STC No. SA02238AT, please contact Gary Wechsler using a method described in this notice under **FOR FURTHER INFORMATION CONTACT**. If you are the heir of the owner, or the owner by transfer, of STC No. SA02238AT, you must provide a notarized copy of your government-issued identification with a letter and background establishing your ownership of the STC and, if applicable, your relationship as the heir to the deceased holder of the STC.

Conclusion

If the FAA does not receive any response by October 10, 2023, the FAA will consider STC No. SA02238AT abandoned, and the FAA will proceed with the release of the requested data. This action is for the purpose of maintaining the airworthiness of an aircraft and enhancing aviation safety.

Issued on April 8, 2023.

Christina Underwood,

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

[FR Doc. 2023–07822 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Submission Deadline for Schedule Information for Chicago O'Hare International Airport, John F. Kennedy International Airport, Los Angeles International Airport, Newark Liberty International Airport, and San Francisco International Airport for the Winter 2023/2024 Scheduling Season

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

ACTION: Notice of submission deadline.

SUMMARY: Under this notice, the FAA announces the submission deadline of May 11, 2023, for Winter 2023/2024 flight schedules at Chicago O'Hare International Airport (ORD), John F. Kennedy International Airport (JFK), Los Angeles International Airport (LAX), Newark Liberty International Airport (EWR), and San Francisco International Airport (SFO).

DATES: Schedules should be submitted by May 11, 2023.

ADDRESSES: Schedules may be submitted to the Slot Administration Office by email to: *7-AWA-slotadmin@faa.gov.*

FOR FURTHER INFORMATION CONTACT: Al Meilus, Manager, Slot Administration and Capacity Analysis, FAA ATO System Operations Services, AJR–G, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–2822; email *Al.Meilus@faa.gov.*

SUPPLEMENTARY INFORMATION: This document provides routine notice to carriers serving capacity-constrained airports in the United States, including ORD, JFK, LAX, EWR, and SFO. In particular, this notice announces the

deadline for carriers to submit schedules for the Winter 2023/2024 scheduling season. The FAA deadline coincides with the schedule submission deadline established in the Calendar of Coordination Activities as published by the International Air Transport Association (IATA).[1]

General Information for All Airports

The FAA has designated JFK as a Level 3 airport consistent with the Worldwide Slot Guidelines (WSG).[2] The FAA currently limits scheduled operations at JFK by order that expires on October 26, 2024.[3]

The FAA has designated EWR, LAX, ORD, and SFO as Level 2 airports [4] subject to a schedule review process premised upon voluntary cooperation. The Winter 2023/2024 scheduling season is from October 29, 2023, through March 30, 2024, in recognition of the WSG winter scheduling period.

The FAA is primarily concerned about scheduled and other regularly conducted commercial operations during designated hours, but carriers may submit schedule plans for the entire day. The designated hours for the Winter 2023/2024 scheduling season are: at EWR and JFK, from 0600 to 2300 Eastern Time (1100 to 0400 UTC); at LAX and SFO, from 0600 to 2300 Pacific Time (1400 to 0700 UTC); and at ORD, from 0600 to 2100 Central Time (1200 to 0300 UTC). These hours are unchanged from previous scheduling seasons.

Carriers should submit schedule information in sufficient detail including, at minimum, the marketing or operating carrier, flight number, scheduled time of operation, frequency, aircraft equipment, and effective dates. IATA standard schedule information format and data elements for communications at Level 2 and Level 3 airports in the IATA Standard Schedules Information Manual (SSIM) Chapter 6 may be used. The WSG provides additional information on schedule submissions at Level 2 and Level 3 airports. Some carriers at JFK manage and track slots through FAA-assigned Slot ID numbers corresponding to an arrival or departure slot in a particular half-hour on a particular day of week and date. The FAA has a similar voluntary process for tracking schedules at EWR with Reference IDs, and certain carriers are managing their schedules accordingly. The primary users of IDs are United States and Canadian carriers that have the highest frequencies and considerable schedule changes throughout the season and can benefit from a simplified exchange of information not dependent on full flight details. Carriers are encouraged to submit schedule requests at those airports using Slot or Reference IDs.

As stated in the WSG, schedule facilitation at a Level 2 airport is based on the following: (1) schedule adjustments are mutually agreed upon between the carriers and the facilitator; (2) the intent to avoid exceeding the airport's coordination parameters; (3) the concepts of historic precedence and series of slots do not apply at Level 2 airports (although WSG recommends giving priority to approved services that plan to operate unchanged from the previous equivalent season at Level 2 airports); and (4) the facilitator should adjust the smallest number of flights by the least amount of time necessary to avoid exceeding the airport's coordination parameters. Consistent with the WSG, the success of Level 2 in the United States depends on the voluntary cooperation of carriers.

The FAA considers several factors and priorities that are consistent with the WSG as it reviews schedule and slot requests at Level 2 and Level 3 airports, including (1) historic slots or services from the previous equivalent season over new demand for the same timings; (2) services that are unchanged over services that plan to change time or other capacity relevant parameters; (3) introduction of year-round services; (4) effective period of operation; (5) regularly planned operations over *ad hoc* operations; and (6) other operational factors that may limit a carrier's timing flexibility.

The FAA seeks to maintain close communications with carriers and terminal schedule facilitators on potential runway schedule issues or terminal and gate issues that may affect the runway times. In addition to applying these priorities from the WSG, the U.S. Government has adopted a number of measures and procedures to promote competition and new entry at U.S. slot-controlled and schedule-facilitated airports.

Slot management in the United States differs in some respects from procedures in other countries. In the United States, the FAA is responsible for facilitation and coordination of runway access for takeoffs and landings at Level 2 and Level 3 airports; however, the airport authority or its designee is responsible for facilitation and coordination of terminal/gate/airport facility access. The process with the individual airports for terminal access and other airport services is separate from, and in addition to, the FAA schedule review based on runway capacity.

Generally, the FAA uses average hourly runway capacity throughput for airports and performance metrics in conducting its schedule review at Level 2 airports and determining the scheduling limits at Level 3 airports included in FAA rules or orders.[5] The FAA also considers other factors that can affect operations, such as capacity changes due to runway, taxiway, or other airport construction, air traffic control procedural changes, airport surface operations, and historical or projected flight delays and congestion.

Finally, the FAA notes that the schedule information submitted by carriers to the FAA may be subject to disclosure under the Freedom of Information Act (FOIA). The WSG also provides for release of information at certain stages of slot coordination and schedule facilitation. In general, once it acts on a schedule submission or slot request, the FAA may release information on slot allocation or similar slot transactions, or schedule information reviewed as part of the schedule facilitation process. The FAA does not expect that practice to change, and most slot and schedule information would not be exempt from release under FOIA. The FAA recognizes that some carriers may submit information on schedule plans that is both customarily and actually treated as private. Carriers that submit such confidential schedule information should clearly mark the information, or any relevant portions

[1] *https://www.iata.org/contentassets/4ede2aabfcc14a55919e468054d714fe/calendar-coordination-activities.pdf.*

[2] The FAA generally applies the WSG to the extent there is no conflict with U.S. law or regulation. The FAA recognizes the WSG has been replaced by the Worldwide Airports Slot Guidelines (WASG) edition 1, effective June 1, 2020, and subsequently WASG edition 2, effective July 1, 2022. The WASG is published jointly by Airports Council International-World, IATA, and the Worldwide Airport Coordinators Group (WWACG). While the FAA is considering whether to implement certain changes to the Guidelines in the United States, it will continue to apply WSG edition 9.

[3] Operating Limitations at John F. Kennedy International Airport, 73 FR 3510 (Jan. 18, 2008), as most recently extended 87 FR 65161 (Oct. 28, 2022). The slot coordination parameters for JFK are set forth in this Order.

[4] These designations remain effective until the FAA announces a change in the **Federal Register**.

[5] The FAA typically determines an airport's average adjusted runway capacity or typical throughput for Level 2 airports by reviewing hourly data on the arrival and departure rates that air traffic control indicates could be accepted for that hour, commonly known as ''called'' rates. The FAA also reviews the actual number of arrivals and departures that operated in the same hour. Generally, the FAA uses the higher of the two numbers, called or actual, for identifying trends and schedule review purposes. Some dates are excluded from analysis, such as during periods when extended airport closures or construction could affect capacity.

thereof, as proprietary information (''PROPIN''). The FAA will take the necessary steps to protect properly designated information to the extent allowable by law.

EWR General Information

Consistent with the WSG, carriers are asked for their voluntary cooperation to adjust schedules to meet the targeted scheduling limits in order to minimize potential congestion and delay. For the Winter 2023/2024 scheduling season, the voluntary, targeted hourly scheduling limits remains at 79 operations and 43 operations per half-hour.[6] To help with a balance between arrivals and departures, the targeted maximum number of scheduled arrivals or departures, respectively, is 43 in an hour and 24 in a half-hour. These targets are expected to allow some higher levels of operations in certain periods (not to exceed the hourly limits) and some recovery from lower demand in adjacent periods. Consistent with general established practice at EWR, the FAA will accept flights above the limits if the flights were operated as approved, or treated as operated, by the same carrier on a regular basis in the previous corresponding season (*i.e.,* Winter 2022/2023) and consistent with the DOT reassignment of 16 peak-hour runway timings.[7]

Carriers are reminded FAA approval for runway times is separate from the approval process for gates or other airport infrastructure and both are essential for the success of Level 2 at EWR. Schedule facilitation at Level 2 airports is designed to engender collaboration and gain mutual agreement between the carriers and the FAA regarding schedules and potential adjustments to stay within the performance goals and capacity limits of the airport and to mitigate delays and congestion that would result in the need for Level 3 slot controls. The FAA expects that all carriers operating at EWR will respect the targeted scheduling limits and work cooperatively with the FAA in order to avoid unacceptable delays and other adverse operational impacts at the airport.

Issued in Washington, DC, on April 7, 2023.

Alyce Hood-Fleming,

Vice President, System Operations Services.

[FR Doc. 2023–07756 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–13–P

[6] 83 FR 21335 (May 9, 2018).

[7] See Department of Transportation Order 2022–7–1, Docket DOT–OST–2021–0103, served July 5, 2022, ''Reassignment of Schedules at Newark-Liberty International Airport''.

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2015–0323; FMCSA–2016–0007; FMCSA–2016–0008; FMCSA–2018–0052; FMCSA–2019–0036; FMCSA–2020–0046; FMCSA–2020–0047]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to renew exemptions for eight individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have ''no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.'' The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to continue to operate CMVs in interstate commerce.

DATES: The exemptions were applicable on March 17, 2023. The exemptions expire on March 17, 2025.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001, (202) 366–4001, *fmcsamedical@dot.gov.* Office hours are from 8:30 a.m. to 5 p.m. ET Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number (FMCSA–2015–0323, FMCSA–2016–0007, FMCSA–2016–0008, FMCSA–2018–0052, FMCSA–2019–0036, FMCSA–2020–0046, or FMCSA–2020–0047) in the keyword box and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

B. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption request. 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 (Federal Docket Management System), which can be reviewed at *https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices,* the comments are searchable by the name of the submitter.

II. Background

On March 3, 2023, FMCSA published a notice announcing its decision to renew exemptions for eight individuals from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8) to operate a CMV in interstate commerce and requested comments from the public (88 FR 13487). The public comment period ended on April 3, 2023, and no comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that renewing these exemptions would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved by complying with § 391.41(b)(8).

The physical qualification standard for drivers regarding epilepsy found in § 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria [1] to assist medical examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.

III. Discussion of Comments

FMCSA received no comments in this proceeding.

[1] These criteria may be found in APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. *Epilepsy:* § 391.41(b)(8), paragraphs 3, 4, and 5, which is available on the internet at *https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf.*

IV. Conclusion

Based on its evaluation of the eight renewal exemption applications, FMCSA announces its decision to exempt the following drivers from the epilepsy and seizure disorders prohibition in § 391.41(b)(8).

As of March 17, 2023, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following eight individuals have satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers (88 FR 13487):

Kenneth Elder (KY)
Demetris Furman (SD)
Scott Habeck (SD)
Todd Hines (OH)
Scotty Ready, Sr. (WI)
Harold Seaton (KY)
Thomas Smutnik (PA)
Tara Vanhorne (PA)

The drivers were included in docket number FMCSA–2015–0323, FMCSA–2016–007, FMCSA–2016–0008, FMCSA 2018–0052, FMCSA–2019–0036, FMCSA–2020–0046, or FMCSA–2020–0047. Their exemptions were applicable as of March 17, 2023 and will expire on March 17, 2025.

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2023–07781 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2021–0183]

Agency Information Collection Activities; New Information Collection Request: Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA–5872

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for review and approval and invites public comment on the approval of a new ICR titled, Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA–5872. This Information Collection (IC) is voluntary and may be utilized by medical examiners (MEs) responsible for issuing Medical Examiner's Certificates, Form MCSA–5876, to individuals diagnosed with non-insulin-treated diabetes mellitus who operate commercial motor vehicles (CMV) in interstate commerce. MEs choosing to use this IC will do so in an effort to communicate with treating healthcare providers who manage the diabetes care of individuals diagnosed with non-insulin-treated diabetes mellitus who operate CMVs. The information obtained by MEs will assist them in determining whether an individual diagnosed with non-insulin-treated diabetes mellitus meets FMCSA's physical qualification standards.

DATES: Comments must be received on or before June 12, 2023.

ADDRESSES: You may submit comments identified by Federal Docket Management System Docket Number FMCSA–2021–0183 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov/docket/FMCSA-2021-0183/document.* Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.
- *Fax:* (202) 493–2251.

Instructions: All submissions must include the Agency name and docket number. For detailed instructions on submitting comments, see the Public Participation heading below. Note that all comments received will be posted without change to *www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments received, go to *www.regulations.gov,* and follow the online instructions for accessing the docket, or go to the street address listed above.

Privacy Act: In accordance with the Paperwork Reduction Act, FMCSA solicits comments from the public to better inform the Agency about the burden of the proposed ICR. FMCSA 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 (Federal Docket Management System), which can be reviewed at *www.transportation.gov/privacy.*

Public Participation: The Federal eRulemaking Portal is available 24 hours each day, 365 days each year. You can obtain electronic submission and retrieval help and guidelines under the ''FAQ'' section of the Federal eRulemaking Portal website.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001, (202) 366–4001, *fmcsamedical@dot.gov.* Office hours are from 8:30 a.m. to 5 p.m. ET Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Background

The primary mission of FMCSA is to reduce crashes, injuries, and fatalities involving CMVs (large trucks and buses). CMVs are longer, heavier, and more difficult to maneuver than automobiles. Not only does it take a skilled driver to operate them safely, it takes a physically and mentally fit driver to do so as well. Information used to determine and certify driver medical fitness helps to promote and maintain safety on our nation's highways.

FMCSA is required by statute to establish minimum standards for the physical qualifications of drivers who operate CMVs in interstate commerce for non-excepted industries (49 U.S.C. 31136(a)(3) and 31502(b)). The regulations applicable to this collection are outlined in the Federal Motor Carrier Safety Regulations (FMCSRs) at 49 CFR part 391, subpart E. The FMCSRs in § 391.41(b) [1] set forth the

[1] 49 CFR 391.41; Physical qualifications for drivers. Available at *https://www.ecfr.gov/current/*

Continued

physical qualification standards that individuals operating CMVs in interstate commerce who are subject to part 391 must meet. The FMCSRs covering the performance of the CMV physical qualification examination of individuals who operate in interstate commerce by an ME and the related recordkeeping requirements are found at § 391.43. The results of the examination must be recorded in accordance with the requirements set forth in that section; they include preparing and maintaining a Medical Examination Report Form, MCSA–5875, and, if the individual is physically qualified, issuing a Medical Examiner's Certificate, Form MCSA–5876.

The FMCSRs in § 391.41(b)(1) through (13) generally include the physical qualification standards required for the medical certification of individuals who operate a CMV in interstate commerce. The physical qualification standards in § 391.46 address the physical qualification requirements for medical certification of individuals who are diagnosed with diabetes mellitus and are treated with insulin. However, the FMCSRs do not specifically address individuals who are diagnosed with diabetes mellitus and are treated with non-insulin therapy. The type of diabetes mellitus that is not treated with insulin (commonly known as Type 2 diabetes) is recognized as a health concern for the general public.

Non-insulin-treated diabetes mellitus that is not properly managed and controlled may result in diabetes complications and/or target organ damage and in the individual's physical condition being inadequate to enable the driver to operate a CMV safely. The physical qualification standards in the FMCSRs broadly address some of the conditions and symptoms that may be attributable to complications from non-insulin-treated diabetes mellitus. Examples include the loss of limb and limb impairment standards (§ 391.41(b)(1) and (2)); the cardiovascular standard (§ 391.41(b)(4)); the rheumatic, arthritic, orthopedic, muscular, neuromuscular, or vascular standard (§ 391.41(b)(7)); and the loss of consciousness standard (§ 391.41(b)(8)).

In performing a thorough assessment and evaluation of an individual diagnosed with non-insulin-treated diabetes mellitus, the ME may need to consult with the individual's treating healthcare provider who manages the individual's diabetes. The ME may find this helpful in determining whether the individual has any medical conditions or symptoms, such as frequent episodes of severe hypoglycemia, that may prevent the individual from meeting the physical qualification standards and receiving a Medical Examiner's Certificate, Form MCSA–5876. This voluntary collection would assist the ME by ensuring that the treating healthcare provider includes the appropriate information, via the Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA–5872, in a standardized manner, which would assist the ME in making an informed and sound physical qualification determination.

In May 2021, FMCSA's Medical Review Board (MRB) deliberated on the topic and contents of a draft Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA–5872 (Task 21–2). FMCSA directed the MRB to review and comment on whether the information on the proposed form provided sufficient information concerning the treatment, management, and control of an individual's non-insulin-treated diabetes mellitus condition to assist a ME in making an appropriate physical qualification determination. The Agency also requested that the MRB identify any areas of ambiguity as well as additional information that FMCSA should include on the form. Based on its review, the MRB made some recommendations to improve the clarity and quality of information on the Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA–5872, which is provided from the individual's treating healthcare provider to the ME.

There is no required collection frequency for the Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA–5872, because the use of this IC is voluntary and at the discretion of the ME.

The Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA–5872, will be available as a fillable pdf and may be downloaded from the FMCSA website. Treating healthcare providers may provide the form to the individual, or fax or scan and email the form directly to the ME. Consistent with OMB's commitment to minimizing respondents' recordkeeping and paperwork burdens and the increased use of secure electronic modes of communication, the Agency anticipates that approximately 50 percent of the Non-Insulin-Treated Diabetes Mellitus Assessment Forms, MCSA–5872, will be transmitted electronically.

The information collected on the Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA–5872, will be used by the ME who requests completion of the form and will not be available to the public. The Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA–5872, will become a part of the individual's physical qualification examination records that are maintained and retained by the ME for a period of at least 3 years from the date of the examination.[2]

Title: Non-Insulin-Treated Diabetes Mellitus Assessment Form, MCSA–5872.

OMB Control Number: 2126–00XX.

Type of Request: New collection.

Respondents: Treating healthcare providers of individuals who are diagnosed with non-insulin treated diabetes mellitus who operate CMVs.

Estimated Number of Respondents: 242,057 respondents.

Estimated Time per Response: 8 minutes.

Expiration Date: N/A. This is a new ICR.

Frequency of Response: Other (Voluntary use at the medical discretion of the ME).

Estimated Total Annual Burden: 32,274 hours.

Public Comments Invited: You are asked to comment on any aspect of this IC, including: (1) whether the proposed collection is necessary for FMCSA to perform its functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information. The Agency will summarize or include your comments in the request for OMB's clearance of this information collection.

Issued under the authority of 49 CFR 1.87.

Thomas P. Keane,

Associate Administrator, Office of Research and Registration.

[FR Doc. 2023–07823 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2022–0233]

Crash Preventability Determination Program

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

title-49/subtitle-B/chapter-III/subchapter-B/part-391/subpart-E.

[2] The burden for the ME to file and retain the driver examination forms is covered in the Medical Qualification Requirements ICR, OMB Control Number 2126–0006, which is currently due to expire on March 31, 2025.

ACTION: Notice and request for comments.

SUMMARY: To address industry concerns about all crashes being used in the Agency's Safety Measurement System (SMS), since May 2020 FMCSA has been operating the Crash Preventability Determination Program (CPDP). This program reviews 16 specific crash types and modifies information in the SMS to distinguish not preventable crashes. The existing program was an expansion of the Agency's previous demonstration program that reviewed eight specific crash types. Through the incorporation of this information into SMS, FMCSA is better positioned to identify unsafe carrier and driver behaviors and prioritize carriers for interventions, by excluding not preventable crashes when calculating a motor carrier's Crash Indicator Behavior Analysis Safety Improvement Category measure and percentile Based on the Agency's experiences with the crash types and its reviews of crash eligibility, FMCSA proposes modifying existing crash types to broaden eligibility, removing the distinction between direct and indirect strikes, and differentiating some types for improved reporting and use of the data to identify ways to reduce crashes involving non-motorists, in alignment with the Department of Transportation's National Roadway Safety Strategies at *www.transportation.gov/NRSS.* In addition, FMCSA proposes that four new crash types be included in the program. FMCSA seeks comments on these proposed changes. FMCSA will respond to comments it receives on the proposal and announce the start of the updated CPDP through a subsequent **Federal Register** notice.

DATES: Comments must be received on or before June 12, 2023.

ADDRESSES: You may submit comments identified by Docket Number FMCSA–2022–0233 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov/docket/FMCSA-2022-0233/document.* Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations, U.S. DOT, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Dockets Operations, U.S. DOT, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except for Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.
- *Fax:* (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Mr. Catterson Oh, Compliance Division, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; (202) 366–6160; *Catterson.Oh@dot.gov.* If you have questions on viewing or submitting material to the docket, call Dockets Operations at (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2022–0233), indicate the specific section of this document to which your comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *https://www.regulations.gov/docket/FMCSA-2022-0233/document,* click on this notice, click ''Comment,'' and type your comment into the text box on the following screen.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period and may change this notice based on your comments.

Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to the notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to the notice, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as ''PROPIN'' to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the notice. Submissions containing CBI should be sent to Mr. Brian Dahlin, Chief, Regulatory Evaluation Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this notice.

B. Viewing Comments and Documents

To view any documents mentioned as being available in the docket, go to *https://www.regulations.gov/docket/FMCSA-2022-0233/document* and choose the document to review. To view comments, click this notice then click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy

FMCSA solicits comments from the public to better inform its processes. FMCSA 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—Federal Docket Management System), which can be reviewed at *https://www.govinfo.gov/content/pkg/FR-2008-01-17/pdf/E8-785.pdf.*

II. Background

Since its implementation in 2010, FMCSA's Safety Measurement System (SMS) has used safety performance information in the Behavior Analysis and Safety Improvement Categories (BASICs), in addition to recordable crashes involving commercial motor vehicles (CMVs), to prioritize carriers for safety interventions (75 FR 18256). The Crash Indicator BASIC uses crashes from the previous 24 months to calculate percentiles for motor carriers.

In addition, the public SMS website lists motor carriers' recordable crashes. Although the Crash Indicator BASIC percentiles have never been publicly available, stakeholders have expressed concern that the use of all crashes in SMS, without an indication of preventability, may give an inaccurate impression about the risk posed by the company. In response to this concern, FMCSA announced a demonstration program on July 27, 2017, to evaluate the preventability of certain categories of crashes (82 FR 35045). Based on its experience in conducting the demonstration program, and the strong support for continuing and expanding this program, FMCSA initiated the Crash Preventability Determination Program (CPDP).

Since May 2020, FMCSA has accepted Requests for Data Review (RDRs) in its DataQs system to evaluate the preventability by the CMV driver of the following 16 crash types, which were implemented as described in a May 6, 2020, **Federal Register** notice (85 FR 27017). This was an expansion from the Agency's previous demonstration program.

Struck in the Rear type of crash when the CMV was struck:

1. in the rear; or

2. on the side at the rear.

Wrong Direction or Illegal Turns type of crash when the CMV was struck:

3. by a motorist driving in the wrong direction; or

4. by another motorist in a crash when a driver was operating in the wrong direction; or

5. by a vehicle that was making a U-turn or illegal turn.

Parked or Legally Stopped type of crash when the CMV was struck:

6. while legally stopped at a traffic control device (*e.g.,* stop sign, red light, or yield) or while parked, including while the vehicle was unattended.

Failure of the other vehicle to Stop type of crash when the CMV was struck:

7. by a vehicle that did not stop or slow in traffic; or

8. by a vehicle that failed to stop at a traffic control device.

Under the Influence type of crash when the CMV was struck:

9. by an individual under the influence (or related violation, such as operating while intoxicated), according to the legal standard of the jurisdiction where the crash occurred; or

10. by another motorist in a crash where an individual was under the influence (or related violation such as operating while intoxicated), according to the legal standard of the jurisdiction where the crash occurred.

Medical Issues, Falling Asleep or Distracted Driving type of crash when the CMV was struck:

11. by a driver who experienced a medical issue that contributed to the crash; or

12. by a driver who admitted falling asleep or admitted distracted driving (*e.g.,* cellphone, global positioning system (GPS), passengers, other).

Cargo/Equipment/Debris or Infrastructure Failure type of crash when the CMV:

13. was struck by cargo, equipment, or debris (*e.g.,* fallen rock, fallen trees, unidentifiable items on the road), or a crash resulting from an infrastructure failure.

Animal Strike type of crash when the CMV:

14. struck an animal.

Suicide type of crash when the CMV:

15. struck an individual committing or attempting to commit suicide.

Rare or Unusual type of crash when the CMV:

16. Was involved in a crash type that seldom occurs and does not meet another eligible crash type (*e.g.,* non-motorist involved crashes, being struck by an airplane or skydiver or being struck by a deceased driver).

Between May 1, 2020, and December 30, 2022, 39,133 RDRs were submitted to FMCSA. Approximately 72.5 percent of the submitted RDRs were eligible, meaning they were one of the 16 specific crash types. Approximately 96 percent of the eligible crashes were found to have been not preventable.

FMCSA maintains quarterly statistics on the program on its website at *www.fmcsa.dot.gov/crash-preventability-determination-program.* As of December 30, 2022, information from the program is as follows:

TABLE 1—CRASH PREVENTABILITY PROGRAM DETERMINATIONS BY CRASH TYPE

Crash type	Total determinations	Not preventable	Preventable	Undecided
1. When the CMV was struck by a motorist driving under the influence (or related offense)	1,206	1,157	19	30
2. When the CMV was struck by a motorist driving in the wrong direction	1,288	1,195	36	57
3. When the CMV was struck in the rear	11,280	10,860	201	219
4. When the CMV was struck while legally stopped or parked, including when the vehicle was unattended	1,931	1,858	40	33
5. When the CMV was struck by an individual committing or attempting to commit suicide by stepping or driving in front of the CMV	54	51	2	1
6. When the CMV sustained disabling damage after striking an animal in the roadway	584	581	3	0
7. When the crash was a result of an infrastructure failure or the CMV was struck by cargo, equipment, or debris (*e.g.,* fallen rock, fallen trees, unidentifiable items in the road)	1,018	986	18	14
8. When the CMV was struck on the side at the rear	2,311	2,196	59	56
9. When the CMV was struck by another motorist in a crash when a driver was operating in the wrong direction	64	55	0	9
10. When the CMV was struck by a vehicle that was making a U-turn or illegal turn	414	399	6	9
11. When the CMV was struck by a vehicle that did not stop or slow in traffic	726	702	11	13
12. When the CMV was struck by a vehicle that failed to stop at a traffic control device	3,306	3,205	40	61
13. When the CMV was struck by another motorist in a crash where an individual was under the influence (or related violation such as operating while intoxicated)	56	55	0	1
14. When the CMV was struck by a driver who experienced a medical issue which contributed to the crash	199	196	0	3

TABLE 1—CRASH PREVENTABILITY PROGRAM DETERMINATIONS BY CRASH TYPE—Continued

Crash type	Total determinations	Not preventable	Preventable	Undecided
15. When the CMV was struck by a driver who admitted to falling asleep or admitted to distracted driving (*e.g.,* cellphone, GPS, passengers, other). ..	965	940	15	10
16. When the CMV was involved in a crash type that seldom occurs and does not meet another eligible crash type (*e.g.,* non-motorist involved crashes, being struck by an airplane or skydiver or being struck by a deceased driver)	294	254	9	31
Total	25,696	24, 690	459	547

As of December 30, 2022, 7,669 unique carriers had submitted RDRs. Of these, 3,138 carriers submitted 1 RDR, 3,837 carriers submitted between 2 and 9 RDRs, and 694 carriers submitted 10 or more RDRs. The highest number of RDRs submitted by 1 carrier was 942 RDRs.

For the majority of crashes that were determined to be preventable, the CMV driver was operating with a pre-crash out-of-service (OOS) condition under the North American Standard OOS Criteria, which includes the driver not being properly licensed on the day of the crash. Many of these OOS violations were identified through post-crash inspections that noted the pre-crash violations. The Agency explained in its May 6, 2020, **Federal Register** notice that in these circumstances, crashes would be found to be preventable (85 FR 27017).

The undecided determinations were primarily due to the submitter's failure to provide, after FMCSA's request, documentation confirming the validity of the driver's commercial driver's license (CDL) or medical certification on the date of the crash or to resolve conflicting information on the documentation provided about the crash. Undecided determinations were also issued when a submitter did not provide drug and alcohol testing results or explain why testing did not occur for fatal crashes.

III. Implementation Proposal

A. Proposed List of Eligible Crash Types

FMCSA proposes changes to existing crash types and adds four new crash types to expand the CPDP to review even more crashes each year for preventability. These proposed changes are expected to double the size of the current program and provide more data for analysis of the impacts of a carrier's not preventable crashes on its overall safety. FMCSA would analyze these changes to existing crash types and new crash types for 24 months but may announce changes earlier if certain crash types cannot be consistently reviewed or there is insufficient information to make eligibility and preventability determinations.

These changes and its incorporation into SMS allow us to further refine our prioritization to ensure the carriers and drivers with riskiest behaviors are identified for prioritization. In addition, the Agency believes that continued growth of the CPDP and the use of more preventability information in assessing motor carriers will provide an improved indication of a motor carrier's crash risk.

Changes to Existing Crash Types

FMCSA proposes changes to existing crash types to broaden the crash types to allow more crashes to be eligible.

The current crash types to be changed are:

1. CMV was struck by a motorist driving in the wrong direction.
2. CMV was struck by another motorist in a crash when a driver was operating in the wrong direction.
3. CMV was struck by a vehicle that was making a U-turn or illegal turn.
4. CMV was struck by a vehicle that did not stop or slow in traffic.
5. CMV was struck by a vehicle that failed to stop at a traffic control device.
6. CMV was struck by an individual under the influence (or related violation, such as operating while intoxicated), according to the legal standard of the jurisdiction where the crash occurred.
7. CMV was struck by another motorist in a crash where an individual was under the influence (or related violation such as operating while intoxicated), according to the legal standard of the jurisdiction where the crash occurred.
8. CMV was struck by a driver who experienced a medical issue which contributed to the crash.
9. CMV was struck by a driver who admitted falling asleep or admitted distracted driving (*e.g.,* cellphone, GPS, passengers, other).
10. CMV was struck by cargo, equipment, or debris (*e.g.,* fallen rock, fallen trees, unidentifiable items in the road); or crash was a result of an infrastructure failure.
11. CMV was involved in a crash type that seldom occurs and does not meet another eligible crash type (*e.g.,* non-motorist involved crashes, being struck by an airplane or skydiver or being struck by a deceased driver).

The proposed revised crash types are:

1. CMV was struck because another motorist was driving in the wrong direction.
2. CMV was struck because another motorist was making a U-turn or illegal turn.
3. CMV was struck because another motorist did not stop or slow in traffic.
4. CMV was struck because another motorist failed to stop at a traffic control device.
5. CMV was struck because another individual was under the influence (or related violation, such as operating while intoxicated), according to the legal standard of the jurisdiction where the crash occurred.
6. CMV was struck because another motorist experienced a medical issue which contributed to the crash.
7. CMV was struck because another motorist fell asleep.
8. CMV was struck because another motorist was distracted (*e.g.,* cellphone, GPS, passengers, other).
9. CMV was struck by cargo, equipment, or debris (*e.g.,* fallen rock, fallen trees, unidentifiable items in the road);
10. CMV crash was a result of an infrastructure failure.

These changes would allow more crashes to be submitted for consideration in the program.

11. CMV was involved in a crash with a non-motorist.

This change would create a separate type for these events. These crashes are currently the predominant type submitted in the Rare and Unusual crash type. This change will allow the Agency to distinguish these events and use the information to identify ways to reduce the increasing number of non-motorist crashes in alignment with the Department's National Roadway Safety

Strategy objectives of Safer People and Safer Roads.

New Crash Types

In addition, FMCSA proposes to test the following four additional crash types. These crashes were submitted during the determination program but did not qualify for one of the current crash types. However, the police accident reports (PARs), especially when paired with other supporting documents, particularly videos, provided sufficient information to potentially reach a preventability determination.

1. CMV was struck on the side by a motorist operating in the same direction. Currently, the crash type is limited to side strikes at the very rear of the vehicle (*e.g.,* 5:00 and 7:00 points of impact).
2. CMV was struck because another motorist was entering the roadway from a private driveway or parking lot.
3. CMV was struck because another motorist lost control of their vehicle. FMCSA reviewed many PARs that included this information but were ineligible for the program under the current crash types.
4. Any other type of crash involving a CMV where a video demonstrates the sequence of events of the crash.

FMCSA believes that the submission of videos could allow it to review crashes that are not in the 21 other types.

As a result, a full list of the eligible crash types would be:

1. CMV was struck in the rear by a motorist.
2. CMV was struck on the side at the rear by a motorist.
3. CMV was struck while legally stopped at a traffic control device or parked, including while the vehicle was unattended.
4. CMV was struck because another motorist was driving in the wrong direction.
5. CMV was struck because another motorist was making a U-turn or illegal turn.
6. CMV was struck because another motorist did not stop or slow in traffic.
7. CMV was struck because another motorist failed to stop at a traffic control device.
8. CMV was struck because another individual was under the influence (or related violation, such as operating while intoxicated), according to the legal standard of the jurisdiction where the crash occurred.
9. CMV was struck because another motorist experienced a medical issue which contributed to the crash.
10. CMV was struck because another motorist fell asleep.
11. CMV was struck because another motorist was distracted (*e.g.,* cellphone, GPS, passengers, other).
12. CMV was struck by cargo or equipment from another vehicle, or debris (*e.g.,* fallen rock, fallen trees, unidentifiable items in the road);
13. CMV crash was a result of an infrastructure failure.
14. CMV struck an animal.
15. CMV struck an individual committing or attempting to commit suicide.
16. CMV was struck on the side by a motorist operating in the same direction as CMV.
17. CMV was struck because another motorist was entering the roadway from a private driveway or parking lot.
18. CMV was struck because another motorist lost control of the vehicle.
19. CMV was involved in a crash with a non-motorist.
20. CMV was involved in a crash type that seldom occurs and does not meet another eligible crash type (*e.g.,* being struck by an airplane or skydiver or being struck by a deceased driver in another vehicle).
21. Any other type of crash where a CMV was involved and a video demonstrates the sequence of events of the crash.

B. Reminders on CPDP Process and System Impacts

Since the implementation of CPDP, FMCSA has provided clarification and individual reminders to submitters participating in the program, as questions have arisen. In an effort to assist the public in better understanding the CPDP process and system impacts, FMCSA is providing the following reminders.

Preventability Standard

The standard for making a preventability determination remains the same and is set forth in 49 CFR part 385, Appendix B, section II.B(e). The burden continues to be on the submitter to show by compelling evidence that the crash was not preventable. FMCSA will continue to display the current disclaimer on the Safety Management System (SMS) website and will continue to include language in its determination notifications to submitters explaining that a crash preventability determination does not assign fault or legal liability for the crash.

Process

FMCSA will continue to make a determination of preventable if there is evidence that the driver or carrier could have prevented the crash or was prohibited from operating the CMV at the time of the crash. This includes OOS violations and license violations, as previously noted, and driver prohibitions in the Agency's Drug and Alcohol Clearinghouse.

FMCSA will continue to rely on the Motor Carrier Management Information System (MCMIS) crash report to confirm that the driver was properly licensed at the time of the crash. If this information is missing from the MCMIS report or MCMIS indicates the wrong license class for the vehicle being operated, the Commercial Driver's License Information System (CDLIS) report will be used to verify the driver's license. Additionally, the CDLIS report is used to confirm the driver was not operating while suspended due to a drug or alcohol violation. The crash will be deemed preventable if documentation shows that the driver was not qualified.

If CDLIS is used to verify the license and the driver has renewed the license or medical certificate since the date of the crash, evidence of licensing or medical certification on the date of the crash will continue to be requested from the submitter. Failure to provide any requested information will continue to preclude a not preventable determination and result in an undecided determination.

As a reminder, for crashes resulting in a fatality, proper DOT post-accident drug and alcohol testing results or the required explanation of why the tests were not completed or not completed within the timeframes specified in § 382.303(d)(1) and (d)(2), must be submitted. The tests must be conducted in accordance with the requirements of 49 CFR part 40, which requires only the use of a urine specimen for drug testing and either breath or saliva testing for alcohol. An exception for post-accident alcohol testing conducted under the authority of Federal, State, or local officials permits the use of a blood test. The crash will be deemed preventable if the drug or alcohol test results are positive or the driver refuses to submit to a test. More information about proper drug and alcohol testing procedures can be found at *https://www.fmcsa.dot.gov/regulations/drug-alcohol-testing-program.*

Failure to provide requested documents will preclude a not preventable determination and may result in an undecided determination.

Document Requirements

FMCSA will continue to require submitters to provide the complete PAR to participate in the program. The submitter may also provide other documentation, as the burden will remain on the submitter to provide

compelling evidence showing that the crash was eligible and not preventable. Therefore, if only the PAR is submitted and it contains conflicting or insufficient information about the crash (*i.e.,* the narrative is different than the diagram or point of impact information) and FMCSA cannot determine eligibility for one of the 21 crash types, the crash will be deemed not eligible. If the crash is found to be eligible, but FMCSA does not have compelling evidence to make a determination, FMCSA will issue an undecided determination.

Additionally, if the submitter starts an RDR in DataQs without having a PAR, the submitter can save the request as a draft. Once a saved draft is inactive for more than 14 days and the crash is older than 90 days from the date of the crash, CPDP will close these requests. The submitter still has an opportunity to open a new RDR but should ensure that a PAR is uploaded with the request and confirm that the submission is completed.

Impacts to SMS and Pre-Employment Screening Program (PSP)

For any of the 21 crash types noted above, FMCSA will continue to display the crashes in SMS with notations of not preventable, preventable, or undecided and will remove crashes with not preventable determinations from the SMS Crash Indicator BASIC calculation. FMCSA will also note the not preventable determinations in PSP for 5 years. FMCSA will continue to refrain from notating preventable or undecided determinations in PSP because the driver may not be aware when the motor carrier submits a crash that results in one of those determinations.

Crash Preventability Determinations During Investigations and Safety Audits

It should be noted that the Crash Preventability Determination Program does not change FMCSA's processes for reviewing crashes during an investigation or safety audit. If an investigation or audit results in a different determination than was made through this program, FMCSA will review all information provided, and the determination made through this program may change.

Implementation of Crash Type Updates to CPDP

In order to accommodate the needed changes to FMCSA's DataQs system, FMCSA expects that to have a start date for the new crash types. These new crash types will not be retroactive, that is, a crash that occurs before the start date of the new crash types will not become eligible for submission under the CPDP after the start date. The new date will be provided in the subsequent **Federal Register** notice or on the Agency's website for the program.

For unchanged crash types and crash types with wording changes, DataQs will continue to allow submissions for crashes occurring on or after August 1, 2019, up to 5 years from the date of the crash. For example, a crash from 2020 where a CMV was struck because another motorist failed to stop at a traffic control device may be submitted after the DataQs changes are implemented.

In addition, RDRs submitted but not yet receiving a determination in crash types with wording changes will be converted into the new types by FMCSA during the DataQs programming.

The DataQs changes may require the system to be temporarily unavailable to accept new RDRs. System information will be conveyed on the program's website and on DataQs.

IV. Comments Sought

FMCSA seeks comments generally on the proposals described above. However, FMCSA has been advised that obtaining PARs from some States, specifically Oregon, is more complex. FMCSA also seeks information on any other State that generally does not provide a PAR and requests comments on what alternative official document or combination of documents the submitter could provide as a substitute for the required PAR.

Once comments are reviewed, and any needed program changes are made, the Agency will respond to comments received to this notice and announce the start of the updated program in the **Federal Register**.

Robin Hutcheson,

Administrator.

[FR Doc. 2023–07818 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2022–0094; Notice 1]

Hitachi Cable America Inc., Now Known as Proterial Cable America, Inc., and Harley-Davidson Motor Company, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: Hitachi Cable America Inc. (HCA), now known as Proterial Cable America, Inc. (PCA), and Harley-Davidson Motor Company (Harley-Davidson) (collectively, ''the Petitioners'') have determined that certain PVC, Nylon, and ''Revised Socket'' Nylon brake hose assemblies equipped in certain model year (MY) 2008–2022 Harley-Davidson motorcycles, and also sold to Harley-Davidson dealers as replacement parts, do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 106, *Brake Hoses.* HCA filed an original noncompliance report on July 27, 2022, and amended the report on August 25, 2022, October 18, 2022, October 26, 2022, November 16, 2022, and March 30, 2023. Harley-Davidson filed its initial noncompliance report dated August 9, 2022, and amended the report on December 6, 2022, February 7, 2023, February 8, 2023, and March 8, 2023. HCA petitioned NHTSA (the ''Agency'') on August 19, 2022, and amended its petition on November 10, 2022, for a decision that the subject noncompliances are inconsequential as they relate to motor vehicle safety. Harley-Davidson petitioned NHTSA on September 2, 2022, and amended its petition on December 29, 2022, for a decision that the subject noncompliances are inconsequential as they relate to motor vehicle safety. This document announces receipt of the Petitioners' petitions.

DATES: Send comments on or before May 15, 2023.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited in the title of this notice and may be submitted by any of the following methods:

- *Mail:* Send comments by mail addressed to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver comments by hand to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Docket Section is open on weekdays from 10:00 a.m. to 5:00 p.m., except on Federal Holidays.
- *Electronically:* Submit comments electronically by logging onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov/.* Follow the online instructions for submitting comments.

• Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petitions are granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the internet at *https://www.regulations.gov* by following the online instructions for accessing the dockets. The docket ID number for these petitions is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000 (65 FR 19477–78).

FOR FURTHER INFORMATION CONTACT: Manuel Maldonado, General Engineer, NHTSA, Office of Vehicle Safety Compliance, (202) 366–7235.

SUPPLEMENTARY INFORMATION:

I. Overview: The Petitioners determined that certain PVC, Nylon, and ''Revised Socket'' Nylon brake hose assemblies equipped in certain MY 2008–2022 Harley-Davidson Touring, CVO Touring, Trike, Softail, Revolution Max, VRSC, XG750A, and XL Sportster motorcycles, and also sold as replacement parts, do not fully comply with paragraph S5.3 of FMVSS No. 106, *Brake Hoses* (49 CFR 571.106).

HCA filed its initial noncompliance report on July 27, 2022, and amended the report on August 25, 2022, October 18, 2022, October 26, 2022, November 16, 2022, and March 30, 2023, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* HCA petitioned NHTSA on August 19, 2022, and later amended its petition on November 10, 2022, for an exemption from the notification and remedy requirements of 49 U.S.C. chapter 301 on the basis that the subject noncompliances are inconsequential as they relate to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance.*

Harley-Davidson filed its initial noncompliance report on August 9, 2022, and later amended the report on December 6, 2022, February 7, 2023, February 8, 2023, and March 8, 2023, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* Harley-Davidson petitioned NHTSA on September 2, 2022, and amended its petition on December 29, 2022, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance.*

This notice of receipt of the Petitioners' petitions is published under 49 U.S.C. 30118 and 30120 and does not represent any Agency decision or another exercise of judgment concerning the merits of the petitions.

II. Motorcycles and Equipment Involved: Approximately 6,174,355 PVC, Nylon, and ''Revised Socket'' Nylon brake hose assemblies manufactured by HCA, between February 28, 2007, and October 13, 2022, were reported by HCA as the population of the recall. Approximately 1,527,260 MY 2008–2022 Harley-Davidson Touring, CVO Touring, Trike, Softail, Revolution Max, VRSC, XG750A, and XL Sportster motorcycles, manufactured between May 17, 2007, and October 16, 2022, may have been equipped with the noncompliant brake hoses assemblies manufactured by HCA.

III. Noncompliance: The Petitioners explain that certain Nylon, and ''Revised Socket'' Nylon assemblies do not meet high temperature impulse (HTI), brake fluid compatibility (BFC), constriction, whip resistance, and water absorption whip resistance requirements, and certain PVC assemblies did not meet the whip resistance, water absorption whip resistance, constriction, tensile, burst, and high temperature impulse requirements. Therefore, the subject brake hose assemblies do not comply with paragraph S5.3 of FMVSS No. 106.

IV. Rule Requirements: Paragraphs S5.3, S5.3.1, S5.3.2, S5.3.3, S5.3.4, S5.3.7, S5.3.9, and S5.3.12 of FMVSS No. 106 include the requirements relevant to the petitions, and are broadly summarized herein. A hydraulic brake hose assembly must be capable of meeting the requirements when tested under the conditions specified in the standard and the applicable procedures of paragraph S6. Paragraph S5.3.1 pertains to the constriction requirement that every inside diameter of the brake hose assembly shall not be less than 64 percent of the nominal inside diameter of the brake hose. Paragraph 5.3.2 pertains to the expansion and burst strength requirement that the maximum expansion of a hydraulic brake hose assembly not exceed the values specified by Table 1 at the given psi. The hydraulic brake hose assembly must then withstand a water pressure of 4,000 psi for 2 minutes without rupture, then not rupture at the less than 7,000 psi for a ⅛ inch hose or smaller or at less than 5,000 psi for a hose with a diameter larger than ⅛ inch. Paragraph S5.3.3 pertains to the whip resistance requirement that the brake hose assembly not rupture when subjected to a 35-hour continuous run on a flexing machine. Paragraph S5.3.4 pertains to the forces that a brake hose assembly must withstand without separation of the hose from its end fittings. Paragraph S5.3.7 pertains to water absorption and whip resistance, and requires the hose not to rupture when subjected to a 35-hour continuous run on a flexing machine after immersion in water for 70 hours. Paragraph S5.3.9 provides the requirements for BFC after the brake hose assembly has been exposed to brake fluid for a specified time at a specified temperature. These requirements include compliance with constriction, per S5.3.1, as well as withstanding water pressure of 4,000 psi for 2 minutes, and then shall not rupture at less than 5,000 psi. Paragraph S5.3.12 describes the HTI test, which requires the brake hose assembly to withstand pressure cycling, followed by a 2-minute, 4,000 psi pressure hold test, during which the hose shall not rupture, and then shall not subsequently burst at a pressure less than 5,000 psi.

V. Summary of the Petitioners' Petitions: The following views and arguments presented in this section, ''V. Summary of the Petitioners' Petitions,'' are the views and arguments provided by the Petitioners. These views and arguments have not been evaluated by the Agency and do not reflect the views of the Agency. The Petitioners describe

the subject noncompliances and contend that the noncompliances are inconsequential as they relate to motor vehicle safety. The Petitioners' arguments for PVC, Nylon, and ''Revised Socket'' Nylon hoses are combined and considered together, unless otherwise noted.

The Petitioners believe that the subject noncompliances are inconsequential to motor vehicle safety for the following reasons, which are summarized in detail below:

1. The Petitioners state that their own testing yielded ''variable,'' ''inconsistent,'' and ''nonuniform'' results with respect to certain provisions of FMVSS No. 106. Furthermore, they argue that, while there were failures, the leaking exhibited was minimal, and do not pose a significantly greater risk to braking performance.

2. According to the Petitioners, laboratory testing does not reflect use of these brake hose assemblies in the ''real-world.''

3. The Petitioners argue that supplemental testing demonstrates that under extreme conditions, any noncompliances found in the subject brake hose assemblies are inconsequential to motor vehicle safety. Supplemental testing was performed on similar or affected brake hose assemblies, and the Petitioners believe that those test results support a determination of inconsequential noncompliance.

4. The Petitioners contend that prior Agency decisions on petitions for inconsequential noncompliance support a finding of inconsequential noncompliance for the Petitioners' subject petitions.

5. The Petitioners conducted a review and analysis of field data and concluded that the review revealed no documented crashes or injuries attributable to the Petitioners' FMVSS No. 106 noncompliances.

The following summarizes, in more detail, some of the main arguments made by the Petitioners.

With respect to the testing, HCA states that ''failures involved leaks at the pre-crimp, which—as Exponent explains in its Supplemental Technical Report—is not an anticipated failure mode because the rotational test motion applied during Water Whip and Whip testing stresses the hose element, not the end fitting pre-crimp area.'' [1] Further, the petitioners argue that the leaks that were observed did not result in observed pressure loss.

The Petitioners also claim that laboratory testing does not reflect use of these brake hose assemblies in the ''real-world.'' The Petitioners contend that Harley-Davidson motorcycles do not experience the extreme stresses that brake hose assemblies are subjected to during FVMSS No. 106 testing. The Petitioners specifically explain that the ''real-world'' forces that brake hose assemblies are subjected to in the subject vehicles are principally vertical in nature between their upper and lower suspension stopping points. The Petitioners also argue that by contrast, the whip test applies principally rotational force, thus, the Petitioners believe that it does not reflect the way assemblies are typically mounted and utilized on a motorcycle. For this reason, the Petitioners argue that the whip test is sufficient to demonstrate that a brake hose assembly is resistant to dynamic fatigue, but a failure does not necessarily mean that an assembly will fail when exposed to ''real-world'' forces.

HCA's contractor inspected 156 ''real-world'' motorcycles spanning model years 2008–2020, which HCA characterizes as motorcycles that are equipped with brake hose assemblies that are included in the scope of HCA's recall. HCA explains that no signs of hose fatigue were observed on those brake hose assemblies.

The Petitioners also claim that supplemental testing demonstrates that under extreme conditions, any noncompliance found in the subject brake hose assemblies is inconsequential to motor vehicle safety. Supplemental testing was performed on similar or affected brake hose assemblies, and the Petitioners believe that those results support a determination of inconsequential noncompliance.

Supplemental testing established by the Petitioners included full vehicle brake performance and/or accelerated durability testing on similar brake hose assemblies or on samples of affected brake hose assemblies. The Petitioners characterize their supplemental tests in various ways to include the following: accelerated durability testing, full vehicle brake performance testing, ABS certification testing, testing in accordance with FMVSS No. 122, laboratory-based dynamic fatigue test, pressure and time sensitivity testing, room temperature durability testing, elevated temperature durability testing, accelerated durability suspension stroke testing, accelerated durability suspension stroke testing following water absorption, and lifetime accelerated durability testing.

The Petitioners also claim that the following Agency decisions on petitions for inconsequential noncompliance support a finding of inconsequentiality for these petitions:

- Daimler Trucks North America, Grant of Petition for Decision of Inconsequential Noncompliance, 87 FR 14325 (March 14, 2022);
- Coupled Products II, Grant of Petition for Decision of Inconsequential Noncompliance, 70 FR 35774 (June 21, 2005);
- Coupled Products, Grant of Appeal of Decision on Inconsequential Noncompliance, 70 FR 32397 (June 2, 2005);
- General Motors, Grant of Petition for Determination of Inconsequential Noncompliance, 57 FR 1511 (January 14, 1992);
- Volvo GM Heavy Truck Corporation, Grant of Petition for Determination of Inconsequential Noncompliance, 57 FR 1511 (January 14, 1992);
- Navistar International and Mack Trucks, Inc., Grant of Petitions for Determination of Inconsequential Noncompliance, 56 FR 51440 (October 11, 1991);
- Sumitomo Rubber Industries, Inc., Grant of Petition for Decision of Inconsequential Noncompliance; 83 FR 13002 (March 26, 2018);
- Ford Motor Co., Grant of Petition for Determination of Inconsequential Noncompliance; 45 FR 29160 (May 1, 1980);
- Philatron Int'l, Grant of Petition for Determination of Inconsequential Noncompliance; 57 FR 26687 (June 15, 1992); and
- FCA US, Denial of Petition for Determination of Inconsequential Noncompliance, 87 FR 61432 (October 11, 2022).

Finally, the Petitioners petitions included a review and analysis of field data. The Petitioners concluded that the review revealed no documented crashes or injuries attributable to the Petitioners' FMVSS No. 106 noncompliances. The Petitioners searches included the following types of records:

- NHTSA Vehicle Owner Questionnaire (''VOQ'') records;
- Legal claims and lawsuits;
- Warranty data; and
- Customer contacts to Harley-Davidson's Technical Service Team's Call Center.

The Petitioners conclude by stating their belief that the subject noncompliances are inconsequential as they relate to motor vehicle safety and their petitions to be exempted from

[1] *See* HCA's supplemental petition dated November 10, 2022, page 9 available on the docket.

providing notification of the noncompliances, as required by 49 U.S.C. 30118, and a remedy for the noncompliances, as required by 49 U.S.C. 30120, should be granted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject motorcycles and brake hose assemblies that the Petitioners no longer controlled at the time when the Petitioners determined that the noncompliances existed. However, any decision on these petitions does not relieve equipment and motorcycle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant motorcycles and brake hose assemblies under their control after the Petitioners notified distributors and dealers that the subject noncompliances existed.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8)

Otto G. Matheke III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2023–07830 Filed 4–12–23; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Joint Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. Due to unavoidable circumstances with the beginning of the TAP year, we will not be able to meet the 15-calendar notice threshold. This meeting will be held via teleconference.

DATES: The meeting will be held Thursday, April 26, 2022.

FOR FURTHER INFORMATION CONTACT: Rosalind Matherne at 1–888–912–1227 or 202–317–4115.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Thursday, April 26, 2022, at 2 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. For more information, please contact Rosalind Matherne at 1–888–912–1227 or 202–317–4115, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.*

The agenda will include reports from the committees, and subcommittee discussions on priorities the TAP will focus on for the 2023 year. Public input is welcomed.

Dated: April 7, 2023.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2023–07750 Filed 4–12–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting: correction

SUMMARY: In the **Federal Register** notice that was originally published on April 6, 2023, (Volume 88, Number 66, Page 20612) the day for this meeting has been corrected from Wednesday to Thursday, April 13, 2023, at 12 p.m. Eastern Time. All other meeting details remain unchanged.

DATES: The meeting will be held Thursday, April 13, 2023.

FOR FURTHER INFORMATION CONTACT: Conchata Holloway at 1–888–912–1227 or 214–413–6550.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee will be held Thursday, April 13, 2023, at 12 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Conchata Holloway. For more information, please contact Conchata Holloway at 1–888–912–1227 or 214–413–6550, or write TAP Office, 1114 Commerce St. MC 1005, Dallas, TX 75242 or contact us at the website: *http://www.improveirs.org.* The agenda includes: Welcoming; Roll Call; Agenda Review; Designated Federal Officer Report; National Office Report; Chair Report; Minute Review Approval/Denial; Public Comment; Subcommittee Reports; Outreach Report; Screening Report; Internal Communications Briefing; Action Items; Roundtable; and Closing.

Dated: April 7, 2023.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2023–07753 Filed 4–12–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Voluntary Service National Advisory Committee, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. 10, that the VA Voluntary Service (VAVS) National Advisory Committee (NAC) will meet on April 26–28, 2023 at the DoubleTree by Hilton located at 3203 Quebec Street in Denver, Colorado 80207. The meeting sessions will begin and end as follows:

Date(s)	Time(s)
Wednesday, April 26, 2023.	9:00 a.m. to 7:30 p.m. Mountain Time (MT).
Thursday, April 27, 2023.	8:30 a.m. to 4:30 p.m. MT.
Friday, April 28, 2023	9:00 a.m. to 5:00 p.m. MT.

The meeting sessions are open to the public.

The Committee, comprised of 56 major Veteran, civic, and service organizations, advises the Secretary, through the Under Secretary for Health, on the coordination and promotion of volunteer activities and strategic partnerships within VA health care facilities, in the community, and on matters related to volunteerism and charitable giving.

Agenda topics will include the NAC goals and objectives; review of minutes from the April 27–29, 2022 meeting; an update on VA Center for Development and Civic Engagement (CDCE) activities;

Veterans Health Administration update; subcommittee reports; review of standard operating procedures; review of organization data; Federal Advisory Committee Act training provided by the VA Advisory Committee Management Office; embracing whole health and creative arts; inclusion, diversity, equity and access; caregiver volunteering; safe integration of volunteers in impactful assignments; PACT and COMPACT Act implications; and any new business.

The public may submit written statements for the Committee's review to Mr. Prince Taylor, Designated Federal Officer, VA Center for Development and Civic Engagement (15CDCE), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, or email at *Prince.Taylor@VA.gov*. Any member of the public wishing to attend the meeting or seeking additional information should contact Mr. Taylor at 202–461–6948.

Dated: April 10, 2023.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2023–07827 Filed 4–12–23; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 88 Thursday,

No. 71 April 13, 2023

Part II

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for Rufa Red Knot; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R5–ES–2021–0032; FF09E21000 FXES1111090FEDR 234]

RIN 1018–BF87

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for Rufa Red Knot

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; revisions and reopening of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the reopening of the comment period on our July 15, 2021, proposed rule (hereinafter the ''2021 proposed rule'') to designate critical habitat for the rufa red knot (*Calidris canutus rufa*) under the Endangered Species Act of 1973, as amended (Act). In this document, we present revisions to the critical habitat designation we proposed for the species in the 2021 proposed rule. As a result of the critical habitat revisions, we now propose to designate a total of approximately 683,405 acres (276,564 hectares) as critical habitat for the rufa red knot across 127 units (18 of which are further subdivided into 46 subunits) in Massachusetts, New York, New Jersey, Delaware, Virginia, North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Louisiana, and Texas. This amounts to an overall increase of 32,615 acres (13,199 hectares) in our proposed critical habitat designation for the species. This revision includes seven new units in Massachusetts, New York, Virginia, North Carolina, South Carolina, and Georgia; revised units in Massachusetts, New Jersey, South Carolina, Georgia, and Texas; and corrections to reported acreages/hectares for four other units and the total acreage in the 2021 proposed rule. We are reopening the comment period to allow all interested parties the opportunity to comment on the 2021 proposed rule, as well as the revisions described in this document. Comments previously submitted need not be resubmitted, as they will be fully considered in preparation of the final rule. If the determination is finalized, the final rule will include responses to the comments previously received from the 2021 proposed rule and any comments received as part of this document's reopening of comments.

DATES: The comment period for the 2021 proposed rule is reopened. So that we can fully consider your comments in our final determination, submit them on or before May 30, 2023. 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.

ADDRESSES:

Document availability: You may obtain copies of the 2021 proposed rule and associated documents on the internet at *https://www.regulations.gov* under Docket No. FWS–R5–ES–2021–0032.

Written comments: You may submit written comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Search box, enter the docket number or RIN for this rulemaking (presented above in the document headings). For best results, do not copy and paste either number; instead, type the docket number or RIN into the Search box using hyphens. Then, click on the Search button. On the resulting page, in the panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment.''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R5–ES–2021–0032, 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 Public Comments, below, for more information).

FOR FURTHER INFORMATION CONTACT: Eric Schrading, Field Supervisor, U.S. Fish and Wildlife Service, New Jersey Ecological Services Field Office, 4 East Jimmie Leeds Road, Suite 4, Galloway, NJ 08205; telephone 609–382–5272. 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:

Public Comments

We will accept written comments, information, and additional data during this reopened comment period on our July 15, 2021, proposed rule to designate critical habitat for the rufa red knot (86 FR 37410) (hereinafter the ''2021 proposed rule''), the revisions to the proposed critical habitat designation that are described in this document, and our revised draft economic assessment (DEA) of the proposed critical habitat designation. We will consider information and recommendations from all interested parties. We are interested in comments concerning:

(1) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including information to inform the following factors that the regulations identify as reasons why designation of critical habitat may be not prudent:

(a) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(b) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(c) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States; or

(d) No areas meet the definition of critical habitat.

(2) Specific information on:

(a) The amount and distribution of rufa red knot habitat;

(b) What areas, that were occupied at the time of listing (specifically referring to January 12, 2015, which is the effective date for the December 11, 2014, final listing rule (79 FR 73705)) and that contain the physical or biological features essential to the conservation of the species, should be included in the designation and why;

(c) Special management considerations or protection that may be needed in critical habitat areas we are proposing, including managing for the potential effects of climate change; and

(d) What areas not occupied at the time of listing are essential for the conservation of the species. We particularly seek comments regarding:

(i) Whether occupied areas are adequate for the conservation of the species; and

(ii) Specific information regarding whether or not unoccupied areas would, with reasonable certainty, contribute to the conservation of the species and contain at least one physical or biological feature essential to the conservation of the species.

(3) Information on land ownership and land use designations and current or planned activities in the subject areas and their possible impacts on the proposed critical habitat.

(4) Information on the projected and reasonably likely impacts of climate change on the rufa red knot's proposed critical habitat.

(5) Any probable economic, national security, or other relevant impacts of designating any area that may be included in the final designation, and the benefits of including or excluding specific areas.

(6) Information on the extent to which the description of probable economic impacts in the draft economic analysis is a reasonable estimate of the likely economic impacts.

(7) Whether any specific areas we are proposing for critical habitat designation should be considered for exclusion under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any specific area outweigh the benefits of including that area under section 4(b)(2) of the Act, in particular those based on a conservation program or plan, and why. These may include Federal, Tribal, State, county, local, or private lands with permitted conservation plans covering the species in the area such as habitat conservation plans, safe harbor agreements, or conservation easements, or non-permitted conservation agreements and partnerships that would be encouraged by designation of, or exclusion from, critical habitat. Detailed information regarding these plans, agreements, easements, and partnerships is also requested, including:

(a) The location and size of lands covered by the plan, agreement, easement, or partnership;

(b) The duration of the plan, agreement, easement, or partnership;

(c) Who holds or manages the land;

(d) What management activities are conducted;

(e) What land uses are allowable; and

(f) If management activities are beneficial to the rufa red knot and its habitat.

(8) Ongoing or proposed conservation efforts that could result in direct or indirect ecological benefits to the associated habitat for the rufa red knot; as such, those efforts would lend to the recovery of the species and therefore areas covered may be considered for exclusion from the final critical habitat designation.

(9) Whether we could improve our data or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comments or to better effectuate the purposes of the Act.

If you submitted comments or information on the 2021 proposed rule or DEA during the comment period that was open from July 15, 2021, to September 13, 2021, please do not resubmit them. Any such comments are already part of the public record of this rulemaking proceeding, and we will fully consider them in the preparation of our final determination. Once the determination is finalized, the final rule will take into consideration all written comments and any additional information we receive during both comment periods. The final decision may differ from this revised proposed rule, based on our review of all information we receive during this rulemaking proceeding.

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

If you submit a comment via *https://www.regulations.gov,* your entire comment—including any personal identifying information—will be posted on the website. We will post all hardcopy comments on *https://www.regulations.gov* as well. If you submit a hardcopy comment 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.

Comments and materials we receive, as well as supporting documentation we used in preparing the proposed rule and DEA, will be available for public inspection on *https://www.regulations.gov* at Docket No. FWS–R5–ES–2021–0032, or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, New Jersey Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**). You may obtain copies of the proposed rule and the DEA on the internet at *https://www.regulations.gov* at Docket No. FWS–R5–ES–2021–0032, or by mail from the New Jersey Ecological Services Field Office.

Background

It is our intent to discuss in this document only those topics directly relevant to these revisions of the proposed designation of critical habitat. For more information on the species, its habitat, and previous Federal actions concerning the rufa red knot, refer to the 2021 proposed rule. Proposed critical habitat for the rufa red knot consists of the area described in the 2021 proposed rule, as modified by the revisions explained in this document; both together constitute the revised proposed designation of critical habitat.

On July 15, 2021, we published the 2021 proposed rule to designate critical habitat for the federally threatened rufa red knot in 120 units (18 of which are further subdivided into 46 subunits) encompassing approximately 649,066 ac (262,667 ha) in Massachusetts, New York, New Jersey, Delaware, Virginia, North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Louisiana, and Texas. In addition, we announced the availability of a DEA of the proposed critical habitat designation. We accepted comments on the proposed rule and DEA for 60 days, ending September 13, 2021. We also received a congressional request for additional time to review and comment on the proposed rule. Based on information we received during the public comment period and our reanalysis of the best available information, we propose to revise the critical habitat designation and are, therefore, reopening the comment period to allow the public additional time to submit comments on both the 2021 proposed rule as well as the revisions described in this document.

New Information and Revisions to Proposed Critical Habitat

During the public comment period, we received 92 comment letters, 59 of which contained substantive comments on the proposed critical habitat designation. We became aware of some new information during this time period, including some information based on comments received (*i.e.,* site-specific survey or observation data from multiple sources, and flock count data across the range of the species from *bandedbirds.org*). This new information and comments received during the open comment period prompted us to reevaluate the best available information across the range of the species. In some areas, this resulted in the addition or revision of unit boundaries per the methodology used to designate critical habitat (see *https://www.regulations.gov,* Docket No. FWS–

R5–ES–2021–0032, Supplementary Document FWS–R5–ES–2021–0032–0004). This information has resulted in changes to six units described in the 2021 proposed rule's critical habitat designation, and the addition of seven units based on areas that we found to meet the definition of critical habitat. No new areas are being proposed beyond the coastal States and counties already included in the 2021 proposed rule's critical habitat designation. The revised and new units are described in this document.

In this document, we propose certain revisions to the critical habitat designation we proposed for the rufa red knot in the 2021 proposed rule. Because of these revisions, the numbering for some of the critical habitat units has changed from the 2021 proposed rule, although the names and descriptions remain the same for these units/subunits (with the exception of one unit in Georgia (GA–7) with a name change). All revisions to unit numbers are described below and listed in table 1.

Specifically, there are no changes within the States of Alabama, Louisiana, and Mississippi. We corrected acreages, hectares, or both for Unit DE–4 in Delaware, VA–14 in Virginia, GA–9 in Georgia, and FL–1 in Florida that were incorrectly reported in the 2021 proposed rule; no other changes were made to these or other units in Delaware, Virginia, and Florida. We propose the following unit revisions or unit additions in the States of Massachusetts, New York, New Jersey, Virginia, North Carolina, South Carolina, Georgia, and Texas; all revisions or additions are areas occupied by the rufa red knot at the time of listing. Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely, by vagrant individuals). Revisions are summarized here and full descriptions and acreage changes follow in the ''Revised Proposed Critical Habitat Designation'' section, below:

(1) *Massachusetts:* We are revising unit numbers because we are adding one unit based on our review of comments received during the previous open comment period. Specifically, this addition is based on our reanalysis and consideration of observation data (Harrington *et al.* 2010, entire; Faherty 2021a, pers. comm.; Faherty 2021b, pers. comm.), and consideration of flock count observations between 2010 and 2019 from *bandedbirds.org* (BandedBirds 2021, entire). The new Unit MA–1 (Nauset Marsh) occurs in the towns of Orleans and Eastham in Barnstable County, to include the area of Salt Bay Pond, Nauset Bay, Nauset Spit, and Coast Guard Beach. We are also revising Unit MA–2 (Pleasant Bay; formerly Unit MA–1) based on our review of the same *bandedbirds.org* flock count observations. This revised unit begins at the northeastern end of Little Pleasant Bay and continues south along Nauset Beach South and North Beach to North Beach Island, terminating at the natural channel between North Beach Island and South Beach Island (Chatham).

(2) *New York:* We are revising unit numbers because we are adding one unit based on our reanalysis of information in our files (*i.e.,* past surveys by Virginia Tech conducted on Fire Island for the Service between 2016 and 2018). In other words, during our reevaluation of the best available information, we determined an error when applying the methodology and this unit should have been included previously. The new Unit NY–2 (Old Inlet) occurs in Suffolk County, surrounded by the waters of Bellport Bay and the Atlantic Ocean. Also, we corrected the county name on the map for NY–1 to Suffolk County.

(3) *New Jersey:* We are revising the boundary of Unit NJ–1 to reflect the development and growth of a new island east of Little Beach Island. Little Beach Island is within the Edwin B. Forsythe National Wildlife Refuge (NWR). The new island, located approximately 1,250 feet (ft) (381 meters (m)) offshore of Little Beach, is State-owned land. Prior to emerging as a full island in 2020, a smaller exposed shoal was present in this area in 2017, and was known to support rufa red knots during fall migration by 2019. Based on the high quality of this habitat, the high level of use by rufa red knots, and its protection from disturbance, we made a minor adjustment to the boundary of this unit to include the entire island at its current size and configuration. Due to the highly dynamic and shifting nature of this new island, the expanded boundary also includes areas of open waters surrounding the island in which shoaling was indicated in recent years. These minor adjustments to the boundary of this unit were made by referencing recent base maps that show the current extent of the island.

(4) *Virginia:* We are revising some unit numbers because we are adding two units based on rufa red knot occupancy and habitat use information received by The Nature Conservancy (TNC) and also recommended by the State of Virginia (Virginia Department of Wildlife Resources 2021, p. 1; TNC 2021, p. 2; Wilke 2021, pers. comm.). The new Unit VA–12 (Ship Shoal Island) occurs in Northampton County, including both Ship Shoal Island and the area known as Godwin Island. The new unit VA–15 (Fisherman Island) occurs in Northampton County at the mouth of the Chesapeake Bay and just south of the tip of the Eastern Shore peninsula, surrounded by the waters of the Chesapeake Bay and Atlantic Ocean. As noted above, we also corrected the acreage/hectares that were incorrectly reported for Unit VA–14 (Smith Island; formerly VA–13) in the 2021 proposed rule.

(5) *North Carolina:* We are revising some unit numbers because we are adding one unit based on rufa red knot occupancy and habitat use information received from Audubon North Carolina (Audubon North Carolina 2021, p. 2; Addison 2021, pers. comm.). The new Unit NC–6 (Lea-Hutaff Island) occurs in Pender and New Hanover Counties, stretching from the west side of New Topsail Inlet channel west across the Rich Inlet channel to the northeast end of Figure Eight Island.

(6) *South Carolina:* We are revising some unit numbers because we are adding one unit based on our review of comments received from the South Carolina Department of Natural Resources (SCDNR) (SCDNR 2021, p. 3). The new Unit SC–22 (Bay Point Beach) occurs east of Hilton Head Island on the eastern side of Port Royal Sound in Beaufort County. We are also revising and renaming Unit SC–21 (Fripp Island, Pritchards Island, and Little Capers Island Beaches) and revising Unit SC–25 (Turtle Island and Tomkins Island Beaches; formerly Unit SC–24, Turtle Island Beach) based on our review of comments received from the SCDNR (SCDNR 2021, p. 3). Units SC–21 and SC–25 include both a change to the unit name and the unit boundary. The revised Unit SC–21 begins at the Fripp Inlet shoreline of Fripp Island, continues along the Atlantic coast shoreline of Fripp Island, and now extends along the Atlantic coast shoreline of Pritchards Island and Little Capers Island. The revised Unit SC–25 begins at the Calibogue Sound shoreline of Turtle Island and now includes all of Tompkins Island in Calibogue Sound east of Turtle Island, although the adjusted boundary actually resulted in an overall decrease of 27 ac (11 ha) in unit size compared to the 2021 proposed rule.

(7) *Georgia:* We are revising unit numbers because we are adding one unit and revising two units based on our review of comments received from the Georgia Department of Natural Resources (GADNR) (GADNR 2021, p. 2; Smith 2021, pers. comm.). The new Unit GA–1 (Cockspur Island and Daymark Island Beaches) occurs in the Savannah River adjacent to Tybee Island in Chatham County. Units GA–5 and GA–10 include both a change to the unit name and the unit boundary; we also renamed Unit GA–7 to St. Catherine's Island Beach and St. Catherine's Island Bar (formerly St. Catherine's Island Beach). The revised Unit GA–5 (Little Ogeechee River Shoreline and Raccoon Key; formerly Raccoon Key) now begins at the Green Island shoreline of the Little Ogeechee River, continues east along the shorelines of Little Wassaw Island and Pine Island to the Odingsell River entrance behind Wassaw Island. The revised Unit GA–10 (Queens Island, Wolf Island, Egg Island, Little Egg Island, and Little Egg Bar; formerly Wolf Island, Egg Island, Little Egg Island, and Little Egg Island Bar) now begins at the Black River shoreline of Queens Island and extends south along the Wolf Island shoreline, which includes Wolf Island Bar, to the eastern and southern shorelines of Little Egg Island Bar Natural Area southwest to Egg Island in the Altamaha Sound. As noted above, we also corrected the acreage/hectares that were incorrectly reported for Unit GA–9 (Sapelo Island Beach; formerly GA–8), and changed the name for Unit GA–7 to ''St. Catherine's Island Beach and St. Catherine's Island Bar'' (formerly GA–6, St. Catherine's Island Beach) in the 2021 proposed rule.

(8) *Texas:* We are revising two proposed units of critical habitat—Units TX–1 (Rollover Pass to Bolivar Flats) and TX–11 (South Bay/Boca Chica)—based on our reanalysis of the best available information, including comments received during the open comment period. In our review of the flock count observation data from *bandedbirds.org* provided during the open comment period, we identified an error in the proposed boundary of Unit TX–1, which occurs in Galveston County. Based on eBird data and our assessment of habitat features, as described in the 2021 proposed rule, unit description, Unit TX–1 should include additional sand flats habitat on the bayside of Rollover Pass. Additionally, due to an oversight, we are proposing including additional adjacent habitat to the proposed Unit TX–11, which occurs in Cameron County. This unit should be extended to the east of South Bay to include important habitat features that should have been included previously; although the boundary should change to incorporate adjacent habitat features, the detailed unit description will not change.

Finally, when we conducted a reanalysis of the best available information, we determined two incorrect total State acreages for rufa red knot proposed critical habitat that affected the calculation for the overall/total acreage of the proposed critical habitat designation. In short, the total acreages calculated for the States of North Carolina and Florida were incorrectly summed, resulting in the overall proposed critical habitat acreage reported as 649,066 ac (262,668 ha). With the corrected summed values for these two States, the total acreage for the 2021 proposed rule should have been 650,791 ac (263,366 ha). When considering this corrected total acreage and the revisions, additions, and corrections described herein, the revised proposed critical habitat designation total is 683,405 ac (276,564 ha), resulting in an overall increase in proposed critical habitat of 32,615 ac (13,199 ha).

All of the additional unit acreage in the above-described revised and new units were occupied at the time of listing and are currently occupied, contain one or more of the physical or biological features to support life-history functions essential to the conservation of the rufa red knot, and may require special management considerations or protection from threats as described in the 2021 proposed rule. For clarity, we also propose to add short textual descriptions of each proposed unit in the regulatory text of the critical habitat designation.

The Draft Economic Analysis (DEA) for the proposed critical habitat designation, entitled: *Draft Screening Analysis of the Likely Economic Impacts of the Proposed Rule to Designate Critical habitat for the Rufa Red Knot* (IEc 2021a) has been revised to include additional information for the counties containing the new units (MA–2, NY–2, VA–12, VA–15, NC–6, SC–22, and GA–1) and revised units (Units NJ–1, SC–21, SC–25, GA–5, GA–10, TX–1, and TX–11) (IEc 2021b). Based on consultation history for the rufa red knot and with consideration of the areas added in this revised proposed rule, the number of future consultations, including technical assistances, is likely to be approximately 250 per year on average. The additional administrative cost of addressing adverse modification in these consultations is likely to be less than $550,000 per year. This represents a 15 percent increase in cost relative to the April 2021 version of the DEA, which also likely overstates rather than understates the impacts (IEc 2021b, p. 17).

Physical or Biological Features Essential to the Conservation of the Species

For a full description of the physical or biological features essential to the conservation of the rufa red knot, refer to the 2021 proposed rule. No changes were made to the physical or biological features, which include:

(1) Beaches and tidal flats used for foraging;

(2) Upper beach areas used for roosting, preening, resting, or sheltering;

(3) Ephemeral and/or dynamic coastal features used for foraging or roosting;

(4) Ocean vegetation deposits or surf-cast wrack used for foraging and roosting;

(5) Intertidal peat banks used for foraging and roosting;

(6) Features landward of the beach that support foraging or roosting; and,

(7) Artificial habitat mimicking natural conditions or maintaining the physical or biological features 1 to 6 (above).

Revised Proposed Critical Habitat Designation

In total, we now propose to designate approximately 683,405 ac (276,564 ha) in 127 units (18 of which are further subdivided into 46 subunits) as critical habitat for rufa red knot in Massachusetts, New York, New Jersey, Delaware, Virginia, North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Louisiana, and Texas. The proposed critical habitat areas described below constitute our best assessment, at this time, of areas that meet the definition of critical habitat, and all units were occupied at the time of listing and are considered currently occupied by the species. Table 1, below, shows the proposed unit or subunit names, land ownership, and approximate acreage. Where appropriate, table 1 also notes the previous number for units for which the numbering has changed.

As noted in the 2021 proposed rule, the land ownership values in many (but not all) proposed critical habitat units also include a category called ''uncategorized lands.'' For the purposes of this analysis and proposed critical habitat designation, this category refers to open water. Although open water is not rufa red knot habitat *per se,* it is an integral part of the habitat mosaic that these birds require. Rufa red knots use

the edges of certain coastal ponds, marsh blowouts, salt pannes, and sand or mud flats that may be classified by some States as open water if they are submerged during high tides. Additionally, open waters at inlets are regularly reshaped by natural coastal processes that create and maintain dynamic and ephemeral rufa red knot habitat features, such as shoals and spits.

The areas we propose as critical habitat for the rufa red knot are organized by State, north to south; thus, some units were renumbered when new units were included in between other units that were presented in the 2021 proposed rule's critical habitat designation. This document presents brief descriptions of the revised and new units, including the reasons why they meet the definition of critical habitat for the rufa red knot. Also, many of the proposed units presented in the 2021 proposed rule (including some of the revised and new units presented in this document) overlap in part or whole with existing critical habitat designated for one or more other federally threatened species (*i.e.,* the piping plover *(Charadrius melodus),* the loggerhead sea turtle *(Caretta caretta),* the Gulf sturgeon *(Acipenser oxyrinchus desotoi),* and the West Indian manatee *(Trichechus manatus)*), and one federally endangered species (*i.e.,* the aboriginal prickly-apple *(Harrisia aboriginum)*). Table 2, below, shows the acreage of overlap between the rufa red knot proposed critical habitat designation and the existing critical habitat designated for these other federally listed species, including notation of changes based on this revised proposed rule.

Additional considerations for the previously proposed units and the revised or new units presented in this document include:

(1) Most of the units contain highly dynamic barrier beaches and intertidal seashore areas that are covered at high tide and uncovered at low tide. This area has the potential to vary year-to-year. In other words, the precise location of the physical or biological features may shift daily as a result of tides, but also may shift over time somewhat because of the intrinsically dynamic nature of shorelines and due to sea level rise. In general, the physical or biological features we describe are the intertidal areas and sandy beaches up to the vegetated or developed areas that do not contain the physical or biological features.

(2) The availability of different habitats based on the tide cycle may also cause rufa red knots to vary foraging or roosting locations throughout a day and/or forage at night.

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE RUFA RED KNOT

Critical habitat unit or subunit name (State)	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes	Previous unit numbering
Massachusetts					
MA–1 Nauset Marsh	Federal	1,340	543	New Unit	New Unit.
	State	0	0		
	Private/Other	136	55		
	Uncategorized	744	301		
	Total	2,219	899		
MA–2 Pleasant Bay	Federal	126	51	No Change	Formerly MA–1.
	State	0	0	No Change.	
	Private/Other	2,005	812	+409 ac (166 ha).	
	Uncategorized	2,827	1,144	+193 ac (78 ha).	
	Total	4,959	2,007	+602 ac (244 ha).	
MA–3 Monomoy and South Beach Islands.	Federal	4,047	1,638	No Change	Formerly MA–2.
	State	0	0		
	Private/Other	1,045	423		
	Uncategorized	0	0		
	Total	5,093	2,061		
New York					
NY–1 Moriches Inlet	Federal	78	32	No Change	No Change.
	State	63	25		
	Private/Other	163	66		
	Uncategorized	697	282		
	Total	1,001	405		
NY–2 Old Inlet	Federal	1,481	599	New Unit	New Unit.
	State	232	94		
	Private/Other	67	27		
	Uncategorized	0	0		
	Total	1,781	721		
NY–3 Jones Inlet	Federal	0	0	No Change	Formerly NY–2.
	State	710	287		
	Private/Other	1,111	450		

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE RUFA RED KNOT—Continued

Critical habitat unit or subunit name (State)	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes	Previous unit numbering
	Uncategorized	0	0		
	Total	1,821	737		
NY–4 Jamaica Bay	Federal	5,458	2,209	No Change	Formerly NY–3.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	5,458	2,209		
New Jersey					
NJ–1 Brigantine and Little Egg Inlets	Federal	1,560	632	No Change	No Change.
	State	3,187	1,291	No Change.	
	Private/Other	10	4	No Change.	
	Uncategorized	5,194	2,101	+233 ac (95 ha).	
	Total	9,952	4,027	+233 ac (95 ha).	
NJ–2 Seven Mile Beach	Federal	0	0	No Change	No Change.
	State	0	0		
	Private/Other	536	217		
	Uncategorized	0	0		
	Total	536	217		
NJ–3 Hereford Inlet	Federal	0	0	No Change	No Change.
	State	175	71		
	Private/Other	735	297		
	Uncategorized	721	292		
	Total	1,631	660		
NJ–4 Two Mile Beach	Federal	128	52	No Change	No Change.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	128	52		
NJ–5 Cape May Bayshore	Federal	133	54	No Change	No Change.
	State	44	18		
	Private/Other	167	67		
	Uncategorized	858	347		
	Total	1,202	487		
NJ–6 Dennis Creek	Federal	0	0	No Change	No Change.
	State	279	113		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	279	113		
NJ–7 Heislerville	Federal	0	0	No Change	No Change.
	State	524	211		
	Private/Other	459	186		
	Uncategorized	127	52		
	Total	1,110	449		
NJ–8 Egg Island	Federal	0	0	No Change	No Change.
	State	1,908	773		
	Private/Other	32	13		
	Uncategorized	14	5		
	Total	1,955	791		
NJ–9 Newport Neck	Federal	0	0	No Change	No Change.
	State	202	82		
	Private/Other	176	71		

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE RUFA RED KNOT—Continued

Critical habitat unit or subunit name (State)	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes	Previous unit numbering
	Uncategorized	93	38		
	Total	472	191		
Delaware					
DE–1A St. Jones North	Federal	0	0	No Change	No Change.
	State	37	15		
	Private/Other	3	1		
	Uncategorized	3	1		
	Total	43	18		
DE–1B St. Jones South	Federal	0	0	No Change	No Change.
	State	1	0.5		
	Private/Other	2	0.6		
	Uncategorized	0	0		
	Total	3	1		
DE–2A North Brokonbridge Gut	Federal	0	0	No Change	No Change.
	State	2	1		
	Private/Other	91	37		
	Uncategorized	0	0		
	Total	93	37		
DE–2B South Brokonbridge Gut	Federal	0	0	No Change	No Change.
	State	0	0		
	Private/Other	70	29		
	Uncategorized	0	0		
	Total	70	29		
DE–3A Main Harbor	Federal	0	0	No Change	No Change.
	State	32	13		
	Private/Other	0	0		
	Uncategorized	29	12		
	Total	61	25		
DE–3B Rawley Island Roost	Federal	0	0	No Change	No Change.
	State	1,139	461		
	Private/Other	153	62		
	Uncategorized	6	2		
	Total	1,298	525		
DE–3C Slaughter Beach	Federal	1	0.25	No Change	No Change.
	State	59	24		
	Private/Other	2	1		
	Uncategorized	528	213		
	Total	590	239		
DE–4 Prime Hook	Federal	482	195	+2 ac (0 ha); correction	No Change.
	State	0	0	No Change.	
	Private/Other	6	2	No Change.	
	Uncategorized	14	6	−49 ac (19 ha); correction.	
	Total	503	203	−46 ac (19 ha); correction.	
Virginia					
VA–1 Assateague Island	Federal	2,817	1,140	No Change	No Change.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	2,817	1,140		
VA–2A Wallops Island North	Federal	540	218	No Change	No Change.
	State	0	0		

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE RUFA RED KNOT—Continued

Critical habitat unit or subunit name (State)	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes	Previous unit numbering
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	540	218		
VA–2B Wallops Island South	Federal	31	13	No Change	No Change.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	31	13		
VA–3 Assawoman Island	Federal	633	256	No Change	No Change.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	633	256		
VA–4 Metompkin Island	Federal	64	26	No Change	No Change.
	State	56	22		
	Private/Other	1,239	502		
	Uncategorized	110	44		
	Total	1,468	594		
VA–5 Cedar Island	Federal	203	82	No Change	No Change.
	State	77	31		
	Private/Other	920	372		
	Uncategorized	1,074	434		
	Total	2,274	920		
VA–6 Parramore Island	Federal	0	0	No Change	No Change.
	State	0	0		
	Private/Other	5,631	2,280		
	Uncategorized	1,171	473		
	Total	6,802	2,753		
VA–7 Chimney Pole Marsh	Federal	0	0	No Change	No Change.
	State	1,224	496		
	Private/Other	285	116		
	Uncategorized	495	200		
	Total	2,004	811		
VA–8 Hog Island	Federal	0	0	No Change	No Change.
	State	16	7		
	Private/Other	2,966	1,201		
	Uncategorized	253	101		
	Total	3,235	1,309		
VA–9 Cobb Island	Federal	0	0	No Change	No Change.
	State	16	7		
	Private/Other	1,778	720		
	Uncategorized	547	221		
	Total	2,342	948		
VA–10 Little Cobb Island	Federal	0	0	No Change	No Change.
	State	0	0		
	Private/Other	82	33		
	Uncategorized	0	0		
	Total	82	33		
VA–11 Wreck Island	Federal	0	0	No Change	No Change.
	State	1,270	514		
	Private/Other	0	0		
	Uncategorized	0	0		

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE RUFA RED KNOT—Continued

Critical habitat unit or subunit name (State)	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes	Previous unit numbering
	Total	1,270	514		
VA–12 Ship Shoal Island	Federal	0	0	New Unit	New Unit.
	State	426	172		
	Private/Other	1,941	785		
	Uncategorized	60	24		
	Total	2,426	982		
VA–13 Myrtle Island	Federal	0	0	No Change	Formerly VA–12.
	State	0	0		
	Private/Other	1,028	417		
	Uncategorized	388	156		
	Total	1,416	573		
VA–14 Smith Island	Federal	0	0	No Change to Unit But Corrected Acreage.	Formerly VA–13.
	State	0	0		
	Private/Other	3,258	1,319		
	Uncategorized	0	0		
	Total	3,258	1,319		
VA–15 Fisherman Island	Federal	2,413	977	New Unit	New Unit.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	2,413	977		
North Carolina					
NC–1A Hatteras Island and Shoals	Federal	4,940	1,999	No Change	No Change.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	814	329		
	Total	5,754	2,329		
NC–1B Ocracoke Island	Federal	1,427	577	No Change	No Change.
	State	3,612	1,462		
	Private/Other	0	0		
	Uncategorized	575	233		
	Total	5,613	2,271		
NC–2A North Core Banks	Federal	6,534	2,644	No Change	No Change.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	1,654	669		
	Total	8,187	3,313		
NC–2B South Core Banks	Federal	3,094	1,252	No Change	No Change.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	3,094	1,252		
NC–3 Shackleford Island	Federal	4,972	2,012	No Change	No Change.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	4,972	2,012		
NC–4 Emerald Isle–Atlantic Beach	Federal	0	0	No Change	No Change.
	State	1,908	772		
	Private/Other	122	50		
	Uncategorized	0	0		

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE RUFA RED KNOT—Continued

Critical habitat unit or subunit name (State)	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes	Previous unit numbering
	Total	2,030	822		
NC–5 New Topsail Inlet–Topsail Beach.	Federal	0	0	No Change	No Change.
	State	0	0		
	Private/Other	1,612	652		
	Uncategorized	0	0		
	Total	1,612	652		
NC–6 Lea-Hutaff Island	Federal	0	0	New Unit	New Unit.
	State	72	29		
	Private/Other	427	173		
	Uncategorized	586	237		
	Total	1,085	439		
NC–7 Cape Fear–Fort Fisher	Federal	0	0	No Change	Formerly NC–6.
	State	1,713	693		
	Private/Other	274	111		
	Uncategorized	0	0		
	Total	1,986	804		
NC–8 Ocean Isle Beach	Federal	0	0	No Change	Formerly NC–7.
	State	182	73		
	Private/Other	116	47		
	Uncategorized	0	0		
	Total	298	120		
NC–9 Sunset Beach–Bird Island	Federal	0	0	No Change	Formerly NC–8.
	State	345	139		
	Private/Other	39	16		
	Uncategorized	0	0		
	Total	384	155		
South Carolina					
SC–1 Garden City Beach	Federal	0	0	No Change	No Change.
	State	267	108		
	Private/Other	349	141		
	Uncategorized	0	0		
	Total	616	249		
SC–2 Huntington Beach State Park–Litchfield Beach.	Federal	0	0	No Change	No Change.
	State	80	32		
	Private/Other	1,554	629		
	Uncategorized	0	0		
	Total	1,634	661		
SC–3 Sand and South Island Beaches.	Federal	0	0	No Change	No Change.
	State	7,843	3,174		
	Private/Other	129	52		
	Uncategorized	283	115		
	Total	8,256	3,341		
SC–4 Murphy Island Beach	Federal	0	0	No Change	No Change.
	State	8,312	3,364		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	8,312	3,364		
SC–5 North Cape Island Beach	Federal	775	313	No Change	No Change.
	State	495	200		

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE RUFA RED KNOT—Continued

Critical habitat unit or subunit name (State)	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes	Previous unit numbering
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	1,270	514		
SC–6 South Cape and Lighthouse Island Beaches.	Federal	1,552	628	No Change	No Change.
	State	485	196		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	2,037	824		
SC–7 Raccoon Key Complex and White Banks Beaches.	Federal	5,324	2,154	No Change	No Change.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	5,324	2,154		
SC–8 Marsh Island	Federal	415	168	No Change	No Change.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	415	168		
SC–9 Bulls Island Beach	Federal	5,200	2,104	No Change	No Change.
	State	941	381		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	6,141	2,485		
SC–10 Capers Island Beach	Federal	0	0	No Change	No Change.
	State	2,534	1,026		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	2,534	1,026		
SC–11 Dewees Island Beach	Federal	0	0	No Change	No Change.
	State	265	107		
	Private/Other	1,547	626		
	Uncategorized	0	0		
	Total	1,812	733		
SC–12 Isle of Palms Beach	Federal	0	0	No Change	No Change.
	State	754	305		
	Private/Other	3,363	1,361		
	Uncategorized	0	0		
	Total	4,117	1,666		
SC–13 Sullivan's Island Beach	Federal	83	34	No Change	No Change.
	State	694	281		
	Private/Other	1,005	407		
	Uncategorized	0	0		
	Total	1,782	721		
SC–14 Folly Beach	Federal	0	0	No Change	No Change.
	State	0	0		
	Private/Other	1,989	805		
	Uncategorized	0	0		
	Total	1,989	805		
SC–15 Bird Key Stono	Federal	0	0	No Change	No Change.
	State	294	119		

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE RUFA RED KNOT—Continued

Critical habitat unit or subunit name (State)	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes	Previous unit numbering
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	294	119		
SC–16 Kiawah and Seabrook Island Beaches.	Federal	0	0	No Change	No Change.
	State	1,399	566		
	Private/Other	9,850	3,986		
	Uncategorized	0	0		
	Total	11,250	4,553		
SC–17 Deveaux Bank	Federal	0	0	No Change	No Change.
	State	1,328	538		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	1,328	538		
SC–18 Edisto Island Beaches	Federal	0	0	No Change	No Change.
	State	650	263		
	Private/Other	1,093	442		
	Uncategorized	0	0		
	Total	1,743	705		
SC–19 Pine and Otter Island Beaches.	Federal	0	0	No Change	No Change.
	State	6,296	2,548		
	Private/Other	6	2		
	Uncategorized	0	0		
	Total	6,302	2,550		
SC–20 Harbor and Hunting Island Beaches.	Federal	0	0	No Change	No Change.
	State	3,246	1,313		
	Private/Other	820	331		
	Uncategorized	0	0		
	Total	4,066	1,645		
SC–21 Fripp, Pritchards, and Little Capers Islands' Beaches.	Federal	0	0	No Change	No Change.
	State	4,055	1,641	+3,750 ac (1,517 ha).	
	Private/Other	6,123	2,478	+5,694 ac (2,304 ha).	
	Uncategorized	0	0	No Change.	
	Total	10,178	4,119	+9,444 ac (3,822 ha).	
SC–22 Bay Point Island Beach	Federal	0	0	New Unit	New Unit.
	State	553	224		
	Private/Other	1,145	464		
	Uncategorized	0	0		
	Total	1,698	687		
SC–23 Hilton Head Island Beach	Federal	0	0	No Change	Formerly SC–22.
	State	1,015	411		
	Private/Other	667	270		
	Uncategorized	0	0		
	Total	1,682	681		
SC–24 Daufuskie Island Beach	Federal	0	0	No Change	Formerly SC–23.
	State	0	0		
	Private/Other	6,370	2,578		
	Uncategorized	0	0		
	Total	6,370	2,578		

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE RUFA RED KNOT—Continued

Critical habitat unit or subunit name (State)	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes	Previous unit numbering
SC–25 Turtle Island and Tomkins Island Beaches.	Federal	0	0	No Change	Formerly SC–24..
	State	1,771	717	−27 ac (11 ha).	
	Private/Other	0	0	No Change.	
	Uncategorized	0	0	No Change.	
	Total	1,771	717	−27 ac (11 ha).	
SC–26 Jones Island Beach	Federal	785	318	No Change	Formerly SC–25.
	State	2,240	907		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	3,025	1,225		
Georgia					
GA–1 Cockspur Island and Daymark Island Beaches.	Federal	708	287	New Unit	New Unit.
	State	94	38		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	802	325		
GA–2 Tybee Island Beach	Federal	0	0	No Change	Formerly GA–1.
	State	6	2		
	Private/Other	1,721	697		
	Uncategorized	319	129		
	Total	2,046	828		
GA–3 Little Tybee Island Complex	Federal	0	0	No Change	Formerly GA–2.
	State	0	0		
	Private/Other	8,265	3,345		
	Uncategorized	0	0		
	Total	8,265	3,345		
GA–4 Wassaw Island Beach	Federal	3,001	1,215	No Change	Formerly GA–3.
	State	0	0		
	Private/Other	274	111		
	Uncategorized	1,020	412		
	Total	4,296	1,738		
GA–5 Little Ogeechee River Shoreline and Raccoon Key.	Federal	3,136	1,267	+3,136 ac (1,267 ha)	Formerly GA–4.
	State	1,435	581	−164 ac (66 ha).	
	Private/Other	0	0	No Change.	
	Uncategorized	0	0	No Change.	
	Total	4,571	1,850	+2,972 ac (1,203 ha).	
GA–6 Ossabaw Island Beach	Federal	0	0	No Change to Unit But Corrected Hectares.	Formerly GA–5.
	State	28,621	11,582		
	Private/Other	0	0		
	Uncategorized	3,736	1,512		
	Total	32,357	13,095		
GA–7 St. Catherine's Island Beach and St. Catherine's Island Bar.	Federal	0	0	No Change to Unit But Corrected Hectares.	Formerly GA–6.
	State	2,106	853		
	Private/Other	11,810	4,779		
	Uncategorized	2,046	828		
	Total	15,962	6,460		
GA–8 Blackbeard Island Beach	Federal	4,954	2,006	No Change	Formerly GA–7.
	State	80	32		

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE RUFA RED KNOT—Continued

Critical habitat unit or subunit name (State)	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes	Previous unit numbering
	Private/Other	0	0		
	Uncategorized	1,287	519		
	Total	6,321	2,557		
GA–9 Sapelo Island Beach	Federal	0	0	Total Hectares Corrected	Formerly GA–8.
	State	2,481	1,004		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	2,481	1,004		
GA–10 Queens Island, Wolf Island, Egg Island, Little Egg Island, and Little Egg Island Bar.	Federal	5,527	2,237	+2,552 ac (1,033 ha)	Formerly GA–9.
	State	261	106	+21 ac (9 ha).	
	Private/Other	1,865	755	+1,865 ac (755 ha).	
	Uncategorized	4,248	1,719	+2,155 ac (872 ha).	
	Total	11,901	4,816	+6,593 ac (2,668 ha).	
GA–11 Little St. Simon's Island Beach.	Federal	0	0	No Change	Formerly GA–10.
	State	113	46		
	Private/Other	7,462	3,022		
	Uncategorized	1,479	596		
	Total	9,053	3,664		
GA–12 Sea and St. Simon's Island Beaches.	Federal	0	0	No Change	Formerly GA–11.
	State	4	2		
	Private/Other	3,448	1,395		
	Uncategorized	581	235		
	Total	4,033	1,631		
GA–13 Jekyll Island Beach	Federal	0	0	No Change	Formerly GA–12.
	State	5,944	2,406		
	Private/Other	0	0		
	Uncategorized	343	139		
	Total	6,287	2,545		
GA–14 Little Cumberland and Cumberland Island Beaches.	Federal	23,367	9,456	No Change to Unit But Corrected Hectares.	Formerly GA–13.
	State	1,685	682		
	Private/Other	0	0		
	Uncategorized	3,085	1,248		
	Total	28,137	11,387		
Florida					
FL–1 Nassau Sound–Fort George Sound–Fort George Inlet Complex.	Federal	996	404	No Change to Unit But Corrected Hectares.	No Change.
	State	522	211		
	Private/Other	27	11		
	Uncategorized	2,779	1,125		
	Total	4,324	1,750		
FL–2 Ponce Inlet Complex	Federal	16,660	6,742	No Change	No Change.
	State	3,005	1,216		
	Private/Other	0	0		
	Uncategorized	18	7		
	Total	19,683	7,965		
FL–3 Merritt Island National Wildlife Refuge Impoundments.	Federal	6,947	2,811	No Change	No Change.
	State	0	0		

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE RUFA RED KNOT—Continued

Critical habitat unit or subunit name (State)	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes	Previous unit numbering
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	6,947	2,811		
FL–4A Cape Romano Complex	Federal	13,138	5,317	No Change to Unit But Corrected Hectares.	No Change.
	State	12,605	5,101		
	Private/Other	0	0		
	Uncategorized	470	190		
	Total	26,213	10,608		
FL–4B Marco Island	Federal	0	0	No Change	No Change.
	State	408	165		
	Private/Other	8	3		
	Uncategorized	0	0		
	Total	416	168		
FL–5 Marco Bay Complex	Federal	0	0	No Change	No Change.
	State	3,531	1,429		
	Private/Other	58	24		
	Uncategorized	0	0		
	Total	3,589	1,453		
FL–6A Cocohatchee Inlet Complex	Federal	0	0	No Change	No Change.
	State	9	4		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	9	4		
FL–6B Barefoot Beach	Federal	0	0	No Change	No Change.
	State	18	7		
	Private/Other	21	9		
	Uncategorized	0	0		
	Total	39	16		
FL–7A Lovers Key	Federal	0	0	No Change	No Change.
	State	4	1		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	4	1		
FL–7B Estero Island	Federal	0	0	No Change	No Change.
	State	171	69		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	171	69		
FL–8 Bunche Beach	Federal	23	9	No Change	No Change.
	State	264	107		
	Private/Other	47	19		
	Uncategorized	0	0		
	Total	334	135		
FL–9A J.N. "Ding" Darling National Wildlife Refuge.	Federal	3,451	1,397	No Change	No Change.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	3,451	1,397		
FL–9B Sanibel Island	Federal	307	124	No Change	No Change.
	State	0	0		

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE RUFA RED KNOT—Continued

Critical habitat unit or subunit name (State)	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes	Previous unit numbering
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	307	124		
FL–10A Don Pedro	Federal	0	0	No Change	No Change.
	State	147	60		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	147	60		
FL–10B Stump Pass Beach State Park.	Federal	0	0	No Change	No Change.
	State	11	4		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	11	4		
FL–11 Siesta Key	Federal	0	0	No Change	No Change.
	State	53	21		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	53	21		
FL–12A Lido Key	Federal	0	0	No Change	No Change.
	State	81	33		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	81	33		
FL–12B Longboat Key	Federal	0	0	No Change	No Change.
	State	369	149		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	369	149		
FL–13 North Anna Maria Island	Federal	56	23	No Change	No Change.
	State	889	360		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	945	383		
FL–14 Egmont Key	Federal	15	6	No Change	No Change.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	15	6		
FL–15A Fort De Soto County Park	Federal	0	0	No Change	No Change.
	State	0	0		
	Private/Other	427	173		
	Uncategorized	0	0		
	Total	427	173		
FL–15B Shell Key Preserve	Federal	0	0	No Change	No Change.
	State	322	130		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	322	130		
FL–15C Saint Petersburg Beach	Federal	0	0	No Change	No Change.
	State	107	43		
	Private/Other	0	0		

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE RUFA RED KNOT—Continued

Critical habitat unit or subunit name (State)	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes	Previous unit numbering
	Uncategorized	0	0		
	Total	107	43		
FL–16 Indian Shores–Redington Beach.	Federal	0	0	No Change	No Change.
	State	196	79		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	196	79		
FL–17 Belleair Beach	Federal	0	0	No Change	No Change.
	State	123	50		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	123	50		
FL–18A Caladesi Island	Federal	0	0	No Change	No Change.
	State	259	105		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	259	105		
FL–18B Honeymoon Island	Federal	0	0	No Change	No Change.
	State	294	119		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	294	119		
FL–18C Three Rooker Bar	Federal	0	0	No Change	No Change.
	State	335	136		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	335	136		
FL–19 Anclote Key	Federal	0	0	No Change	No Change.
	State	1,547	626		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	1,547	626		
FL–20 Cedar Keys Complex	Federal	2,498	1,011	No Change to Unit But Corrected Hectares.	No Change.
	State	7,792	3,153		
	Private/Other	5,928	2,399		
	Uncategorized	19,407	7,854		
	Total	35,626	14,417		
FL–21 St. Marks National Wildlife Refuge.	Federal	2,074	839	No Change	No Change.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	2,074	839		
FL–22A Mashes Sands	Federal	0	0	No Change	No Change.
	State	262	106		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	262	106		
FL–22B Bald Point State Park	Federal	0	0	No Change	No Change.
	State	439	178		

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE RUFA RED KNOT—Continued

Critical habitat unit or subunit name (State)	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes	Previous unit numbering
	Private/Other	6	2		
	Uncategorized	0	0		
	Total	445	180		
FL–22C Alligator Point	Federal	0	0	No Change	No Change.
	State	0	0		
	Private/Other	722	292		
	Uncategorized	0	0		
	Total	722	292		
FL–23A Turkey Point Shoal	Federal	0	0	No Change	No Change.
	State	531	215		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	531	215		
FL–23B Lanark Reef	Federal	0	0	No Change	No Change.
	State	805	326		
	Private/Other	61	25		
	Uncategorized	0	0		
	Total	865	350		
FL–23C East Dog Island	Federal	0	0	No Change	No Change.
	State	0	0		
	Private/Other	771	312		
	Uncategorized	0	0		
	Total	771	312		
FL–23D West Dog Island	Federal	0	0	No Change	No Change.
	State	0	0		
	Private/Other	751	304		
	Uncategorized	0	0		
	Total	751	304		
FL–23E McKissack Beach, Carrabelle	Federal	0	0	No Change	No Change.
	State	114	46		
	Private/Other	3	1		
	Uncategorized	0	0		
	Total	117	47		
FL–23F East St. George Island State Park.	Federal	0	0	No Change	No Change.
	State	978	396		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	978	396		
FL–23G St. George Island State Park and Bayshore Shoals.	Federal	0	0	No Change	No Change.
	State	162	65		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	162	65		
FL–24A Little St. George Island State Park–West.	Federal	0	0	No Change	No Change.
	State	953	386		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	953	386		

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE RUFA RED KNOT—Continued

Critical habitat unit or subunit name (State)	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes	Previous unit numbering
FL–24B St. Vincent National Wildlife Refuge.	Federal	742	300	No Change	No Change.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	742	300		
FL–24C Flagg Island Shoals	Federal	0	0	No Change	No Change.
	State	517	209		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	517	209		
FL–25A Cape San Blas to Indian Pass.	Federal	0	0	No Change	No Change.
	State	133	54		
	Private/Other	486	197		
	Uncategorized	0	0		
	Total	620	251		
FL–25B St. Joseph Bay–Eastern Shore.	Federal	0	0	No Change	No Change.
	State	761	308		
	Private/Other	66	27		
	Uncategorized	0	0		
	Total	827	335		
Alabama					
AL–1 Dauphin Island	Federal	484	196	No Change	No Change.
	State	848	343		
	Private/Other	3,834	1,552		
	Uncategorized	0	0		
	Total	5,167	2,091		
Mississippi					
MS–1 Ship Island	Federal	2,452	993	No Change	No Change.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	2,452	993		
MS–2 Cat Island	Federal	686	278	No Change	No Change.
	State	1,305	528		
	Private/Other	129	52		
	Uncategorized	0	0		
	Total	2,121	858		
Louisiana					
LA–1 Chandeleur Islands	Federal	7,632	3,088	No Change	No Change.
	State	0	0		
	Private/Other	0	0		
	Uncategorized	0	0		
	Total	7,632	3,088		
LA–2 Barataria Barrier Islands and Headlands.	Federal	0	0	No Change	No Change.
	State	126	51		
	Private/Other	7,669	3,104		
	Uncategorized	0	0		
	Total	7,795	3,155		

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE RUFA RED KNOT—Continued

Critical habitat unit or subunit name (State)	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes	Previous unit numbering
LA–3 Terrebonne Barrier Islands	Federal	0	0	No Change	No Change.
	State	2,900	1,173		
	Private/Other	2,172	879		
	Uncategorized	0	0		
	Total	5,072	2,052		
LA–4 Southwest Louisiana Beaches	Federal	0	0	No Change	No Change.
	State	1,497	606		
	Private/Other	4,633	1,875		
	Uncategorized	0	0		
	Total	6,130	2,481		
Texas					
TX–1 Rollover Pass to Bolivar Flats ..	Federal	0	0	No Change	No Change.
	State	482	195	+214 ac (87 ha).	
	Private/Other	996	403	No Change.	
	Uncategorized	0	0	No Change.	
	Total	1,478	598	+214 ac (87 ha).	
TX–2 West Galveston Island	Federal	0	0	No Change	No Change.
	State	307	124		
	Private/Other	282	114		
	Uncategorized	0	0		
	Total	590	239		
TX–3 Cedar Lake to Colorado River	Federal	0	0	No Change to Unit But Corrected Hectares.	No Change.
	State	1,075	435		
	Private/Other	128	52		
	Uncategorized	0	0		
	Total	1,204	487		
TX–4 Mustang Island	Federal	0	0	No Change	No Change.
	State	395	160		
	Private/Other	253	102		
	Uncategorized	0	0		
	Total	648	262		
TX–5 Mollie Beattie Coastal Habitat ..	Federal	0	0	No Change	No Change.
	State	505	205		
	Private/Other	218	88		
	Uncategorized	0	0		
	Total	723	293		
TX–6 North Padre Island	Federal	2,487	1,007	No Change	No Change.
	State	68	27		
	Private/Other	262	106		
	Uncategorized	0	0		
	Total	2,817	1,140		
TX–7 Upper Laguna Madre/Nighthawk Bay.	Federal	273	111	No Change	No Change.
	State	816	330		
	Private/Other	68	28		
	Uncategorized	0	0		
	Total	1,157	469		
TX–8 Dagger Hill–Yarborough Pass–Nine Mile Hole.	Federal	9,731	3,938	No Change to Unit But Corrected Hectares.	No Change.
	State	23,042	9,325		
	Private/Other	0	0		
	Uncategorized	0	0		

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE RUFA RED KNOT—Continued

Critical habitat unit or subunit name (State)	Land ownership by type	Approx. acres	Approx. hectares	Proposed changes	Previous unit numbering
	Total	32,773	13,263		
TX–9 Pintail Lake–Padre Island–La Punta Larga.	Federal	25,881	10,474	No Change to Unit But Corrected Hectares.	No Change.
	State	34,165	13,826		
	Private/Other	34,125	13,810		
	Uncategorized	0	0		
	Total	94,171	38,110		
TX–10 Peyton's Bay–Arroyo Colorado–Three Islands–Gabrielson Island.	Federal	8,145	3,296	No Change	No Change.
	State	25,316	10,245		
	Private/Other	2,190	886		
	Uncategorized	0	0		
	Total	35,651	14,427		
TX–11 South Bay–Boca Chica	Federal	5,536	2,242	No Change	No Change.
	State	4,080	1,652	+157 ac (63 ha).	
	Private/Other	5,784	2,342	No Change.	
	Uncategorized	0	0	No Change.	
	Total	15,400	6,236	+157 ac (63 ha).	

* Totals may not sum due to rounding. Rounding in some cases has been corrected/updated in this table.

TABLE 2—CO-OCCURRING CRITICAL HABITAT DESIGNATIONS THAT OVERLAP PROPOSED CRITICAL HABITAT FOR RUFA RED KNOT

State	Area of overlap with designated critical habitat in acres (ac)/hectares (ha) (# of proposed rufa red knot units or subunits overlapping)					Total overlap (combined) for each state in acres (ac)/ hectares (ha)
	Piping Plover	Loggerhead Sea Turtle	West Indian Manatee	Gulf Sturgeon	Aboriginal Prickly-apple	
North Carolina [1]	11,495 ac/4,652 ha (11).	3,438 ac/1,391 ha (4).	N/A	N/A	N/A	14,069 ac/5,693 ha.
South Carolina [1]	5,615 ac/2,272 ha (14).	6,007 ac/2,431 ha (14).	N/A	N/A	N/A	9,399 ac/3,804 ha.
Georgia [1]	15,877 ac/6,425 ha (12).	10,903 ac/4,412 ha (7).	N/A	N/A	N/A	21,698 ac/8,781 ha.
Florida	7,617 ac/3,082 ha (20).	7,114 ac/2,879 ha (17).	20,720 ac/8,385 ha (11).	8,970 ac/3,630 ha (11).	77 ac/31 ha (4)	37,801 ac/15,297 ha.
Alabama	2,381 ac/963 ha (1).	N/A	N/A	N/A	N/A	2,381 ac/963 ha.
Mississippi	4,538 ac/1,837 ha (2).	N/A	N/A	1,866 ac/755 ha (2).	N/A	4,488 ac/1,816 ha.
Louisiana	17,154 ac/6,942 ha (4).	N/A	N/A	N/A	N/A	17,154 ac/6,942 ha.
Texas [1]	154,097 ac/ 62,361 ha (11).	N/A	N/A	N/A	N/A	154,097 ac/ 62,361 ha.
Total [2]	218,774 ac/ 88,537 ha (74).	27,463 ac/11,114 ha (40).	20,720 ac/8,385 ha (11).	10,836 ac/4,385 ha (13).	77 ac/31 ha (4)	261,087 ac/ 105,659 ha.

[1] The amount of rufa red knot proposed critical habitat overlapping with piping plover designated critical habitat increased by 852 ac (345 ha) in North Carolina, 660 ac (267 ha) in South Carolina, 508 ac (205 ha) in Georgia, and 371 ac (150 ha) in Texas; this resulted in a total increase of 2,413 ac (976 ha) for piping plover compared to the July 15, 2021, proposed rule. The amount of rufa red knot proposed critical habitat overlapping with loggerhead sea turtle designated critical habitat was corrected for North Carolina, to include adding acreage for the new NC–6 unit, to 3,438 ac (1,391 ha); overlap also increased by 692 ac (280 ha) in South Carolina, resulting in a total increase of 608 ac (246 ha) for loggerhead compared to the July 15, 2021, proposed rule.

[2] Totals may not sum due to rounding.

The revised proposed critical habitat designation is defined by the map or maps, as modified by any accompanying regulatory text, presented at the end of this document under Proposed Regulation Promulgation. The rule portion of this document depicts all the proposed critical habitat units, including those originally proposed July 15, 2021, and unchanged via this document. Because we are adding proposed critical habitat units, the paragraph designations have changed, so we are setting forth the entire proposed rule in this document instead

of just the new and revised proposed critical habitat units.

We include more detailed information on the boundaries of the revised proposed critical habitat designation in the discussion of new and revised proposed individual units below. For units for which we are not proposing any changes from the July 15, 2021, proposed rule, please refer to information at *https://www.regulations.gov* under Docket No. FWS–R5–ES–2021–0032.

Unit MA–1: Nauset Marsh

Unit MA–1 consists of approximately 2,219 ac (899 ha) of highly dynamic barrier beaches and intertidal (*i.e.,* seashore that is covered at high tide and uncovered at low tide) areas in the towns of Orleans and Eastham in Barnstable County, Massachusetts. The unit includes exposed intertidal flats, shoals, mudflats, and intertidal salt marsh pannes in Salt Pond Bay and Nauset Bay, and ephemeral tidal pools, primary sand dunes, and beaches associated with Nauset Spit (Orleans and Eastham) and Coast Guard Beach (Eastham). The southern end of the unit begins at Nauset Spit north of Mill Pond where the peninsula is bordered by bay and oceanside waters, and heads east following the mainland shoreline past Woods Cove (but not including the cove) to the shoreline of Fort Hill (Eastham). The unit then follows the shoreline around Salt Pond Bay to the north end of Nauset Bay where the boundary continues east across Coast Guard Beach to mean low low water (MLLW; *i.e.,* the lowest of the low tides per day averaged over a 19-year period) on the ocean side. The eastern unit border continues south crossing the inlet between Coast Guard Beach and Nauset Spit (Eastham) following oceanside MLLW until the spit is no longer bordered by the bay and ocean, at which point the boundary heads west. Lands within this unit include approximately 1,340 ac (543 ha; 60 percent) in Federal ownership, 136 ac (55 ha; 6 percent) in private/other ownership, and 744 ac (301 ha; 34 percent) that are uncategorized. General land use within this unit is primarily recreational, including offshore and surf fishing, shellfish digging (both recreational and commercial), boating, over-sand vehicle use, sunbathing, swimming, and walking.

Unit MA–1 is occupied by the species and contains one or more of the physical or biological features essential to the conservation of the species. The unit contains a high concentration of rufa red knots during the fall migration period, serving as an important southbound stopover site in the New England portion of the subspecies' range. Additionally, this location consistently supports large concentrations of migrating rufa red knots annually due to the large intertidal areas and beach habitat that provides multiple foraging and roosting habitat areas for the birds to build energy resources for migration.

Threats identified within Unit MA–1 include disturbance of foraging and roosting rufa red knots by humans and human activities including but not limited to, pets and domestic animals, off-road vehicles (ORVs), powered and unpowered boats, surf kites, and surf fishing, predation (especially by migrating raptors and owls), possible modification or loss of habitat (*i.e.,* dredging), and natural or human-caused disasters (*i.e.* hurricanes, oil spills). Special management considerations or protection measures to reduce or alleviate the threats may include managing access to rufa red knot foraging habitat and adjacent saltmarsh and upland roosting habitat during migration (through restrictions on timing, locations, and types of activities), and addressing the impacts of potential oil spills through protective spill response plans and training (see Special Management Considerations or Protection in the 2021 proposed rule). The National Park Service (NPS) lands within the unit (*i.e.,* Cape Cod National Seashore) are managed under a comprehensive shorebird management plan (NPS 2018, entire).

Unit MA–2: Pleasant Bay

Unit MA–2 consists of approximately 4,959 ac (2,007 ha) of highly dynamic barrier beaches and intertidal areas in the towns of Chatham and Orleans in Barnstable County, Massachusetts. The unit includes exposed intertidal flats, shoals, mudflats, and intertidal salt marsh pannes in Little Pleasant Bay and Pleasant Bay, and ephemeral tidal pools, primary sand dunes, and beaches associated with Nauset Beach South (Orleans), North Beach (Chatham), and North Beach Island (Chatham). The unit begins at the northeastern end of Little Pleasant Bay going east to the edge of the saltmarsh, continuing south on the interior of Nauset Beach South approximately 1.7 mi (2.7 km) then east to MLLW on the east side of Nauset Beach South, continuing south along Nauset Beach South and North Beach to North Beach Island at MLLW and terminating at the natural channel between North Beach Island and South Beach Island (Chatham). The western side of the unit runs offshore of the mainland, west of small islands in Pleasant and Little Pleasant Bays (Little Sipson Island, Strong Island, and Tern Island) and east of Hog Island and Sampson Island, incorporating intertidal lands associated with the islands. Lands within this unit include approximately 126 ac (51 ha; 3 percent) in Federal ownership, 2,005 ac (812 ha; 40 percent) in private/other ownership, and 2,827 ac (1,144 ha; 57 percent) that are uncategorized. General land use within this unit is primarily recreational, including offshore and surf fishing, shellfish digging (both recreational and commercial), boating, over-sand vehicle use, sunbathing, swimming, and walking.

Unit MA–2 is occupied by the species and contains one or more of the physical or biological features essential to the conservation of the species. The unit contains a high concentration of rufa red knots during the spring and fall migration periods, serving as an important northbound and southbound stopover site in the New England portion of the subspecies' range. Additionally, this location consistently supports a few thousand migrating rufa red knots due to the large intertidal areas and beach habitat that provides multiple foraging and roosting habitat areas for the birds to build energy resources for migration.

Threats identified within Unit MA–2 include disturbance of foraging and roosting rufa red knots by humans and human activities including but not limited to, pets and domestic animals, ORVs, powered and unpowered boats, surf kites, and surf fishing, predation (especially by migrating raptors and owls), possible modification or loss of habitat (*e.g.,* dredging or mining of sand flats), and natural or human-caused disasters (*i.e.,* oil spills). Special management considerations or protection measures to reduce or alleviate the threats may include managing access to rufa red knot foraging habitat and adjacent saltmarsh and upland roosting habitat during migration (through restrictions on timing, locations, and types of activities), and addressing the impacts of potential oil spills through protective spill response plans and training (see Special Management Considerations or Protection in the 2021 proposed rule). The National Park Service (NPS) manages Cape Cod National Seashore under a comprehensive shorebird management plan (NPS 2018, entire) (Shorebird Plan). However, due to the small and isolated nature of NPS inholdings in this unit, these areas are not actively managed under the Shorebird Plan.

Unit NY–2: Old Inlet

Unit NY–2 (Old Inlet) consists of 1,781 ac (721 ha) of highly dynamic beach, sand flats, bay islands, back bay shoreline, intertidal areas, and surface water within the town of Brookhaven, Suffolk County, New York. The unit is irregularly shaped and bounded to the south by the Atlantic Ocean, to the west by the Fire Island National Seashore's Federal Otis G. Pike Wilderness Area, and to the east by the continuation of the Federal wilderness area. Its northern boundary lies approximately in the lower third of Bellport Bay. Additionally, portions of the northern and southern areas of the unit are not contiguous, as they are separated by a vegetated dune and washover areas. Lands within this unit include approximately 1,481 ac (599 ha; 83 percent) in Federal ownership; 232 ac (94 ha; 13 percent) in State ownership; and 67 ac (27 ha; 4 percent) in private/other ownership (including the town of Brookhaven). General land use within this unit is recreational activities (*e.g.,* fishing, bird watching, boating, open space use). Coastal engineering structures are absent, but beach nourishment programs are implemented along the ocean beach to the east by the U.S. Army Corps of Engineers at Smith Point County Park (via coordination and agreements with the State of New York and Suffolk County).

Unit NY–2 is occupied by the species and contains one or more of the physical or biological features essential to the conservation of the species. This unit contains a high concentration of rufa red knots during the fall migration period, serving as an important southbound stopover site. The area has a relatively undeveloped character that provides protection from intensive human uses. Episodic storm events have also contributed to habitat creation, and, in turn, optimal rufa red knot habitat conditions. The bay islands and associated wetlands are managed for wildlife, which provides some limits to the amount of disturbance that rufa red knots or their habitat may experience from recreation and other human activities (*e.g.,* commercial shell fishing, dredging, and shoreline dock/pier projects).

Threats identified within Unit NY–2 include: (1) Sea level rise; (2) coastal engineering activities (*e.g.,* beach nourishment that could remove habitat, preclude the formation of habitat such as exposed shoals, and impact adjacent shoreline habitats by altering currents and sediment transport/deposition patterns); (3) predation in nonbreeding areas; and (4) human disturbance (*e.g.,* recreational fishing and driving, and motorized boat traffic or aircraft that create noise disturbance). Special management considerations or protection measures to reduce or alleviate the threats may include reducing disturbance (*e.g.,* humans, pets, vehicles, and watercraft), conducting predator control, and implementing conservation measures that help reduce modification or loss of habitat from soft beach stabilization efforts (*e.g.,* time-of-year restrictions for beach nourishment and dredging activities, establishing temporary sanctuaries and management during certain times of year to address erosion) (see Special Management Considerations or Protection in the 2021 proposed rule).

The town of Brookhaven lands (both marine and estuarine habitats within this unit) are managed in cooperation with the New York State Wildlife Action Plan (New York State Department of Environmental Conservation 2015, entire). Additionally, the designated South Shore Estuary Reserve implements a Comprehensive Management Plan (South Shore Estuary Reserve Council 2001, entire), which encompasses Units NY–1, NY–2, and NY–3, and serves as a guidance document for municipalities and private/public sectors to conserve or protect habitats and waters within the Reserve. Unit NY–2 is within the boundaries of the Fire Island National Seashore's Federal Otis G. Pike Wilderness Area. The NPS prepared the ''Fire Island National Seashore Wilderness Breach Management Plan/Environmental Impact Statement'' to provide a thorough evaluation to determine the potential benefits and consequences of management strategies prior to making a decision on how to manage the wilderness breach (NPS 2017, entire).

Unit NJ–1: Brigantine and Little Egg Inlets

Unit NJ–1 consists of 9,952 ac (4,027 ha) of beach, dune, shoals, open water, and tidal marsh associated with two inlets (*i.e.,* small arms of the ocean) in Ocean and Atlantic Counties, New Jersey, extending from the northern boundary of the Holgate Unit of Edwin B. Forsythe (Forsythe) NWR, west to the ''Seven Islands'' portion of Great Bay Boulevard Wildlife Management Area, and south nearly to 15th Street North in Brigantine City. To the north, the unit encompasses the Holgate Unit of the Forsythe NWR and includes several areas within the Great Bay Boulevard Wildlife Management Area, owned by the State of New Jersey (*e.g.,* Seven Islands and other islands on either side of Great Bay Boulevard south of Big Sheepshead Creek). The unit also includes portions of Little Beach Island within the Forsythe NWR, and portions of the North Brigantine Natural Area owned by the State of New Jersey. This unit includes extensive areas of shoals and sand or mud flats (such as the new island east of Little Beach Island that is within the Edwin B. Forsythe NWR), which are generally owned by the State. Lands within this unit include approximately 1,560 ac (632 ha; 16 percent) in Federal ownership, 3,187 ac (1,291 ha; 32 percent) in State ownership, 10 ac (4 ha; less than 1 percent) in private/other ownership, and 5,194 ac (2,101 ha; 52 percent) that are uncategorized. General land use within this unit is almost entirely undeveloped and managed for wildlife and other natural resource values, as well as recreation.

Unit NJ–1 is occupied by the species and contains one or more of the physical or biological features essential to the conservation of the species. This unit contains a high concentration of rufa red knots during the spring and fall migration periods, serving as an important northbound and southbound stopover site. This unit has an undeveloped character that provides protection from intensive human uses. The lack of hard structures and other coastal engineering practices in this unit allows optimal rufa red knot habitat conditions to be created and maintained by natural coastal processes, which is a condition that is rare in the mid-Atlantic. The Little Egg Inlet is the only unmodified inlet in New Jersey and one of only two unmodified inlets between Montauk, New York, and Chincoteague, Virginia, a shoreline distance of nearly 350 mi (563 km) (Rice 2016, pp. 24–25). Nearly all the lands in the unit are managed for wildlife, which limits disturbance of rufa red knots from recreation and other human activities.

Threats identified within Unit NJ–1 include: (1) Sea level rise that may accelerate faster than landforms can migrate through natural coastal processes; (2) coastal engineering activities (*e.g.,* ongoing updrift beach nourishment; proposed enlargement of a terminal groin immediately adjacent to the unit's northern limit; ongoing and proposed dredging that could remove habitat (*e.g.,* exposed shoals), preclude habitat formation, and/or impact adjacent shoreline habitats by altering sediment transport/deposition patterns); (3) aquaculture leases; (4) predation in nonbreeding areas; and (5) human disturbance (*e.g.,* recreational fishing and driving in the fall, motorized boat

traffic and aircraft year round). Special management considerations or protection measures to reduce or alleviate the threats may include managing sources of disturbance (*e.g.,* humans, pets, vehicles, and watercraft), managing predator populations, and implementing conservation measures to abate habitat impacts from coastal engineering projects and from sea level rise (see Special Management Considerations or Protection in the July 15, 2021, proposed rule). Federal lands in this unit are managed under the Edwin B. Forsythe NWR Comprehensive Conservation Plan (Service 2004a, entire). State lands within the North Brigantine Natural Area are covered by a Beach Management Plan (Service and New Jersey Department of Environmental Protection 2019, entire).

Unit VA–12: Ship Shoal Island

This unit consists of a total of 2,426 ac (982 ha) in Northampton County, Virginia, including both Ship Shoal Island and the area known as Godwin Island. The north boundary is Red Drum Drain and New Inlet, the south boundary is Ship Shoal Inlet, the west boundary is South Bay, and the east boundary is the Atlantic Ocean. The boundary for the island and marsh complex extends outward past the MLLW line and includes the areas that are slightly inundated with less than 3 in (7.6 cm) of water. The unit is composed of 426 ac (172 ha; 18 percent) in State ownership, 1,941 ac (785 ha; 80 percent) in private/other ownership, and the remaining 60 ac (24 ha; 2 percent) is uncategorized. The island is composed of extensive mud flats, low marsh, sandy beaches, overwash areas, and tidal channels. General land use within this unit is scientific research (*e.g.,* surveys and monitoring for nesting shorebirds); this area is closed to visitor use at all times for scientific research and safety reasons (TNC 2017, p. 1).

Unit VA–12 is occupied by the species and contains one or more of the physical or biological features essential to the conservation of the species. This unit is essential to the conservation of the species because it is used by rufa red knots in conjunction with other proposed critical habitat units with large concentrations of rufa red knots observed during the spring migration season and provides high-quality habitat that is protected from disturbance. Additionally, rufa red knots are known to move from island to island daily within the barrier island chain; the whole chain of islands serves as important foraging and roosting habitat for the rufa red knot. Therefore, inclusion of unit VA–12 accurately captures how rufa red knots are using the available habitat along Virginia's Eastern Shore.

The threats identified within Unit VA–12 include: (1) Natural (*e.g.,* hurricanes) or human-caused (*e.g.,* oil spills) disasters, and (2) erosional processes and accelerated loss of shoreline habitat in response to climate change and sea level rise. Special management considerations or protection measures to reduce or alleviate the threats may include managing scientific research activity access to rufa red knot foraging habitat and adjacent upland roosting habitat during migration, and establishing temporary sanctuaries and management during certain times of year to address erosion (see Special Management Considerations or Protection in the 2021 proposed rule). The island is owned and managed by TNC as part of the Virginia Coast Reserve, management of which is identified in a Conservation Action Plan that outlines priorities and strategies for conservation activities (Wilke 2020, pers. comm.).

Unit VA–15: Fisherman Island

This unit consists of a total of 2,413 ac (977 ha) in Northampton County, Virginia. The unit is an oval-shaped island located at the mouth of the Chesapeake Bay and is just south of the tip of the Eastern Shore peninsula. The island is surrounded by the waters of the Chesapeake Bay and Atlantic Ocean. It is bisected by U.S. Route 13 and the Chesapeake Bay Bridge–Tunnel complex. The interior boundary is along the dune line where the habitat changes from sandy beach with little vegetation to densely vegetated dunes or marshland, as well as densely vegetated forested or herbaceous vegetation landward of the beach and primary dune. The unit extends seaward past the MLLW line and includes areas that are slightly inundated with less than 3 in (7.6 cm) of water. The unit is federally owned by the Service's Eastern Shore of Virginia NWR. General land use within this unit includes low-impact recreational day use (*e.g.,* hiking, bird watching, photography) only provided through guided tours from September through February. In addition, scientific research (*e.g.,* survey and monitoring of natural resources, such as federally listed species) may occur year-round.

Unit VA–15 is occupied by the species and contains one or more of the physical or biological features essential to the conservation of the species. This unit is essential to the conservation of the species because it is used by rufa red knots in conjunction with other proposed critical habitat units with large concentrations of rufa red knots observed during the spring migration season and provides high-quality habitat that is protected from disturbance. Additionally, rufa red knots are known to move from island-to-island daily within the barrier island chain; the whole chain of islands serves as important foraging and roosting habitat for the rufa red knot. Therefore, inclusion of unit VA–15 accurately captures how rufa red knots are using the available habitat along Virginia's Eastern Shore.

Threats identified within Unit VA–15 include: (1) Disturbance of foraging and roosting rufa red knots by trespass recreational beach use, (2) natural (*e.g.,* hurricanes) or human-caused (*e.g.,* oil spills) disasters, and (3) accelerated loss of shoreline habitat from erosional processes in response to sea level rise. Special management considerations or protection measures to reduce or alleviate the threats may include managing access to rufa red knot foraging habitat and adjacent upland roosting habitat during migration (through restrictions on timing, locations, and types of activities), and establishing temporary sanctuaries and management during certain times of year to address erosion (see Special Management Considerations or Protection in the 2021 proposed rule). Currently, Eastern Shore of Virginia and Fisherman Island NWRs address some of these threats in their Comprehensive Conservation Plan (Service 2004b, entire) and Habitat Management Plan (Service 2018, entire).

Unit NC–6: Lea-Hutaff Island

Unit NC–6 consists of approximately 1,085 ac (439 ha) of occupied habitat including all of Lea-Hutaff Island in Pender and New Hanover Counties consisting of shoreline habitat that stretches approximately 4.8 mi (7.7 km) from the west side of the New Topsail Inlet channel west across the Rich Inlet channel to the toe of the primary dune or dense vegetation line on the northeast end of Figure Eight Island. This unit includes from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins and where the physical or biological features no longer occur. This unit also includes the emergent sand shoals within the flood-tidal and ebb-tidal deltas associated with the west side of the New Topsail Inlet channel, and the emergent sand shoals within the flood-tidal and ebb-tidal deltas on the west side of Rich Inlet channel. Lands within this unit include approximately 72 ac (29 ha; 7 percent) in State ownership, and 427 ac (173 ha; 39

percent) in private/other ownership, and 586 ac (237 ha; 54 percent) that are uncategorized. State lands in this unit include parcels on the northeast end of Lea-Hutaff Island. General land use within this unit includes low-impact recreational day use (*e.g.,* hiking, bird watching, photography and shell collecting). Additionally, scientific research (*e.g.,* survey and monitoring of natural resources, such as federally listed species) may occur year-round.

Unit NC–6 is occupied by the species and contains one or more of the physical or biological features essential to the conservation of the species. This unit contains a high concentration of rufa red knots during the spring migration period, serving as an important northbound stopover site. Approximately 852 ac (345 ha) of this unit overlap with designated critical habitat for the federally threatened piping plover (66 FR 36038, July 10, 2001) and 238 ac (96 ha) overlap with the federally threatened loggerhead sea turtle (79 FR 39756, July 10, 2014).

Threats identified within Unit NC–6 include: (1) Depredation by native and nonnative predators; (2) modification or loss of habitat or both due to erosion and sea level rise; and (3) response to natural and human-caused disasters (*i.e.,* hurricanes, oil spills). Special management considerations or protection measures to reduce or alleviate the threats may include managing access to rufa red knot foraging habitat and adjacent saltmarsh and upland roosting habitat during migration (through restrictions on timing, locations, and types of activities), conducting habitat management or restoration (*e.g.,* living shorelines, raising marsh elevations, facilitated shoreline migration), managing predator populations, managing human activities that disturb foraging rufa red knots, and managing sediment sources both within the unit and adjacent Rich Inlet and New Topsail Inlet (see Special Management Considerations or Protection in the 2021 proposed rule). State lands within this unit are managed under the 2015 North Carolina Wildlife Action Plan (NCWRC 2015, entire).

Unit SC–21: Fripp, Pritchards, and Little Capers Islands' Beaches

Unit SC–21 consists of 10,178 ac (4,119 ha) of Fripp Island, Pritchards Island, and Little Capers Island, barrier islands off the coast in Beaufort County, South Carolina. The unit boundary begins on the shoreline of Fripp Island on the south side of Fripp Inlet and extends southwest along the Atlantic Ocean shorelines of Fripp Island, Pritchards Island, and Little Capers Island to the eastern side of Trenchards Inlet where the boundary follows the southern shoreline of the Story River. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with Fripp, Skull, and Trenchards Inlets as well as the unnamed inlets along the Little Capers Island shoreline. Lands within this unit include approximately 4,055 ac (1,641 ha; 40 percent) in State ownership and 6,123 ac (2,478 ha; 60 percent) in private/other ownership. General land use within this unit includes residential development, tourism, and outdoor recreational use (*e.g.,* beachgoing, birdwatching, boating, and fishing).

Unit SC–21 is occupied by the species and contains one or more of the physical or biological features essential to the conservation of the species. This unit contains a high concentration of rufa red knots during the spring migration period, serving as an important northbound stopover site. The majority of this unit, with the exception of Fripp Island, has remote boat-only access and an undeveloped character that provides protection from intensive human uses. Approximately 660 ac (267 ha) of this unit overlap with designated critical habitat for the federally threatened piping plover (66 FR 36038, July 10, 2001), and 97 ac (39 ha) of this unit overlap with designated critical habitat for the federally threatened loggerhead sea turtle (79 FR 39756, July 10, 2014).

Threats identified within Unit SC–21 include: (1) Disturbance of foraging and roosting red knots by humans and human activities (*e.g.,* off-leash dogs, walking/running/biking through or too close to flocks of red knots, powered boats); (2) depredation by native and nonnative predators; (3) modification or loss of habitat or both due to uncontrolled recreational access, erosion, and sea level rise; and (4) disturbance associated with response to natural and human-caused disasters (*e.g.,* hurricanes, oil spills). Special management considerations or protection measures to reduce or alleviate the threats may include minimizing disturbance to wintering and migrating red knots (*e.g.,* managing recreational access to key rufa red knot foraging and roosting habitat during migration through restrictions on timing, locations, and types of activities) and managing the collection of spawning horseshoe crabs for biomedical use (*e.g.,* limiting location and timing of collection) (see Special Management Considerations or Protection in the 2021 proposed rule). Private/other lands within this unit are managed under the 1992 Comprehensive Beach Management Plan of Beaufort County (Beaufort County Planning Board 1992, entire) and the 2020 Fripp Island Beach Management Plan (Beaufort County 2020, entire).

Unit SC–22: Bay Point Island Beach

Unit SC–22 consists of 1,698 ac (687 ha) of Bay Point Island, a barrier island off the coast in Beaufort County, South Carolina. The unit boundary begins on the Trenchards Inlet shoreline at the entrance to Morse Island Creek and follows the Atlantic Ocean shoreline to the eastern shoreline of Port Royal Round to the western entrance to Morse Island Creek. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with Morse Creek and Trenchards Inlet within the unit boundary. Lands within this unit include approximately 553 ac (224 ha; 33 percent) in State ownership and 1,145 ac (464 ha; 67 percent) in private/other ownership. General land use within this unit includes outdoor recreational use (*e.g.,* beachgoing, boating, birdwatching, and fishing).

Unit SC–22 is occupied by the species and contains one or more of the physical or biological features essential to the conservation of the species. This unit contains a high concentration of rufa red knots during the spring migration period, serving as an important northbound stopover site, particularly when horseshoe crabs are spawning. This unit has remote boat-only access and an undeveloped character that provides protection from intensive human uses. Approximately 595 ac (241 ha) of this unit overlap with designated critical habitat for the federally threatened loggerhead sea turtle (79 FR 39756, July 10, 2014).

Threats identified within Unit SC–22 include: (1) Disturbance of foraging and roosting red knots by humans and human activities (*e.g.,* off-leash dogs, walking too close to flocks of red knots,

powered boats); (2) depredation by native and nonnative predators; (3) modification or loss of habitat or both due to uncontrolled recreational access, erosion, and sea level rise; and (4) disturbance associated with response to natural and human-caused disasters (*e.g.,* hurricanes, oil spills). Special management considerations or protection measures to reduce or alleviate the threats may include minimizing disturbance to wintering and migrating red knots (*e.g.,* managing recreational access to key rufa red knot foraging and roosting habitat during migration through restrictions on timing, locations, and types of activities) (see Special Management Considerations or Protection in the July 15, 2021, proposed rule). Private/other lands within this unit are managed under the 1992 Comprehensive Beach Management Plan of Beaufort County (Beaufort County Planning Board 1992, entire).

Unit SC–25: Turtle Island and Tomkins Island Beaches

Unit SC–25 consists of 1,771 ac (717 ha) on Turtle Island (a sea island) and Tompkins Island (a human-made island) in Calibogue Sound in Jasper County, South Carolina. The unit boundary begins on the southern shoreline of the New River and extends southwest along the Calibogue Sound shoreline to the Wright River shoreline of Turtle Island. The unit boundary also includes the entire Calibogue Sound shoreline of Tompkins Island located east of Turtle Island. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the unnamed inlet in the center of the Turtle Island shoreline. Lands within this unit are entirely in State ownership as SCDNR's Turtle Island Wildlife Management Area and a SCDNR seabird sanctuary. General land use within this unit includes wildlife management and outdoor recreational use (*e.g.,* beachgoing, boating, birdwatching, and fishing).

Unit SC–25 is occupied by the species and contains one or more of the physical or biological features essential to the conservation of the species. This unit contains a high concentration of rufa red knots during the spring migration period, serving as an important northbound stopover site, particularly when horseshoe crabs are spawning. This unit also has remote boat-only access and an undeveloped character that provides protection from intensive human uses.

Threats identified within Unit SC–25 include: (1) Disturbance of foraging and roosting red knots by humans and human activities (*e.g.,* off-leash dogs, walking/running through or too close to flocks of red knots, powered boats); (2) depredation by native and nonnative predators; (3) modification or loss of habitat or both due to uncontrolled recreational access, erosion, and sea level rise; and (4) disturbance associated with response to natural and human-caused disasters (*e.g.,* hurricanes, oil spills). Special management considerations or protection measures to reduce or alleviate the threats may include minimizing disturbance to wintering and migrating red knots (*e.g.,* managing recreational access to key rufa red knot foraging and roosting habitat during migration through restrictions on timing, locations, and types of activities) and managing the collection of spawning horseshoe crabs for biomedical use (*e.g.,* limiting location and timing of collection) (see Special Management Considerations or Protection in the 2021 proposed rule). State lands and waters within this unit are managed under the SCDNR's State Wildlife Action Plan (SCDNR 2015, entire).

Unit GA–1: Cockspur Island and Daymark Island Beaches

Unit GA–1 consists of 802 ac (325 ha) of Cockspur and Daymark Islands in the mouth of the Savannah River in Chatham County, Georgia. The unit boundary includes the entire Savannah River and South Channel of the Savannah River shorelines of Cockspur and Daymark Islands and includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and sandy intertidal zone that is covered at high tide and uncovered at low tide). Lands within this unit include approximately 708 ac (287 ha; 88 percent) in Federal ownership as part of the U.S. Coast Guard's Station Tybee and NPS's Fort Pulaski National Monument, and 94 ac (38 ha; 12 percent) in State ownership. General land use within this unit includes a U.S. Coast Guard installation, national monument visitation and recreational day uses (*e.g.,* boating, fishing, birdwatching).

Unit GA–1 is occupied by the species and contains one or more of the physical or biological features essential to the conservation of the species. This unit contains a high concentration of rufa red knots during the spring migration period, serving as an important northbound stopover site, particularly when horseshoe crabs are spawning.

Threats identified within Unit GA–1 include: (1) Disturbance of foraging and roosting red knots by humans and human activities (*e.g.,* off-leash dogs, running/walking/biking through or too close to flocks of red knots, powered boats); (2) depredation by native and nonnative predators; (3) modification or loss of habitat or both due to uncontrolled recreational access, erosion, and sea level rise; and (4) disturbance associated with the response to natural and human-caused disasters (*e.g.,* hurricanes, oil spills). Special management considerations or protection measures to reduce or alleviate the threats may include managing recreational access to key rufa red knot foraging and roosting habitat during migration (through restrictions on timing, locations, and types of activities) and limiting shoreline stabilization project construction windows (*e.g.,* outside of rufa red knot migration windows) (see Special Management Considerations or Protection in the 2021 proposed rule). Federal lands are managed under the Fort Pulaski National Monument Final General Management Plan (NPS 2013, entire) and the U.S. Coast Guard's Environmental Planning Implementation Procedures (U.S. Coast Guard 2020, entire).

Unit GA–5: Little Ogeechee River Shoreline and Raccoon Key

Unit GA–5 consists of 4,571 ac (1,850 ha) of the Little Ogeechee River shoreline along Green Island, Little Wassaw Island, and Pine Island and all of Raccoon Key in Ossabaw Sound in Chatham County, Georgia. The unit boundary begins at the Green Island shoreline of the Little Ogeechee River and continues east along the shorelines of Little Wassaw Island and Pine Island to the Odingsell River entrance behind Wassaw Island. The boundary continues north along the Pine Island and Little Wassaw Island shoreline of the Odingsell River and follows the Little Wassaw Island shoreline along Adams Creek through marshlands south of Skidaway Island to Delegal Creek behind Green Island. The unit includes all emergent land from MLLW to where densely vegetated habitat (not used by the red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the

ephemeral emergent shoals (sand bars) within the Ossabaw entrance. Lands within this unit include approximately 3,136 ac (1,267 ha; 69 percent) in Federal ownership and 1,435 ac (581 ha; 31 percent) in State ownership. General land use within this unit includes wildlife management as part of the Service's Wassaw Island NWR and outdoor recreational use (*e.g.,* beachgoing, boating, fishing, and birdwatching).

Unit GA–5 is occupied by the species and contains one or more of the physical or biological features essential to the conservation of the species. This unit contains a high concentration of rufa red knots during the spring migration period, serving as an important northbound stopover site, particularly when horseshoe crabs are spawning. This unit also has remote boat-only access and an undeveloped character that provides protection from intensive human uses.

Threats identified within Unit GA–5 include: (1) Disturbance of foraging and roosting red knots by humans and human activities (*e.g.,* running/walking through or too close to flocks of red knots, powered boats); (2) depredation by native and nonnative predators; (3) modification or loss of habitat or both due to uncontrolled recreational access, erosion, and sea level rise; and (4) disturbance associated with the response to natural and human-caused disasters (*e.g.,* hurricanes, oil spills). Special management considerations or protection measures to reduce or alleviate the threats may include minimizing disturbance to wintering and migrating red knots (*e.g.,* managing access to red knot foraging and roosting habitat during migration, such as through restrictions on timing, locations, and types of activities) (see Special Management Considerations or Protection in the 2021 proposed rule). State lands within this unit are managed under the GDNR State Wildlife Action Plan (GDNR 2015, entire), and Federal lands are managed under the 2011 Savannah Coastal NWR Complex Comprehensive Conservation Plan (Service 2011, entire).

Unit GA–10: Queens Island, Wolf Island, Egg Island, Little Egg Island, and Little Egg Island Bar

Unit GA–10 consists of 11,901 ac (4,816 ha) of Queens Island, Wolf Island, Egg Island, Little Egg Island, and Little Egg Island Bar at the Altamaha Sound in McIntosh County, Georgia. The unit boundary begins at the Black River shoreline of Queens Island and extends south along the Wolf Island shoreline, which includes Wolf Island Bar, to the eastern and southern shorelines of Little Egg Island Bar Natural Area southwest to Egg Island in the Altamaha Sound. The boundary continues northwest along the Altamaha River shoreline of Egg Island and north along the Little Mud River shoreline of Wolf Island and Rockdedundy River shoreline of Queens Island. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the entrance to Altamaha Sound and Beacon Creek. Lands within this unit include approximately 5,527 ac (2,237 ha; 46 percent) in Federal ownership, 261 ac (106 ha; 2 percent) in State ownership, 1,865 ac (755 ha; 16 percent) in private/other ownership, and 4,248 ac (1,719 ha; 36 percent) that are uncategorized. General land use within this unit includes wildlife management and outdoor recreational use (*e.g.,* beachgoing, boating, fishing, and birdwatching). Federal land use includes management of both Wolf and Egg Islands as part of Wolf Island NWR. Additionally, Wolf Island is a Class I designated wilderness area.

Unit GA–10 is occupied by the species and contains one or more of the physical or biological features essential to the conservation of the species. This unit contains a high concentration of rufa red knots during the spring and fall migration periods, serving as an important northbound and southbound stopover site, particularly when horseshoe crabs are spawning. Additionally, this unit contains a high concentration of rufa red knots during the winter period, providing important wintering habitat on the Southeastern U.S. portion of the subspecies' range for foraging and roosting during a time of the year when rufa red knots are seeking to build energy sources for migration. This location serves as one of five units in Georgia that supports high concentrations of rufa red knots throughout the entire nonbreeding season, and is also important due to its low-level development, remote boat-only access, and protection from intensive human uses. Approximately 1,401 ac (567 ha) of this unit overlap with designated critical habitat for the federally threatened piping plover (66 FR 36038, July 10, 2001).

Threats identified within Unit GA–10 include: (1) Disturbance of foraging and roosting red knots by humans and human activities (*e.g.,* walking/running through or too close to flocks of red knots, powered boats); (2) depredation by native and nonnative predators; (3) modification or loss of habitat or both due to erosion and sea level rise; and (4) disturbance associated with response to natural and human-caused disasters (*e.g.,* hurricanes, oil spills). Special management considerations or protection measures to reduce or alleviate the threats may include minimizing disturbance to wintering and migrating red knots (*e.g.,* managing recreational access to key rufa red knot foraging and roosting habitat during migration through restrictions on timing, locations, and types of activities) (see Special Management Considerations or Protection in the 2021 proposed rule). Federal lands in this unit are managed under the 2011 Savannah Coastal NWR Complex Comprehensive Conservation Plan (Service 2011, entire), and State lands are managed under the GDNR State Wildlife Action Plan (GDNR 2015, entire).

Unit TX–1: Rollover Pass to Bolivar Flats

Unit TX–1 consists of 1,478 ac (598 ha) in Galveston County, Texas. This unit begins bayside of Rollover Pass and extends southwest along the beach front ending at the north jetty on the Bolivar Peninsula. It includes 17 mi (27 km) of Gulf shoreline. The landward boundary is the line indicating the beginning of dense vegetation, and the gulf-side boundary is the MLLW, including emergent lands and intertidal area characterized as highly dynamic beach/seashore that is covered at high tide and uncovered at low tide. The bayside of Rollover Pass and west end of the unit includes lands known as wind tidal flats that are infrequently inundated. Specific habitat types within this unit include: estuarine (bayside) seagrass mud or sand flats that are subtidal, seagrass flats that are nearly flat areas with rooted vascular plants (seagrass) growing below the water surface in subtidal mud or sand substrate; estuarine (bayside) sandy shore (beach/sandbar) rarely exposed due to tidal fluctuation; estuarine (bayside) sandy shore (beach/sandbar) that is irregularly or regularly, depending upon the location, inundated by tides; and marine sandy coastline (beach) irregularly or regularly inundated by tides, depending upon the location (Federal Geographic Data Committee (FGDC) 2013, pp. 11–13, 37). Lands within this unit include approximately 482 ac (195 ha; 33 percent) in State ownership and 996 ac

(403 ha; 67 percent) in private/other ownership. General land use within this unit includes multiple human uses for recreation including both pedestrian and vehicle activity, and ongoing beach maintenance/nourishment activities. The west end of the unit is a well-known birding site (Bolivar Flats) that is protected by the Houston Audubon Society.

Unit TX–1 is occupied by the species and contains one of more of the physical or biological features essential to the conservation of the species. This unit contains a high concentration of rufa red knots during the winter period, providing an important wintering habitat location on the northern Gulf coast U.S. portion of the rufa red knot northern wintering range, especially for an area that also experiences a low level of disturbance during this time period. The intertidal zone and relatively undisturbed beach habitat provide multiple foraging and roosting habitat areas during the time of year when rufa red knots are seeking to build energy resources for migration. The west end portion of the unit overlaps with 1,015 ac (411 ha) of designated critical habitat for the federally threatened piping plover (66 FR 36038, July 10, 2001).

Threats identified within Unit TX–1 include: (1) Disturbance of foraging and roosting rufa red knots and their habitat modification as a result of humans, including recreational activities, domestic animals, and vehicle disturbance (*i.e.,* golf carts, cars, sport-utility vehicles (SUVs), motorcycles, etc.); (2) modification or loss of habitat due to residential and commercial development, beach maintenance and nourishment activities, and sea level rise; (3) predation (residential and migratory raptors); and (4) human-caused disasters and response to natural and human-caused disasters (*e.g.,* hurricanes, oil spills). Special management considerations or protection measures to reduce or alleviate the threats may include conducting public outreach and education, managing access to rufa red knot foraging habitat and adjacent roosting habitat during migration (through restrictions on timing, locations, and types of activities), managing sediment sources to offset erosion and sea level rise, and addressing the impacts of potential oil spills or gas drilling activities through facility placement, as well as spill response plans and training (see Special Management Considerations or Protection in the 2021 proposed rule). The Texas General Land Office State lands are managed under The Open Beaches Act, Texas Natural Resource Code Chapter 61, and The Dune Protection Act, Texas Natural Resource Code Chapter 63. The Audubon lands are managed under the Bolivar Flats Bird Sanctuary Management Plan (Houston Audubon 2017, entire).

Unit TX–11: South Bay–Boca Chica

Unit TX–11 consists of 15,400 ac (6,236 ha) in Cameron County, Texas. The Boca Chica gulf shoreline portion of this unit begins south of the Brownsville Ship Channel and extends approximately 6.5 mi (10 km) to the south. Within the South Bay, the northern boundary is south of Brownsville Ship Channel dredge spoil placement areas, and the southern boundary is north of the Rio Grande River. The eastern boundary is the bayside of the Boca Chica Beach (Gulf of Mexico) up to where dense vegetation begins, and the western boundary is west of the Loma islands up to where dense vegetation begins along the wind tidal flats. The unit includes wind tidal flats and all seagrass beds that are infrequently inundated and/or exposed at low tides and the tidal flats within the area known as South Bay. Specific habitat types within this unit include: estuarine (bayside) seagrass mud or sand flats that are subtidal and are nearly flat areas with rooted vascular plants (seagrass) growing below the water surface in subtidal mud or sand substrate; estuarine (bayside) algal mud or sand flats regularly inundated by tides and are nearly flat areas with a layer of algae growing on a moist mud or sand substrate and are otherwise devoid of vegetation; estuarine (bayside) algal mud or sand flats irregularly inundated by tides; estuarine (bayside) sandy shore (beach/sandbar) rarely exposed due to tidal fluctuation; estuarine (bayside) sandy shore (beach/sandbar) irregularly or regularly inundated by tides, depending upon the location; estuarine (bayside) sandy shore (beach/sandbar), spoils irregularly inundated by tides; and marine sandy coastline (beach) irregularly or regularly inundated by tides, depending upon the location (FGDC 2013, pp. 11–13, 37). Lands within this unit include approximately 5,536 ac (2,242 ha; 36 percent) in Federal ownership, 4,080 ac (1,652 ha; 26 percent) in State ownership, and 5,784 ac (2,342 ha; 38 percent) in private/other ownership. General land use within this unit includes rocket and drone launches and associated Space X space exploration development, and multiple recreational/beachside activities by humans, to include both pedestrian and vehicle activities. This unit is also managed for migratory bird use by the Lower Rio Grande Valley NWR.

Unit TX–11 is occupied by the species and contains one of more of the physical or biological features essential to the conservation of the species. This unit contains a high concentration of rufa red knots during the spring and fall migration periods, serving as an important northbound and southbound stopover site on the northern Gulf coast. Approximately 13,280 ac (5,374 ha)) of this unit overlap designated critical habitat for the federally threatened piping plover (66 FR 36038, July 10, 2001).

Threats identified within Unit TX–11 include: (1) Disturbance of foraging and roosting rufa red knots and their habitat modification as a result of humans, including recreational activities, vehicle disturbance (*i.e.,* golf carts, cars, SUVs, motorcycles, etc.), fishing, waterfowl hunting, and boating; (2) disturbance and habitat modification/erosion resulting from wind energy development and sea level rise; (3) predation (residential and migratory raptors); (4) habitat modification resulting from space exploration development; and (5) human-caused disasters and response to natural and human-caused disasters (*e.g.,* hurricanes, oil spills). Special management considerations or protection measures to reduce or alleviate the threats may include conducting public outreach and education, managing access to rufa red knot foraging habitat and adjacent roosting habitat during migration (through restrictions on timing, locations, and types of activities), managing sediment sources to offset erosion and sea level rise, and addressing the impacts of potential oil spills or gas drilling activities through facility placement, as well as spill response plans and training (see Special Management Considerations or Protection in the 2021 proposed rule). Federal lands are managed in accordance with the 1999 (reprinted) Lower Rio Grande Valley NWR land protection plan (Service 1993, entire). The Texas General Land Office State lands are managed under The Open Beaches Act, Texas Natural Resource Code Chapter 61, and The Dune Protection Act, Texas Natural Resource Code Chapter 63.

Required Determinations

All required determinations included in the 2021 proposed rule, with the exception of the following, are unchanged and apply to this revised proposed rule.

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this revised proposed rule is significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this revised proposed rule in a manner consistent with these requirements.

References Cited

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

Authors

The primary authors of this document are the staff members of the U.S. Fish and Wildlife Service Species Assessment Team and New Jersey Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

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

Proposed Regulation Promulgation

Accordingly, we propose to further amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as proposed to be amended at 86 FR 37410 (July 15, 2021) as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

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

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

■ 2. Amend § 17.95(b), the entry proposed at 86 FR 37410 for ''Knot, rufa red (*Calidris canutus rufa*)'', by revising paragraphs (5) through (125) and adding paragraphs (126) through (132) to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(b) *Birds.*

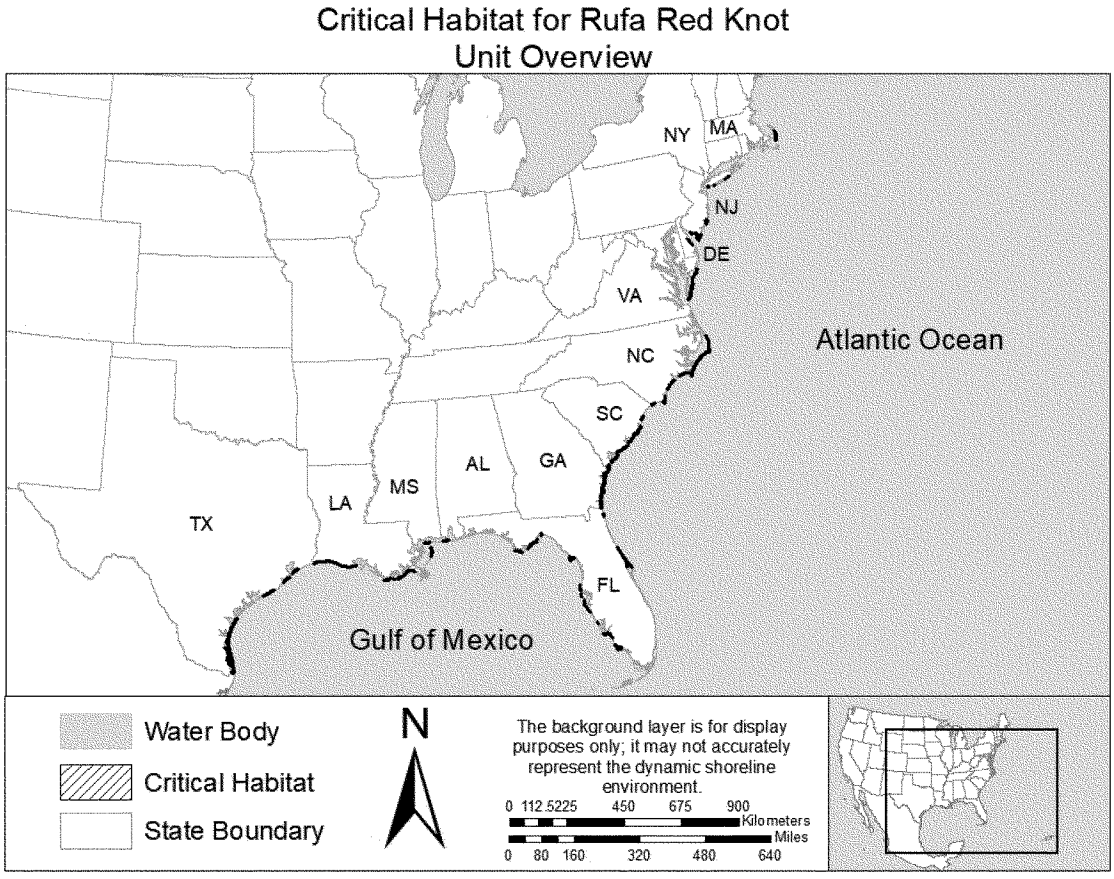
* * * * *

BILLING CODE 4333–15–P

Rufa Red Knot (*Calidris canutus rufa*)

(5) **Note:** Index map follows:

Figure 1 to Rufa Red Knot paragraph (5)



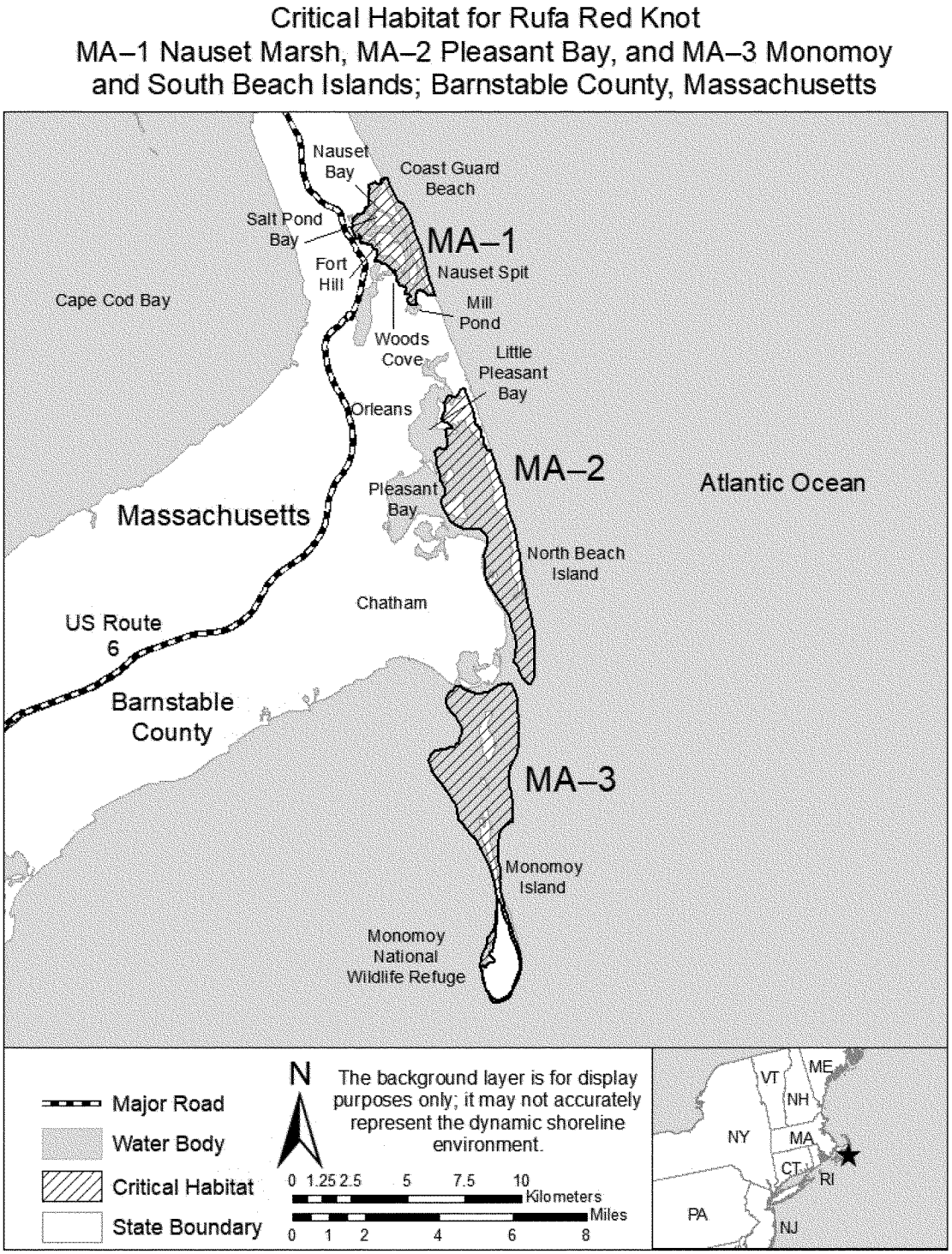
(6) Unit MA–1: Nauset Marsh, Massachusetts.

(i) This unit consists of approximately 2,219 ac (899 ha) of occupied habitat in Barnstable County consisting of exposed intertidal flats, shoals, mud flats, and

intertidal salt marsh pannes in Little Pleasant Bay and Pleasant Bay, and ephemeral tidal pools, primary sand dunes, and beaches associated with Nauset Beach South (Orleans), North Beach (Chatham), and North Beach Island (Chatham). Lands within this unit include approximately 1,340 ac (543 ha) in Federal ownership (including Monomoy National Wildlife Refuge (NWR)), 136 ac (55 ha) in private/other ownership, and 744 ac (301 ha) that are uncategorized.

(ii) Map of Unit MA–1 (Nauset Marsh) follows:

Figure 2 to Rufa Red Knot paragraph (6)(ii)



(7) Unit MA–2: Pleasant Bay, Massachusetts.

(i) Unit MA–2 consists of approximately 4,959 ac (2,007 ha) of occupied habitat in Barnstable County consisting of exposed intertidal sand and mud flats and shoals, ephemeral tidal pools, salt marsh, primary sand

dunes, and beaches associated with North and South Monomoy Islands, Monomoy Island, and the South Beach Island complex. Lands within this unit include approximately 126 ac (51 ha) in Federal ownership (including Cape Cod National Seashore), 2,005 ac (812) in private/other ownership, and 2,827 ac (1,144 ha) that are uncategorized.

(ii) Map of Unit MA–2 is presented at paragraph (6)(ii) of this entry.

(8) Unit MA–3: Monomoy and South Beach Islands, Massachusetts.

(i) Unit MA–3 consists of approximately 5,093 ac (2,061 ha) of occupied habitat in Barnstable County consisting of exposed intertidal sand and mud flats and shoals, ephemeral tidal pools, salt marsh, primary sand dunes, and beaches associated with North and South Monomoy Islands, Monomoy Island, and the South Beach Island complex. Lands within this unit include approximately 4,047 ac (1,638 ha) in Federal ownership (including Monomoy NWR) and 1,045 ac (423) in private/other ownership.

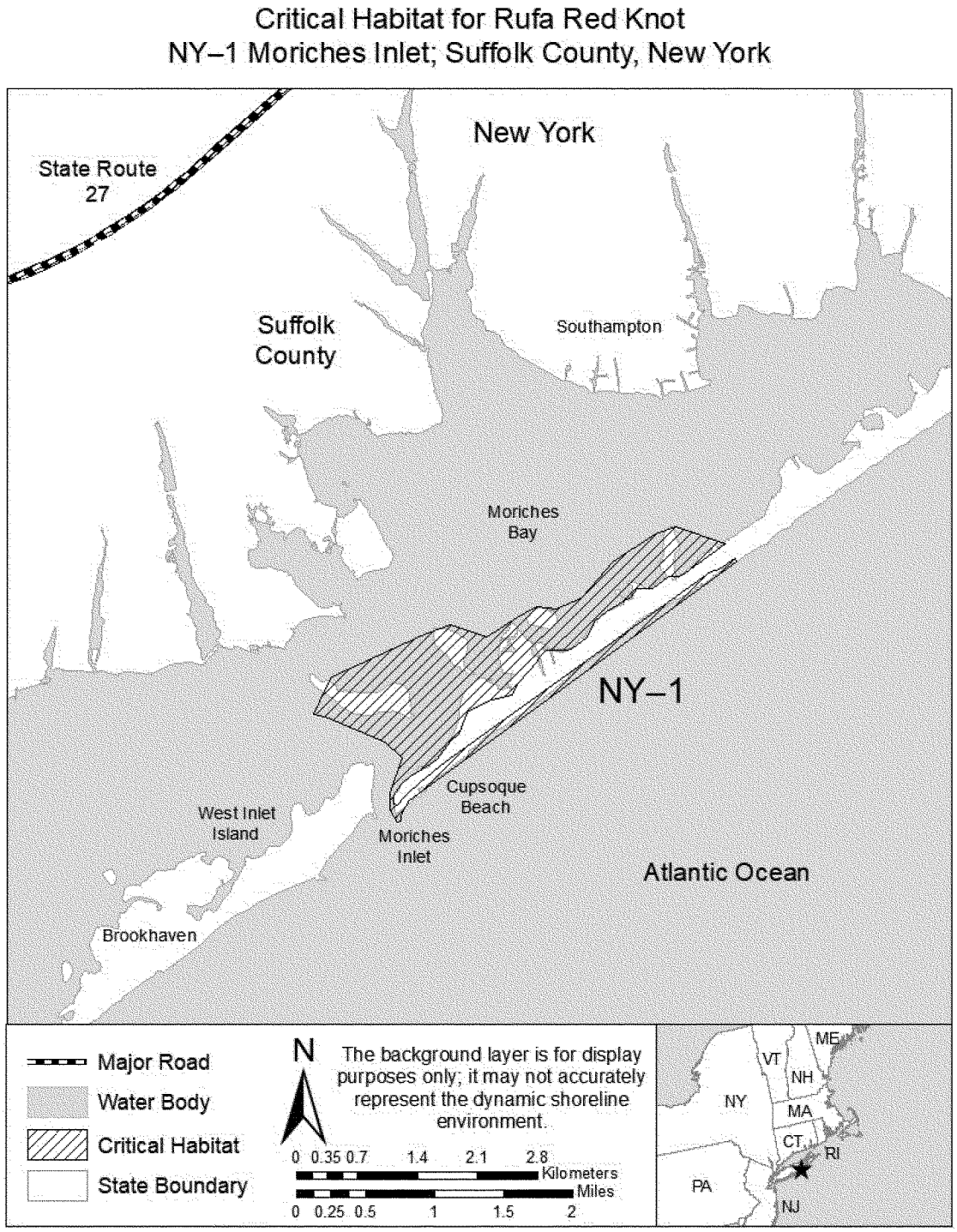
(ii) Map of Unit MA–3 is presented at paragraph (6)(ii) of this entry.

(9) Unit NY–1: Moriches Inlet, New York.

(i) Unit NY–1 consists of approximately 1,001 ac (405 ha) of occupied habitat in Suffolk County consisting of highly dynamic beach, sand flats, bay islands, back bay shoreline, intertidal areas, and surface water within the towns of Brookhaven and Southampton. Lands within this unit include approximately 78 ac (32 ha) in Federal ownership, 63 ac (25 ha) in State ownership, 163 ac (66 ha) in private/other (including the towns of Brookhaven and Southampton) ownership, and 697 ac (282 ha) that are uncategorized. This area includes the South Shore Estuary Reserve.

(ii) Map of Unit NY–1 follows:

Figure 3 to Rufa Red Knot paragraph (9)(ii)

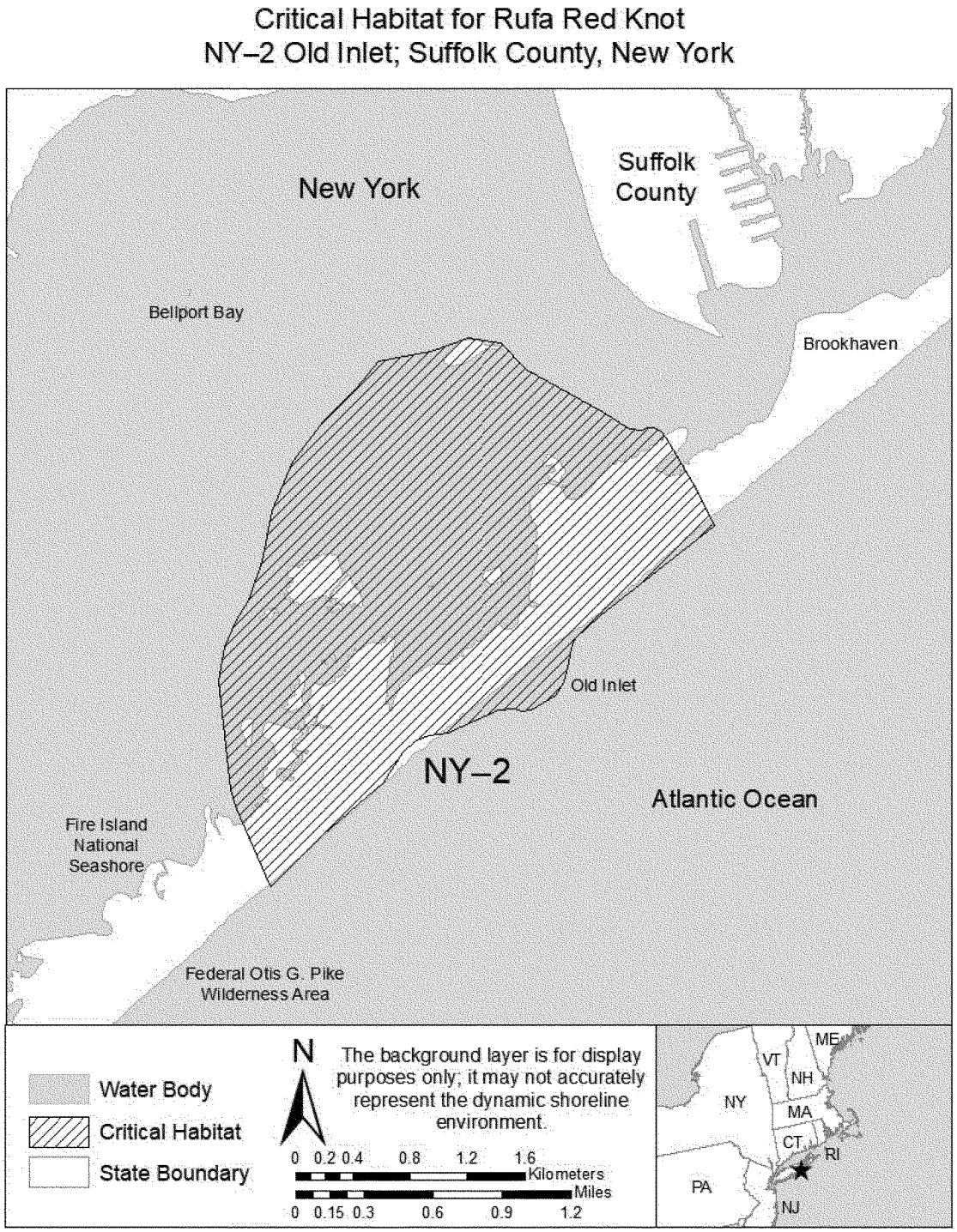


(10) Unit NY–2: Old Inlet, New York.

(i) Unit NY–2 consists of approximately 1,781 ac (721 ha) of occupied habitat in Suffolk County consisting of highly dynamic beach, sand flats, bay islands, back bay shoreline, intertidal areas, and surface water within the town of Brookhaven. Lands within this unit include approximately 1,481 ac (599 ha) in Federal ownership, 232 ac (94 ha) in State ownership, and 67 ac (27 ha) in private/other ownership (including the town of Brookhaven). This unit falls within the Fire Island National Seashore's Federal Otis G. Pike Wilderness Area.

(ii) Map of Unit NY–2 (Old Inlet) follows:

Figure 4 to Rufa Red Knot paragraph (10)(ii)

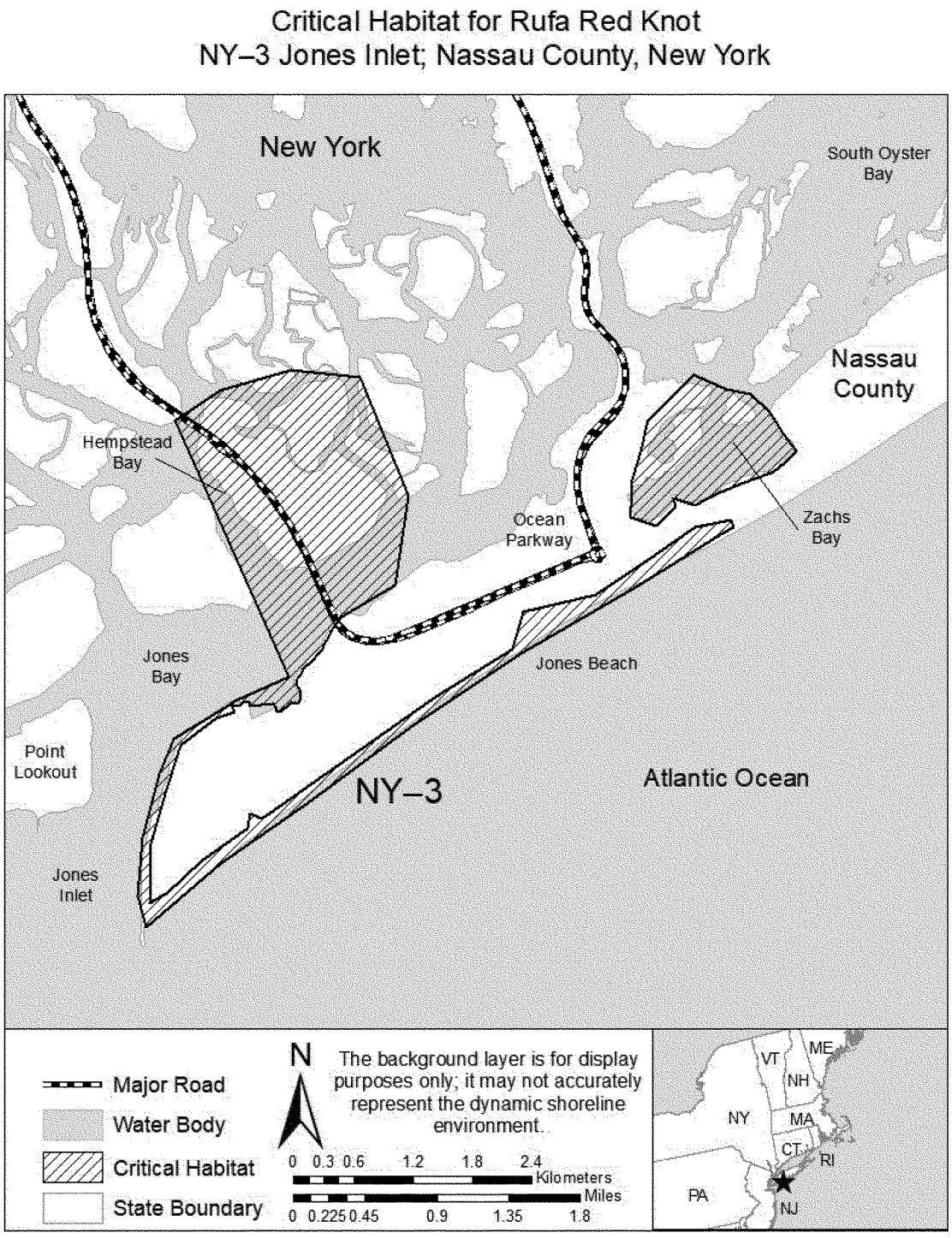


(11) Unit NY–3: Jones Inlet, New York.

(i) Unit NY–3 consists of approximately 1,821 ac (737 ha) of occupied habitat in Nassau County consisting of ocean beach habitat, sand flats, bay islands, and small embayments. It is irregularly shaped and is bounded to the south by the Atlantic Ocean, to the west by Point Lookout, to the north by a line running in Hempstead Bay, and to the east at the eastern extent of Zachs Bay. Lands within this unit include approximately 710 ac (287 ha) in State ownership and 1,111 ac (450 ha) that are under private/other ownership. This area includes the South Shore Estuary Reserve.

(ii) Map of Unit NY–3 follows:

Figure 5 to Rufa Red Knot paragraph (11)(ii)

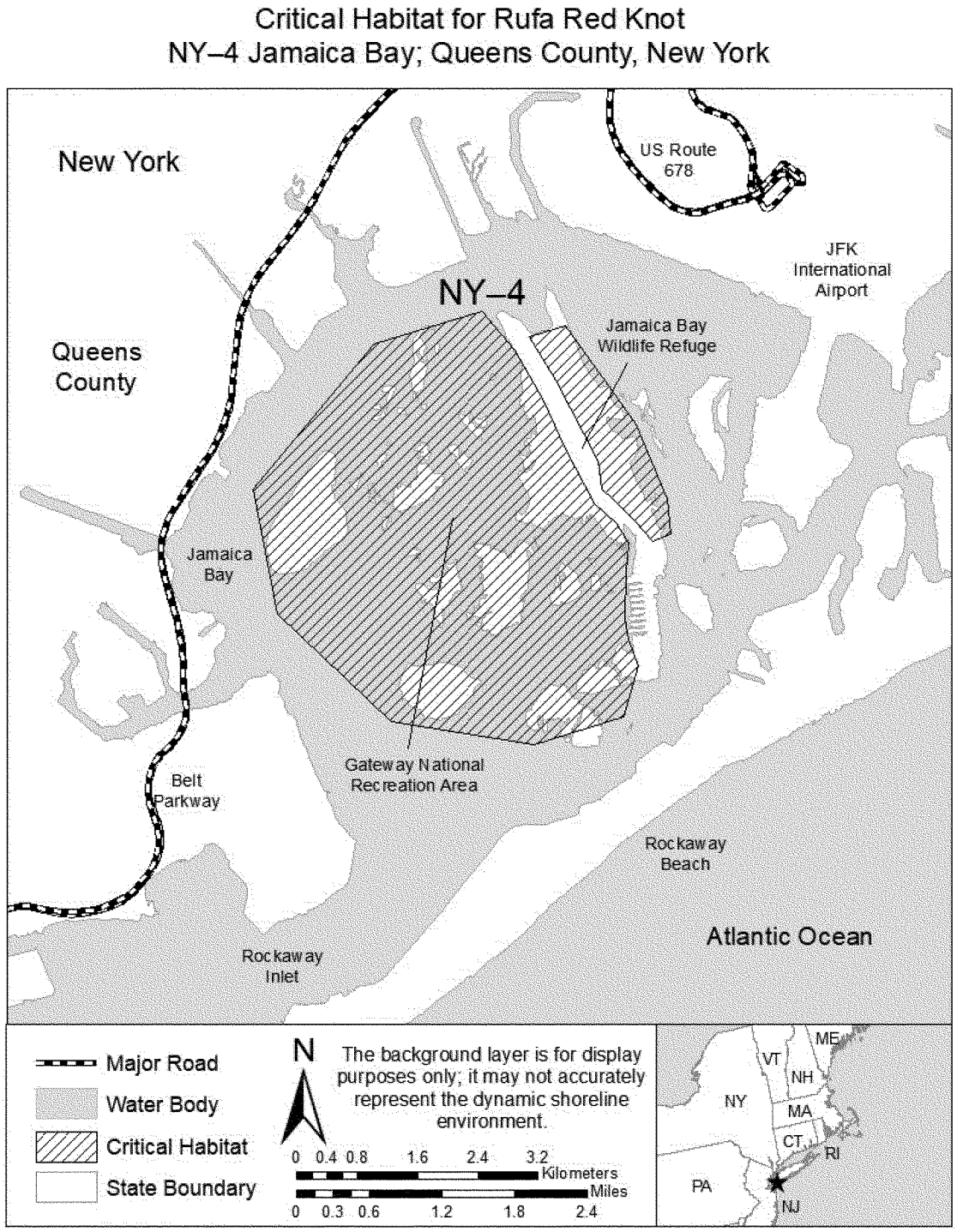


(12) Unit NY–4: Jamaica Bay, New York.

(i) Unit NY–4 consists of approximately 5,458 ac (2,209 ha) of occupied habitat in Queens County consisting of ocean beach habitat that is primarily within the National Park Service's Jamaica Bay Wildlife Refuge, Gateway National Recreation Area, and all under Federal ownership.

(ii) Map of Unit NY–4 follows:

Figure 6 to Rufa Red Knot paragraph (12)(ii)

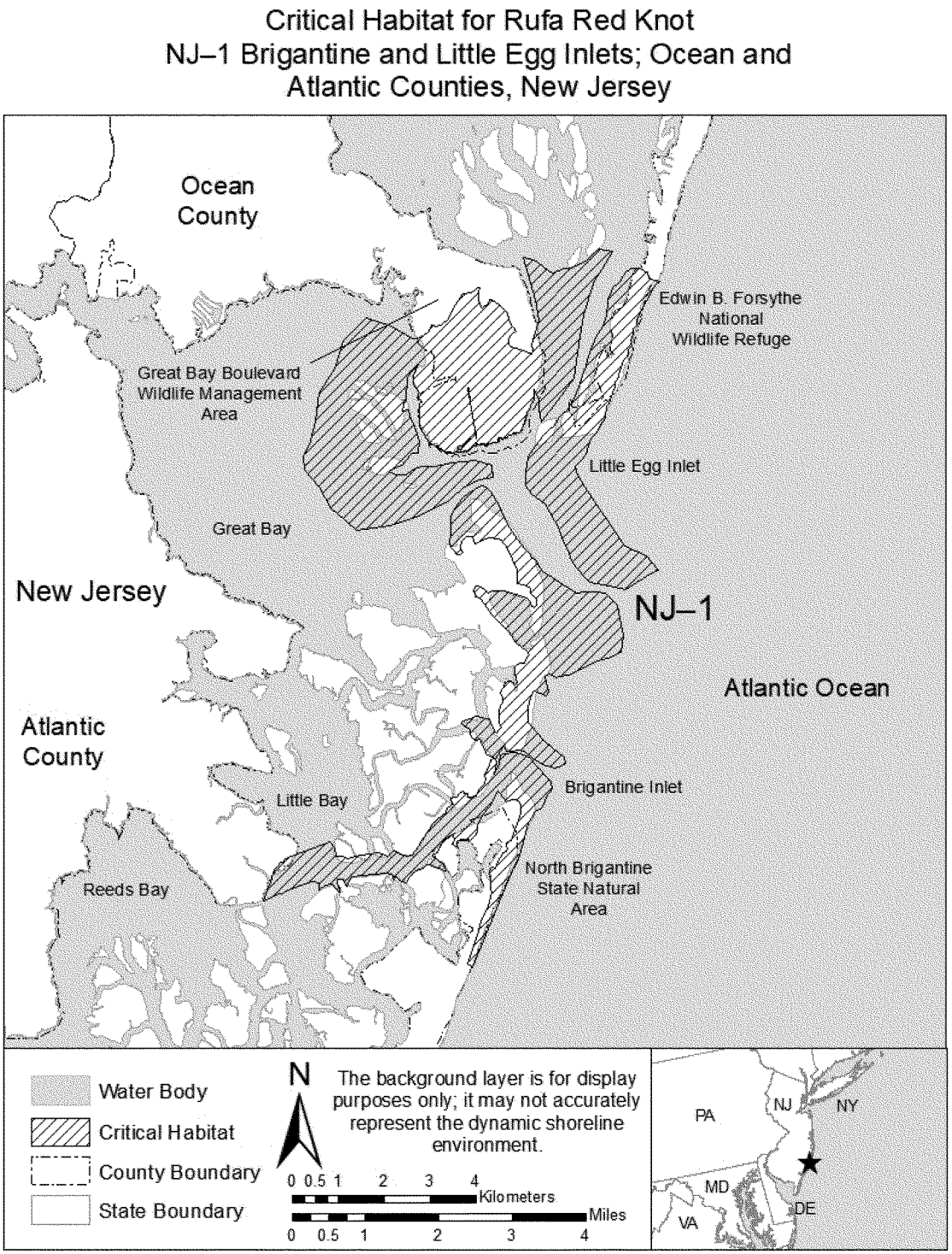


(13) Unit NJ–1: Brigantine and Little Egg Inlets, New Jersey.

(i) Unit NJ–1 consists of approximately 9,952 ac (4,027 ha) of occupied habitat in Ocean and Atlantic Counties consisting of beach, dune, shoals, open water, and tidal marsh associated with two inlets extending from the northern boundary of the Holgate Unit of Edwin B. Forsythe NWR, west to the ''Seven Islands'' portion of Great Bay Boulevard Wildlife Management Area, and south nearly to 15th Street North in Brigantine City. Lands within this unit include approximately 1,560 ac (632 ha) in Federal ownership (Forsythe NWR), 3,187 ac (1,291 ha) in State ownership (including the North Brigantine Natural Area), 10 ac (4 ha) in private/other ownership, and 5,194 ac (2,101 ha) that are uncategorized.

(ii) Map of Unit NJ–1 follows:

Figure 7 to Rufa Red Knot paragraph (13)(ii)

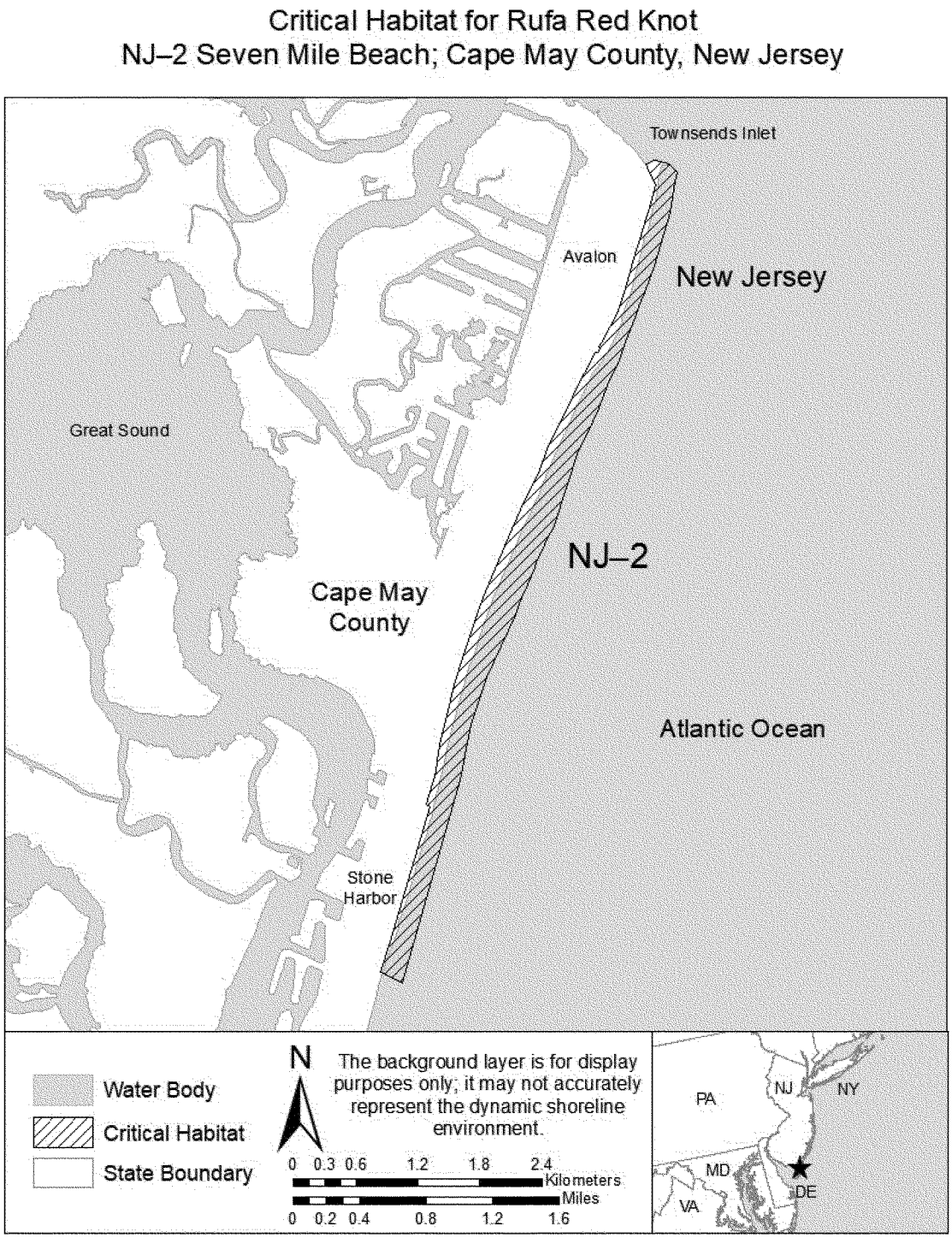


(14) Unit NJ–2: Seven Mile Beach, New Jersey.

(i) Unit NJ–2 consists of approximately 536 ac (217 ha) of occupied habitat in Cape May County consisting of sandy oceanfront beach in Avalon and Stone Harbor Boroughs, from the jetty at 8th Street in Avalon near Townsends Inlet and extending south to 102nd Street in Stone Harbor. All lands within this unit are in private/other ownership.

(ii) Map of Unit NJ–2 follows:

Figure 8 to Rufa Red Knot paragraph (14)(ii)

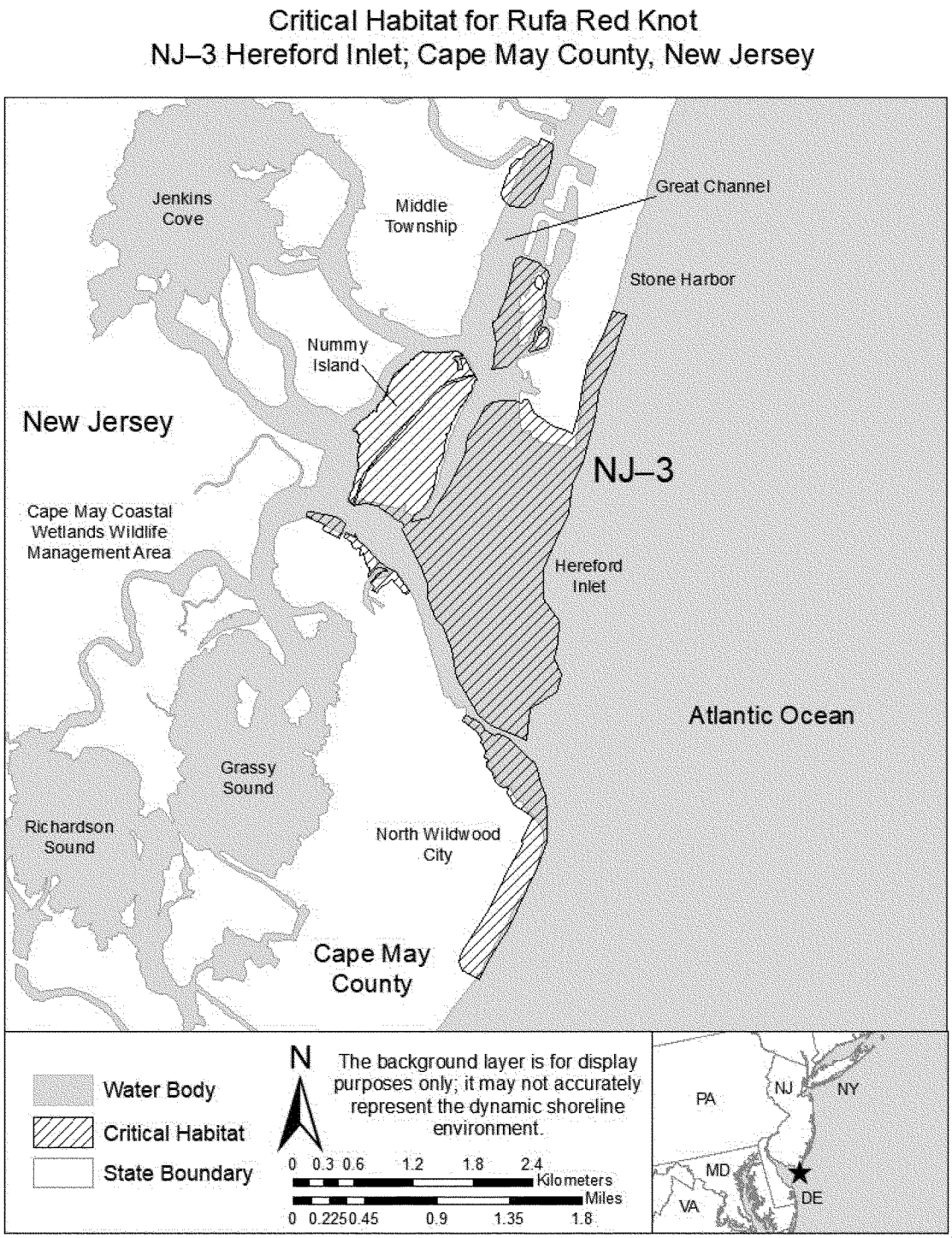


(15) Unit NJ–3: Hereford Inlet, New Jersey.

(i) Unit NJ–3 consists of approximately 1,631 ac (660 ha) of occupied habitat in Cape May County consisting of sandy oceanfront beaches, unstabilized barrier peninsula, undeveloped marsh islands, and several areas of tidal flats and shoals extending along the ocean from 111th Street in Stone Harbor Borough south to 22nd Avenue in North Wildwood City. The unit also includes areas behind the barrier island in Middle Township, Stone Harbor, and North Wildwood extending from Stone Harbor Boulevard south along Great Channel to Nummy Island and the southern shoreline of Grassy Sound Channel. Lands within this unit include approximately 175 ac (71 ha) in State ownership (including the Cape May Coastal Wetlands Wildlife Management Area), 735 ac (297 ha) in private/other ownership, and 721 ac (292 ha) that are uncategorized.

(ii) Map of Unit NJ–3 follows:

Figure 9 to Rufa Red Knot paragraph (15)(ii)

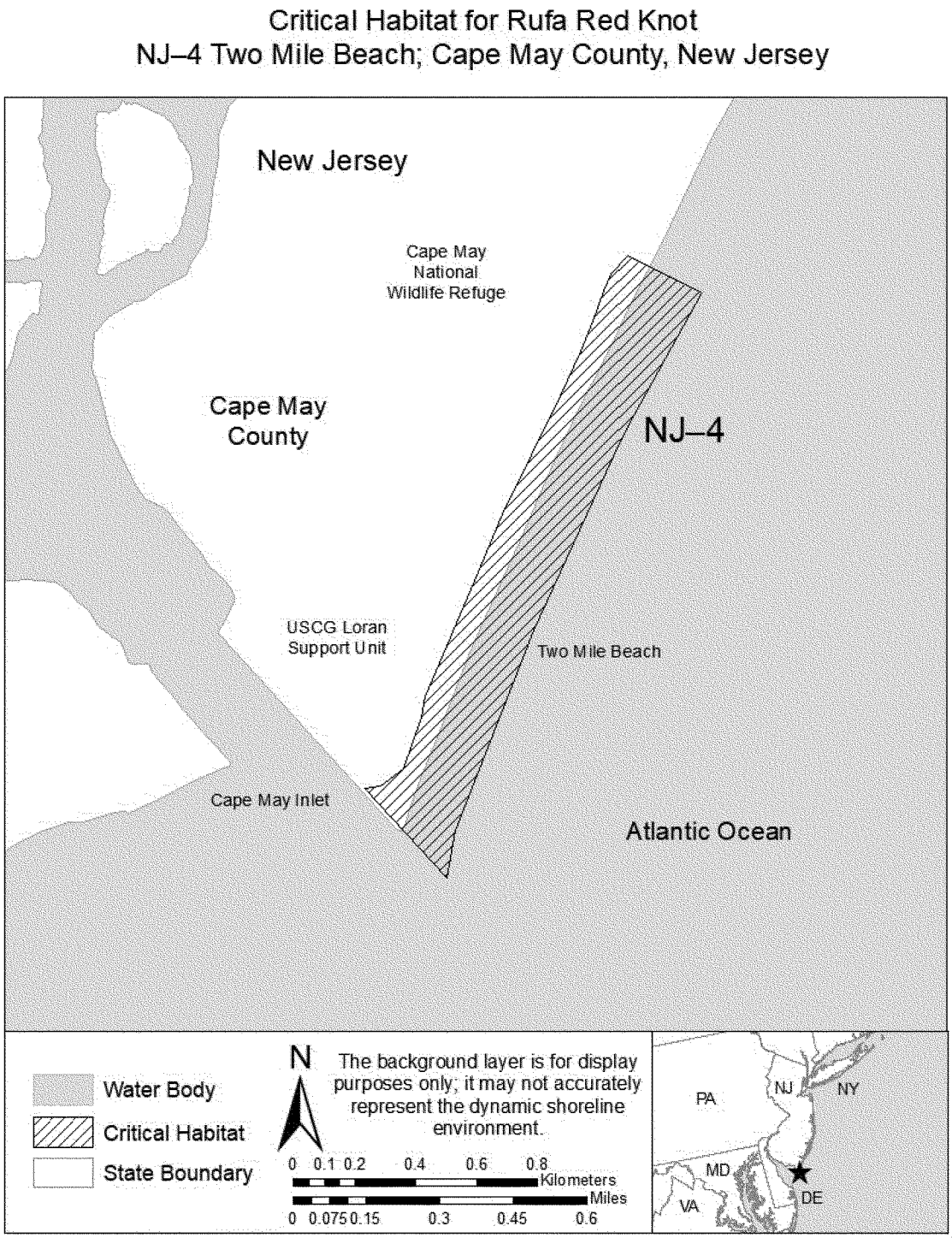


(16) Unit NJ–4: Two Mile Beach, New Jersey.

(i) Unit NJ–4 consists of approximately 128 ac (52 ha) of occupied habitat in Cape May County consisting of sandy oceanfront beach from the northeastern boundary of the Two Mile Beach Unit of Cape May NWR extending southwest to include all beach portions of the U.S. Coast Guard Loran Support Unit, ending at the eastern jetty of the Cape May Inlet. Lands within this unit are all under Federal ownership (Cape May NWR and U.S. Coast Guard).

(ii) Map of Unit NJ–4 follows:

Figure 10 to Rufa Red Knot paragraph (16)(ii)

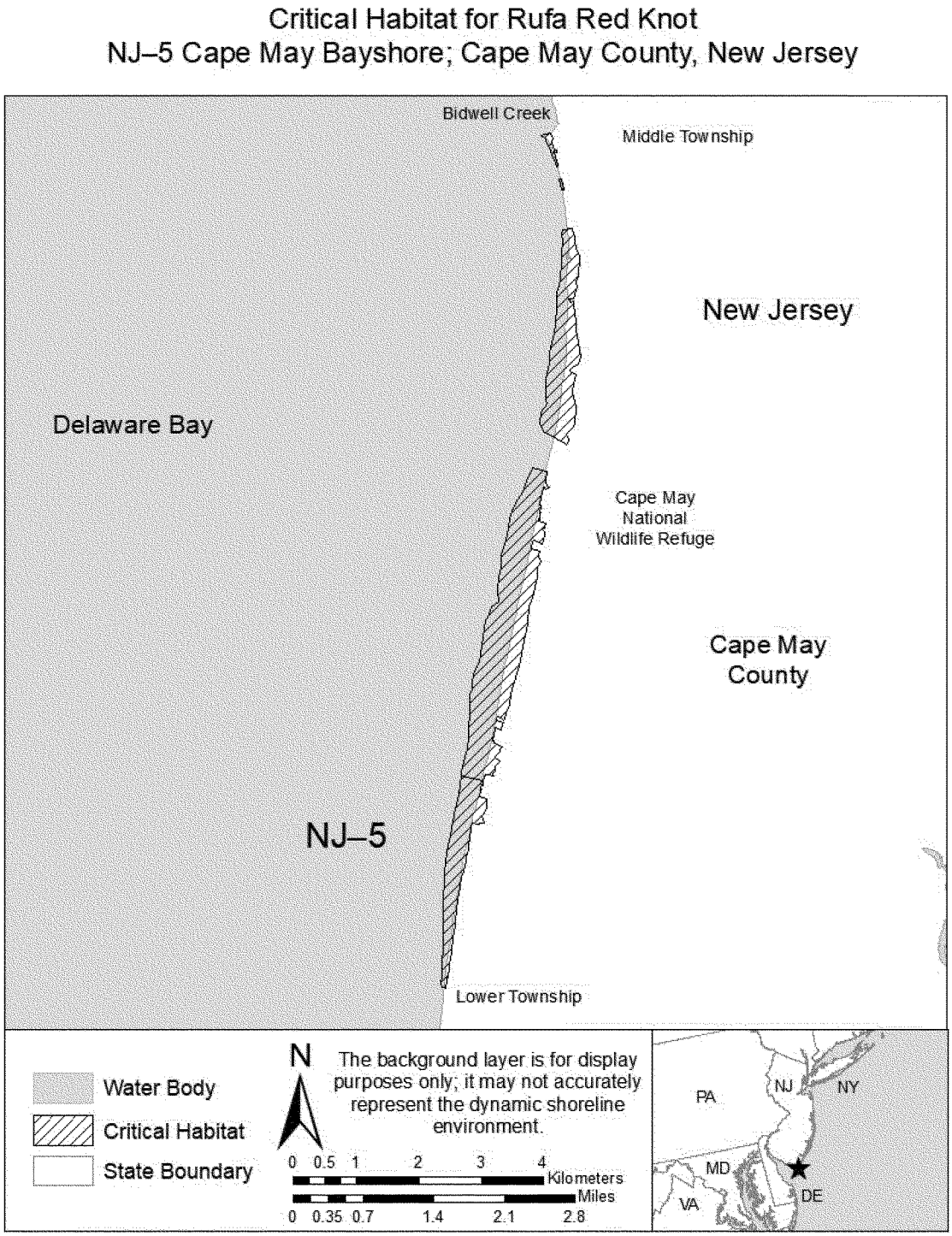


(17) Unit NJ–5: Cape May Bayshore, New Jersey.

(i) Unit NJ–5 consists of approximately 1,202 ac (487 ha) of occupied habitat in Cape May County consisting of Delaware Bay beaches, flats, and shoals from approximately Cloverdale Avenue in Lower Township to the jetty on the south shore of the mouth of Bidwell Creek in Middle Township. Lands within this unit include approximately 133 ac (54 ha) in Federal ownership (Cape May NWR), 44 ac (18 ha) in State ownership, 167 ac (67 ha) in private/other ownership, and 858 ac (347 ha) that are uncategorized.

(ii) Map of Unit NJ–5 follows:

Figure 11 to Rufa Red Knot paragraph (17)(ii)

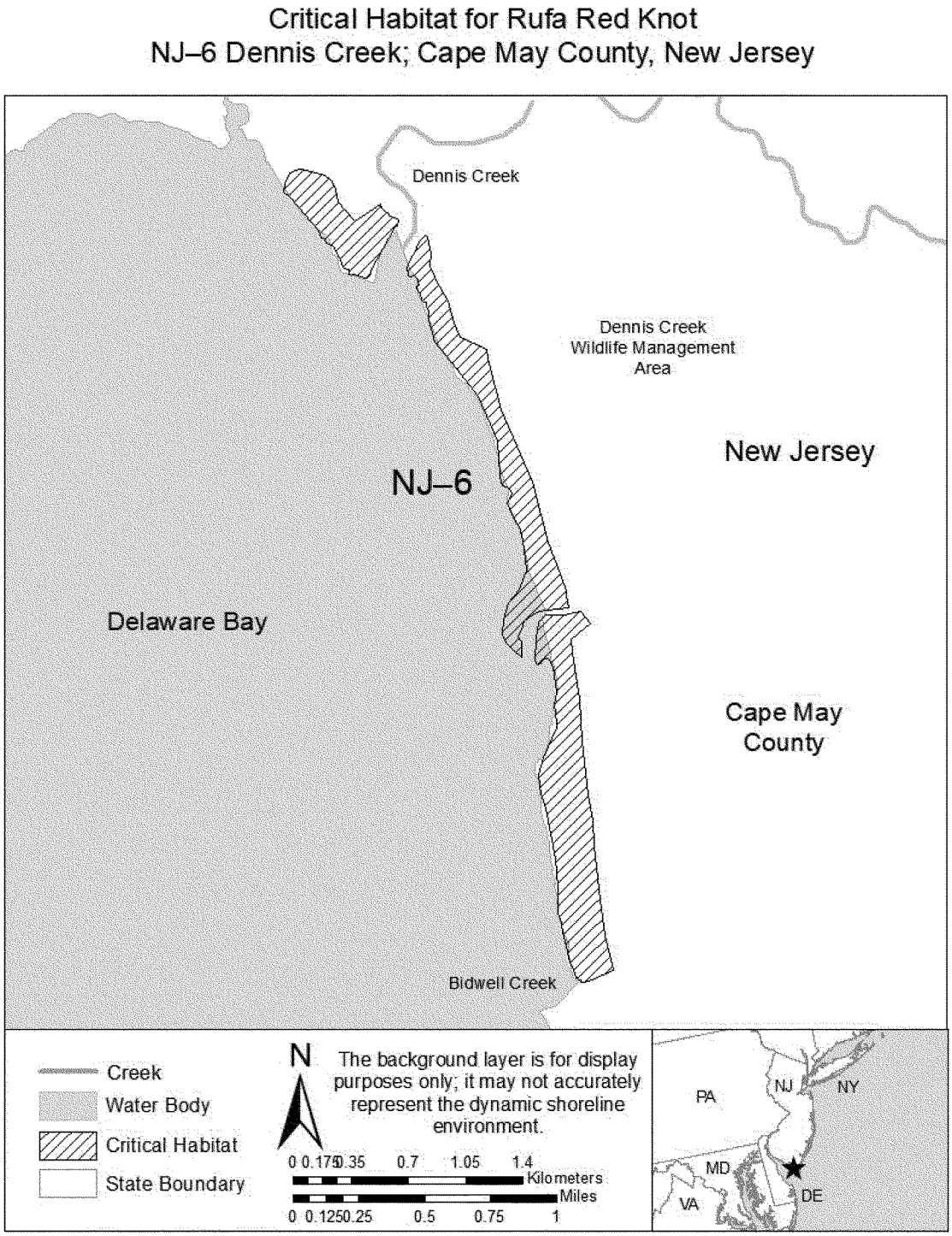


(18) Unit NJ–6: Dennis Creek, New Jersey.

(i) Unit NJ–6 consists of approximately 279 ac (113 ha) of occupied habitat in Cape May County consisting of Delaware Bay beaches, flats, and shoals from the northern shore of Bidwell Creek north to about 0.5 mi (0.8 km) north of Dennis Creek. Lands within this unit are all in State ownership (Dennis Creek Wildlife Management Area).

(ii) Map of Unit NJ–6 follows:

Figure 12 to Rufa Red Knot paragraph (18)(ii)

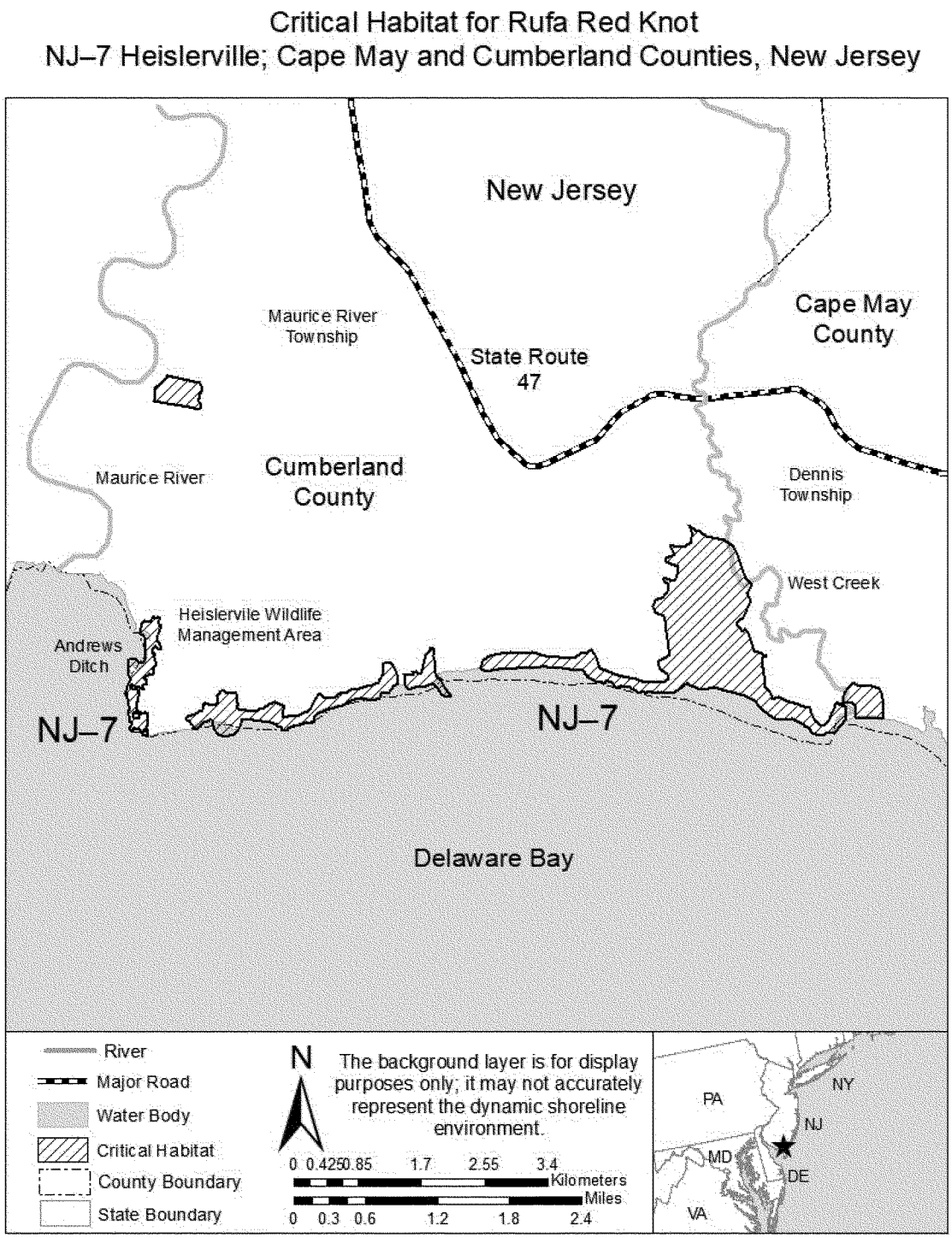


(19) Unit NJ–7: Heislerville, New Jersey.

(i) Unit NJ–7 consists of approximately 1,110 ac (449 ha) of occupied habitat in Cape May and Cumberland Counties consisting of Delaware Bay beaches, flats, shoals, tidal marsh, and open waters from approximately 2,000 ft (0.6 km) east of West Creek in Dennis Township, Cape May County, and extending west to the eastern end of Bay Avenue in Maurice River Township, Cumberland County. The developed area along Bay Avenue is excluded from the unit. West of Bay Avenue, Unit NJ–7 continues north to the mouth of Andrews Ditch in Maurice River Township. Lands within this unit include approximately 524 ac (211 ha) in State ownership (including the Heislerville Wildlife Management Area), 459 ac (186 ha) in private/other ownership, and 127 ac (52 ha) that are uncategorized.

(ii) Map of Unit NJ–7 follows:

Figure 13 to Rufa Red Knot paragraph (19)(ii)

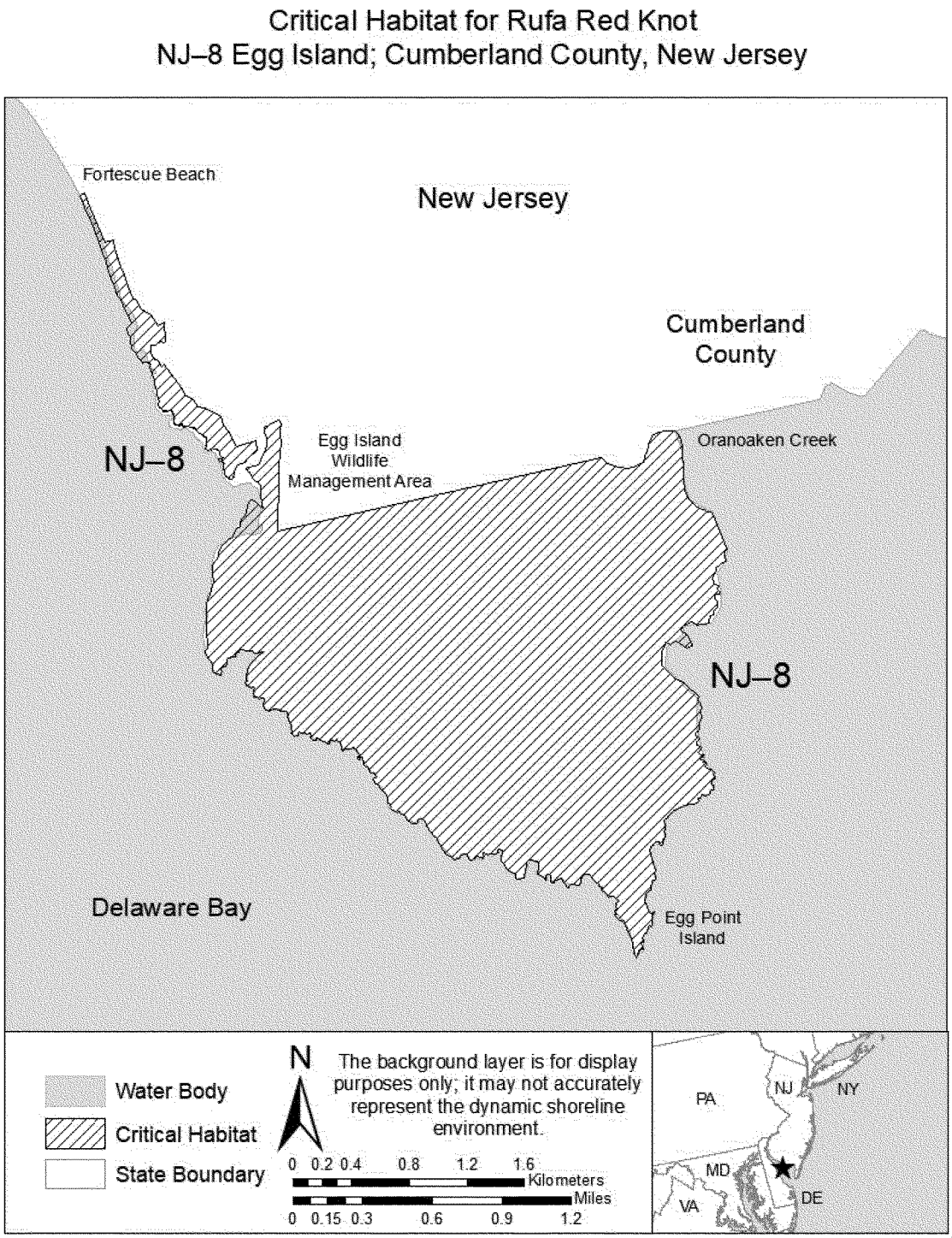


(20) Unit NJ–8: Egg Island, New Jersey.

(i) Unit NJ–8 consists of approximately 1,955 ac (791 ha) of occupied habitat in Cumberland County consisting of Delaware Bay beaches, flats, shoals, tidal marsh, and open waters from the mouth of Oranoaken Creek extending south to Egg Island point, and then northwest to about 850 ft (259 m) past Budney Avenue in the community of Fortescue. Lands within this unit include approximately 1,908 ac (773 ha) in State ownership, 32 ac (13 ha) in private/other ownership, and 14 ac (5 ha) that are uncategorized.

(ii) Map of Unit NJ–8 follows:

Figure 14 to Rufa Red Knot paragraph (20)(ii)

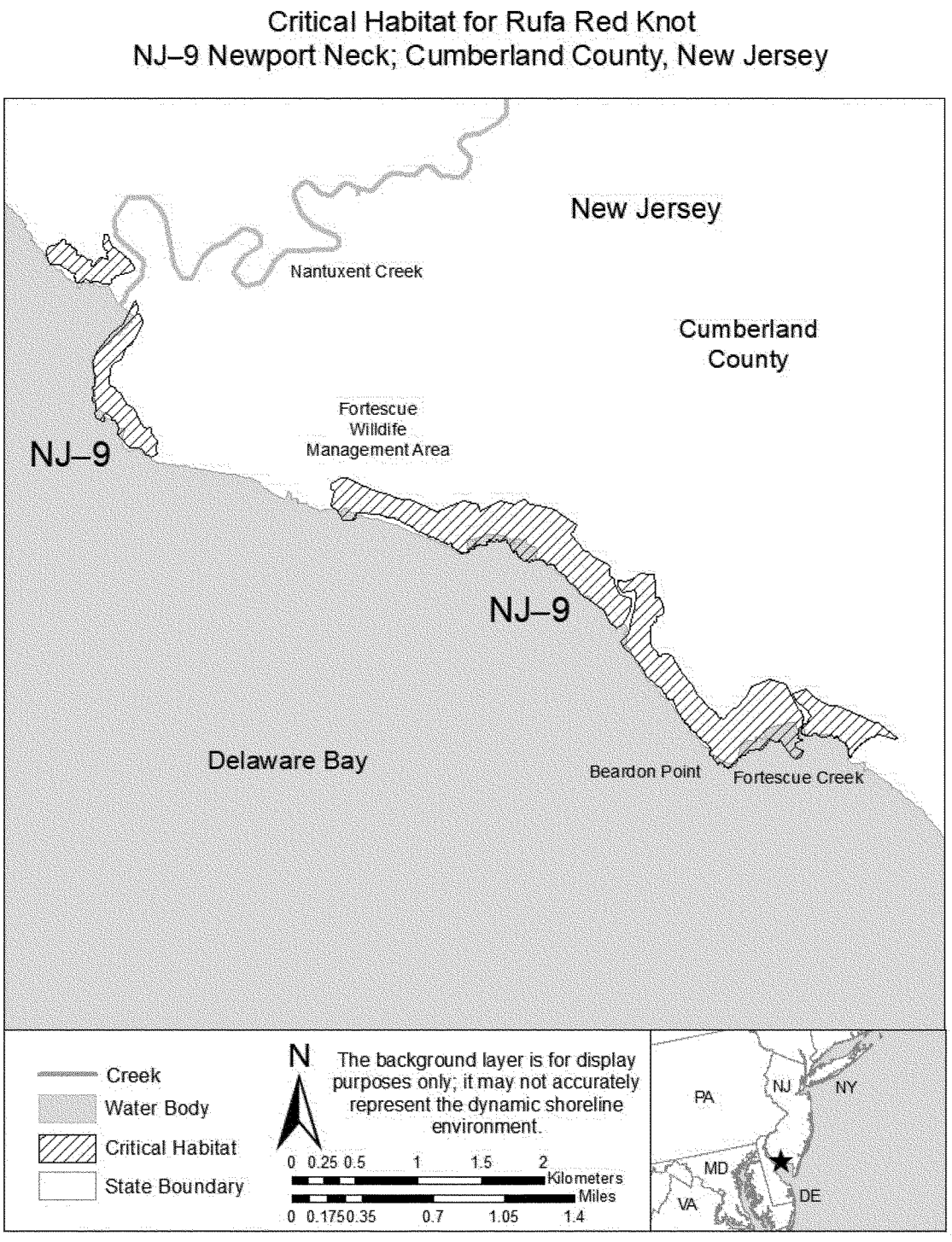


(21) Unit NJ–9: Newport Neck, New Jersey.

(i) Unit NJ–9 consists of approximately 472 ac (191 ha) of occupied habitat in Cumberland County consisting of Delaware Bay beaches, flats, shoals, and tidal marsh from the north bank of the mouth of Fortescue Creek extending northwest to include both sides of the mouth of Nantuxent Creek. Beaches adjacent to the developed community of Gandys Beach are not included in this unit. Lands within this unit include approximately 202 ac (82 ha) in State ownership (including the Fortescue Wildlife Management Area), 176 ac (71 ha) in private/other ownership, and 93 ac (38 ha) that are uncategorized.

(ii) Map of Unit NJ–9 follows:

Figure 15 to Rufa Red Knot paragraph (21)(ii)

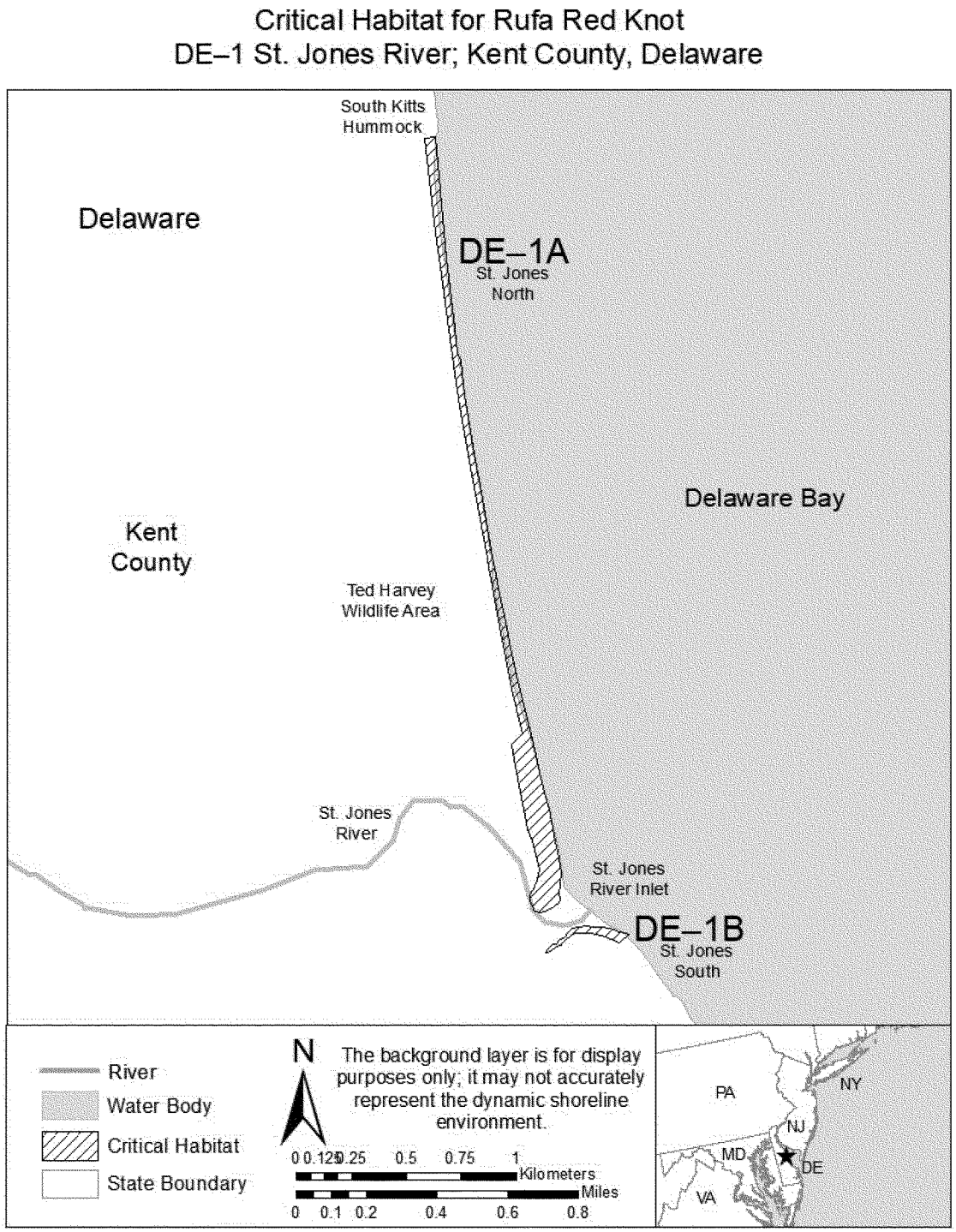


(22) Unit DE–1: St. Jones River, Delaware.

(i) Unit DE–1 consists of two subunits comprising 46 ac (19 ha) of occupied habitat in the St. Jones River area in Kent County. This unit consists of lands owned by the State of Delaware and private landowners.

(ii) Map of Unit DE–1 follows:

Figure 16 to Rufa Red Knot paragraph (22)(ii)



(iii) Subunit DE–1A (St. Jones North) consists of approximately 43 ac (18 ha) of occupied habitat in Kent County consisting of beach shoreline at the north end from South Bay Drive in South Kitts Hummock where there is a jetty into Delaware Bay, and continues to the south where it meets the St. Jones River inlet. The eastern boundary is the mean low low-water line (MLLW) of the Delaware Bay, and the western boundary runs along the dune line where the habitat changes from lightly vegetated, sandy beach to densely vegetated dunes or marsh. Lands within this subunit are approximately 37 ac (15 ha) in State ownership (including the Ted Harvey Wildlife Area), 3 ac (1 ha) of undeveloped beach privately owned by Delaware Wildlands, a conservation organization, and 3 ac (1 ha) that are uncategorized.

(iv) Map of Subunit DE–1A is presented at paragraph (22)(ii) of this entry.

(v) Subunit DE–1B (St. Jones South) consists of approximately 3 ac (1 ha) of occupied habitat in Kent County consisting of beach shoreline at the south side of the inlet to the St. Jones River. The eastern boundary is the MLLW of the Delaware Bay, and the western boundary is where the sandy beach turns to marshy habitat. Lands

within this subunit include approximately 1 ac (0.5 ha) in State ownership and approximately 2 ac (0.6 ha) in private/other ownership.

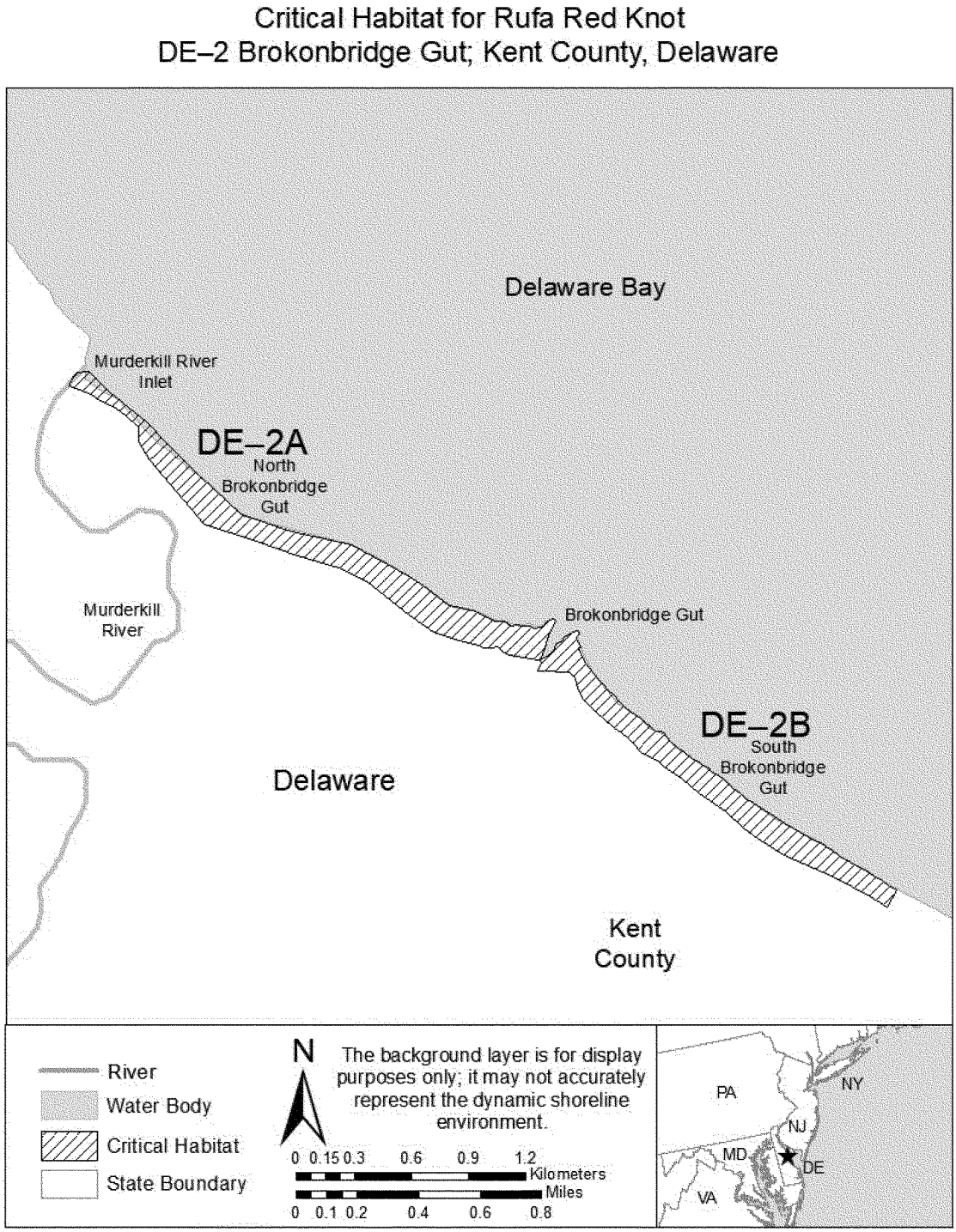
(vi) Map of Subunit DE–1B is presented at paragraph (22)(ii) of this entry.

(23) Unit DE–2: Brokonbridge Gut, Delaware.

(i) Unit DE–2 consists of two subunits comprising 163 ac (66 ha) of occupied habitat in the area where Brokonbridge Gut enters the Delaware Bay in Kent County. This unit consists of lands owned by the State of Delaware and private landowners.

(ii) Map of Unit DE–2 follows:

Figure 17 to Rufa Red Knot paragraph (23)(ii)



(iii) Subunit DE–2A (North Brokonbridge Gut) consists of approximately 93 ac (37 ha) of occupied habitat in Kent County consisting of beach shoreline between the north side of the Brokonbridge Gut inlet to the south side of the Murderkill River inlet. The eastern boundary is the MLLW of the Delaware Bay, and the western

boundary is where the sandy beach turns to marshy habitat. Lands within this subunit are primarily in private/other ownership (91 ac (37 ha)) with a small portion (2 ac (1 ha)) owned by the State.

(iv) Map of Subunit DE–2A is presented at paragraph (23)(ii) of this entry.

(v) Subunit DE–2B (South Brokonbridge Gut) consists of approximately 70 ac (29 ha) of occupied habitat in Kent County consisting of beach shoreline at the south side of the inlet to Brokonbridge Gut. The eastern boundary is the MLLW of the Delaware Bay, and the western boundary is where the sandy beach turns to marshy habitat. Lands within this subunit are all in private/other ownership, primarily owned and protected by a private conservation organization (Delaware Wildlands; 52 ac (21 ha)), with the remaining approximately 18 ac (7 ha) as private, undeveloped land.

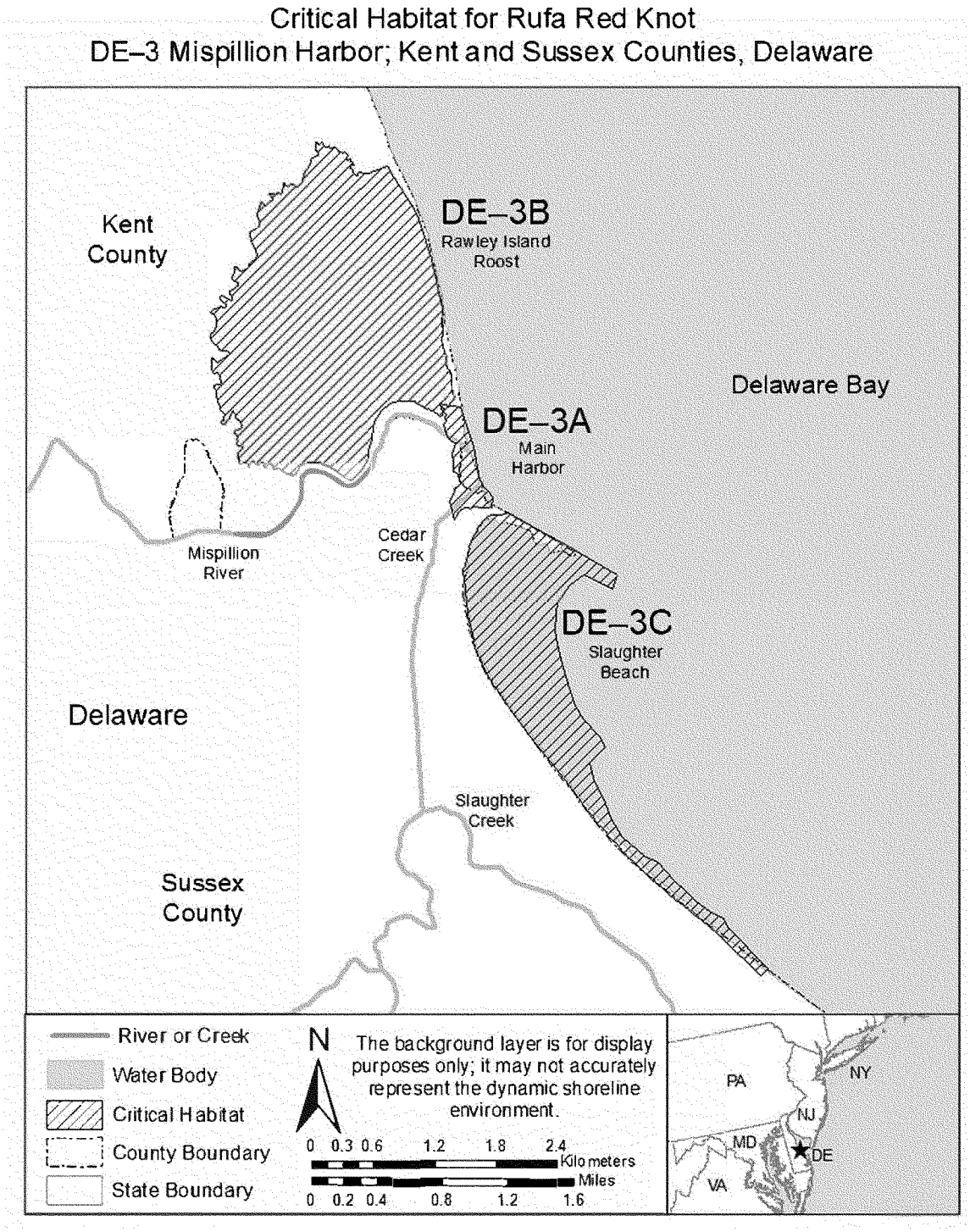
(vi) Map of Subunit DE–2B is presented at paragraph (23)(ii) of this entry.

(24) Unit DE–3: Mispillion Harbor, Delaware.

(i) Unit DE–3 consists of three subunits comprising 1,949 ac (789 ha) of occupied habitat in the Mispillion Harbor area where the Mispillion River and Cedar Creek enter the Delaware Bay in Kent and Sussex Counties. This unit consists of lands owned primarily by the State of Delaware, with minor ownership by Federal and private/other.

(ii) Map of Unit DE–3 follows:

Figure 18 to Rufa Red Knot paragraph (24)(ii)



(iii) Subunit DE–3A (Main Harbor) consists of approximately 61 ac (25 ha) of occupied habitat in Kent and Sussex Counties consisting of beach shoreline at the south side of the inlet to Brokonbridge Gut. The eastern boundary is the MLLW of the Delaware Bay, and the western boundary is where the sandy beach turns to marshy habitat. Lands within this subunit include approximately 32 ac (13 ha; 53 percent) in State ownership and 29 ac (12 ha; 47 percent) that are uncategorized.

(iv) Map of Subunit DE–3A is presented at paragraph (24)(ii) of this entry.

(v) Subunit DE–3B (Rawley Island Roost) consists of approximately 1,298 ac (525 ha) of occupied habitat in Kent County consisting of beach shoreline and marsh on the north side of the Mispillion River, extending north to Graco's Canal. The western boundary is Crooked Gut, and the eastern boundary is the MLLW of the Delaware Bay. Lands within this subunit include approximately 1,139 ac (461 ha) in State ownership (Milford Neck Wildlife Area), 153 ac (62 ha) in private/other ownership, and 6 ac (2 ha) that are uncategorized. Private lands are owned by a combination of a private conservation organization—The Nature

Conservancy (TNC; 148 ac (60 ha))—with a small area of private, undeveloped land that has a conservation easement.

(vi) Map of Subunit DE–3B is presented at paragraph (24)(ii) of this entry.

(vii) Subunit DE–3C (Slaughter Beach) consists of approximately 590 ac (239 ha) of occupied habitat in Sussex County consisting of beach shoreline, marsh, and harbor structures extending from the eastern tip of the dike that outlines the outer tip of the Mispillion Harbor, south along the sandy beach of Slaughter Beach to the southern end of Isaacs Shore Drive. The western boundary is where the lightly vegetated beach becomes marsh in the northern portions of this subunit, or where property parcels end in the southern portion of this subunit. The eastern boundary is the MLLW of the Delaware Bay. Lands within this subunit include approximately 1 ac (0.25 ha) in Federal ownership, 59 ac (24 ha) in State ownership, 2 ac (1 ha) in private/other ownership, and 528 ac (213 ha) that are uncategorized.

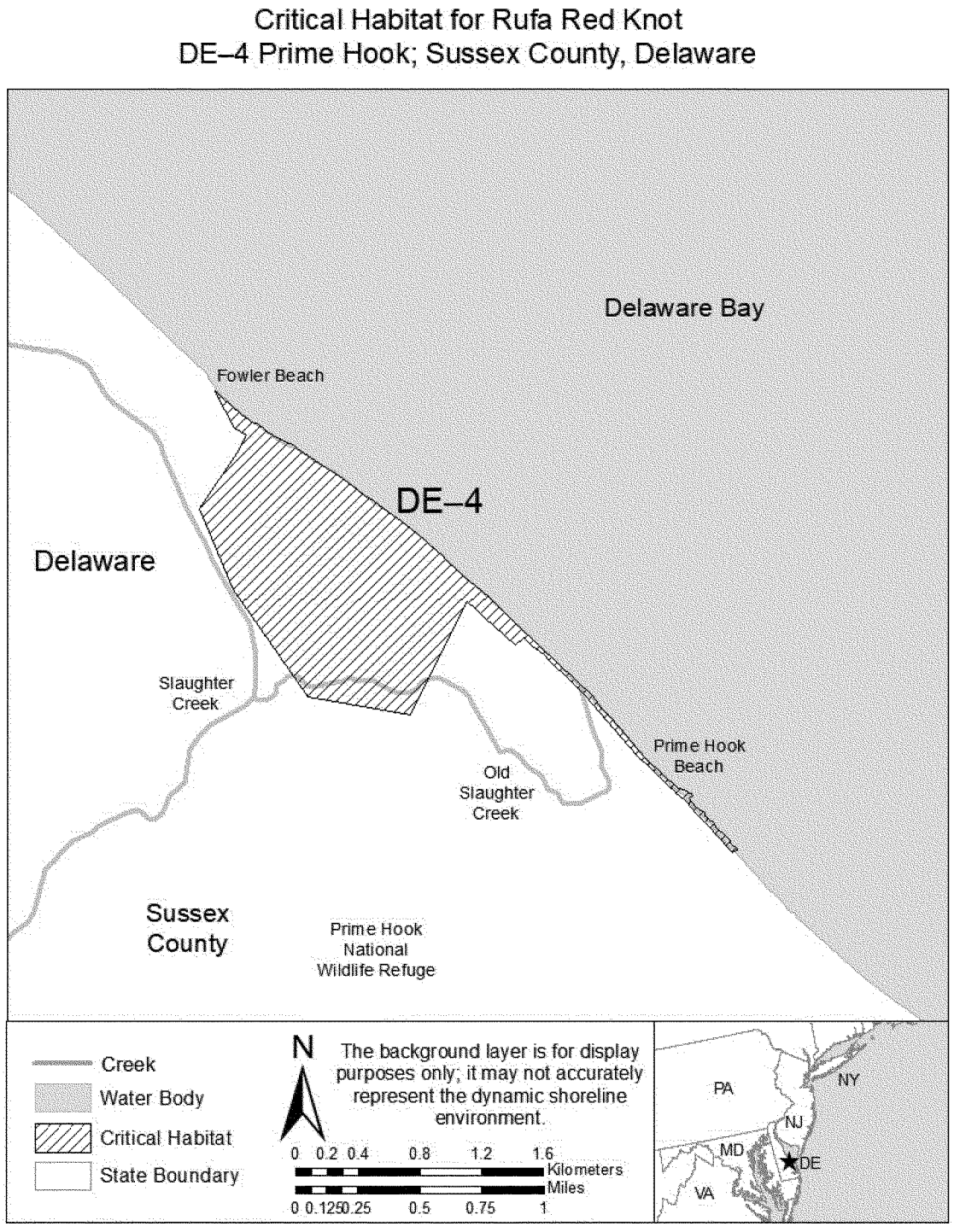
(viii) Map of Subunit DE–3C is presented at paragraph (24)(ii) of this entry.

(25) Unit DE–4: Prime Hook, Delaware.

(i) Unit DE–4 consists of approximately 503 ac (203 ha) of occupied habitat in Sussex County consisting of beach shoreline and marsh from about 1 mi (1.6 km) north of Fowler Beach Road south to the end of South Bayshore Drive. The eastern boundary is the MLLW of the Delaware Bay, and the western boundary in the northern portion of the unit runs along the dune line where the habitat changes from lightly vegetated sandy beach to densely vegetated dunes or marsh. The western boundary of the central portion of this unit includes marsh and shallow open water areas where birds can roost overnight and forage. The western edge of the southern portion of the unit is where property parcels end at the beach. Lands within this unit include approximately 482 ac (195 ha) in Federal ownership (Prime Hook NWR), 6 ac (2 ha) in private/other ownership, and 14 ac (6 ha) that are uncategorized.

(ii) Map of Unit DE–4 follows:

Figure 19 to Rufa Red Knot paragraph (25)(ii)



(26) Unit VA–1: Assateague Island, Virginia.

(i) Unit VA–1 consists of approximately 2,817 ac (1,140 ha) of occupied habitat in Accomack County consisting of beach shoreline from the Virginia–Maryland State line south to the area known as ''The Hook,'' a wide peninsula that curves northwest. The western boundary is along the dune line where the habitat changes from sandy beach with little vegetation to densely vegetated dunes or marshland, as well as densely vegetated forested or herbaceous vegetation landward of the beach and primary dune. The eastern boundary extends seaward past the MLLW line, including dynamic intertidal areas that are covered at high tide and uncovered at low tide, as well as shoaling areas that are inundated with less than 3 in (7.6 cm) of water. All lands within this unit are federally owned (Assateague Island National Seashore and Chincoteague NWR).

(ii) Map of Unit VA–1 follows:

Figure 20 to Rufa Red Knot paragraph (26)(ii)

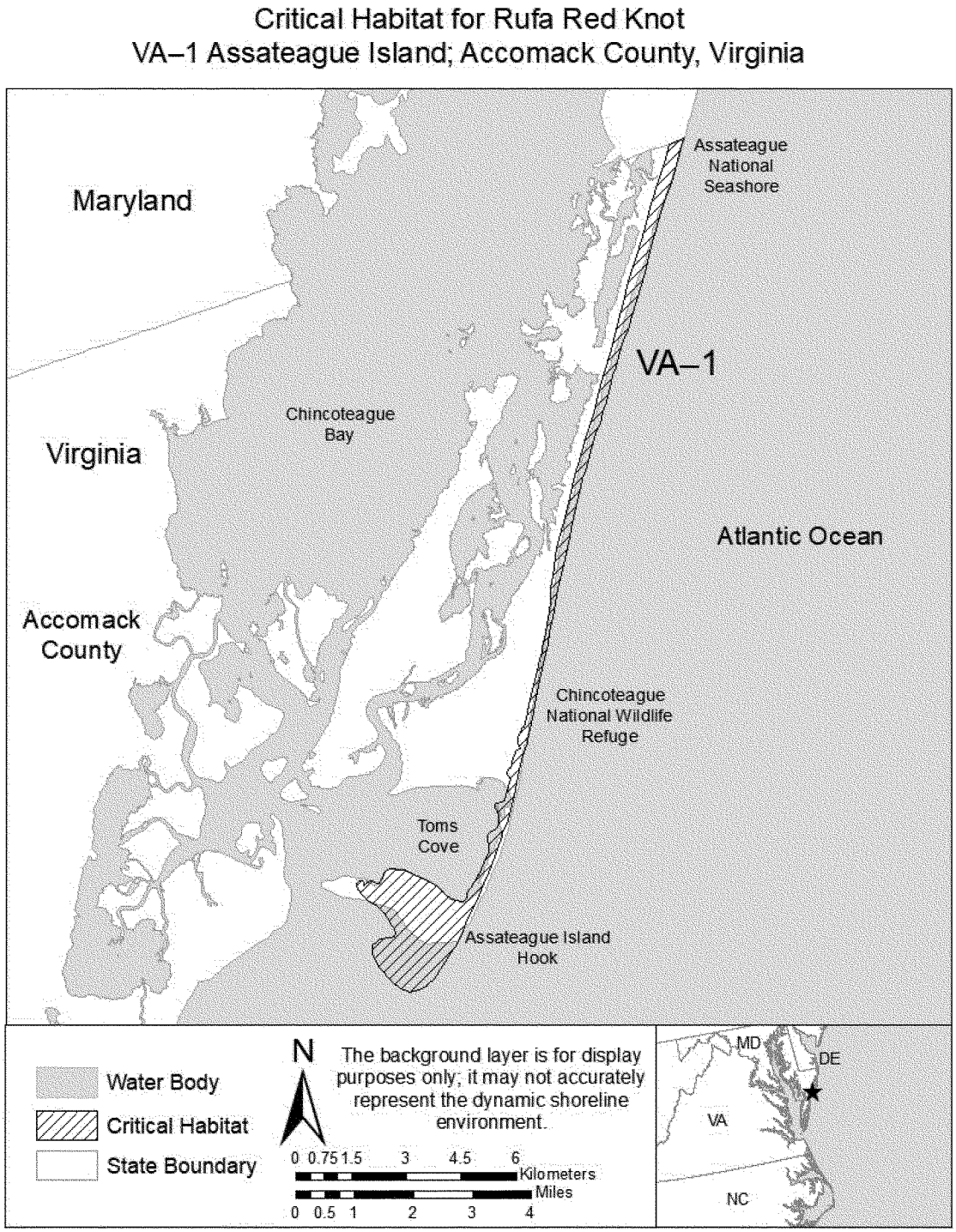
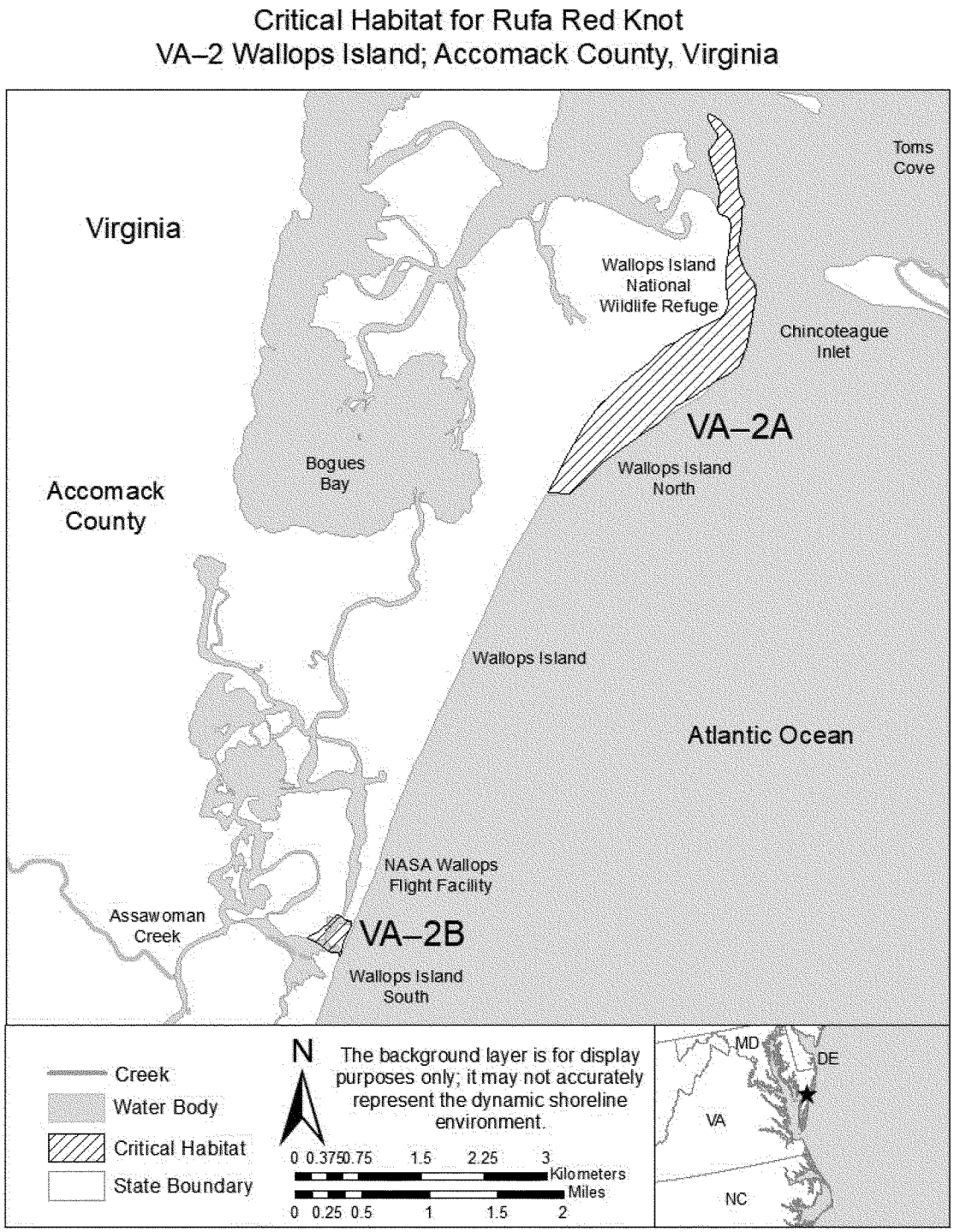


Figure 21 to Rufa Red Knot paragraph (27)(ii)

(27) Unit VA–2: Wallops Island, Virginia.

(i) Unit VA–2 comprises two subunits (totaling 571 ac (231 ha)) of occupied habitat owned and managed by the National Aeronautics and Space Administration (NASA) as part of the Wallops Flight Facility located in Accomack County.

(ii) Map of Unit VA–2 follows:



(iii) Subunit VA–2A (Wallops Island North) consists of approximately 540 ac (218 ha) of occupied habitat in Accomack County consisting of beach shoreline and dynamic intertidal areas. The north and east boundaries of the subunit are Chincoteague Inlet and seaward past the MLLW line and shoaling areas that are inundated with less than 3 in (7.6 cm) of water. The western boundary is along the marsh line where the habitat changes from lightly vegetated sandy beach and exposed peat with little vegetation to densely vegetated marshland, peat banks, or densely vegetated forested or herbaceous vegetation landward of the beach and primary dune. The southern boundary tapers to a point ending at the northern end of the facility's sea wall structure; it extends past the MLLW line and includes the areas that are slightly inundated with less than 3 in (7.6 cm) of water. All lands within this subunit are federally owned by NASA.

(iv) Map of Subunit VA–2A is presented at paragraph (27)(ii) of this entry.

(v) Subunit VA–2B (Wallops Island South) consists of approximately 31 ac (13 ha) of occupied habitat in Accomack County consisting of beach shoreline and dynamic intertidal areas. The northern boundary is the end of the road south of the old runway, the southern

boundary is Assawoman Creek, the western boundary is along the marsh line where the habitat changes from lightly vegetated sandy beach and exposed peat with little vegetation to densely vegetated marshland, peat banks, or densely forested or herbaceous vegetation landward of the beach and primary dune, and the eastern boundary extends seaward past the MLLW line including dynamic intertidal areas that are covered at high tide and uncovered at low tide, as well as shoaling areas that are inundated with less than 3 in (7.6 cm) of water. All lands within this subunit are federally owned by NASA.

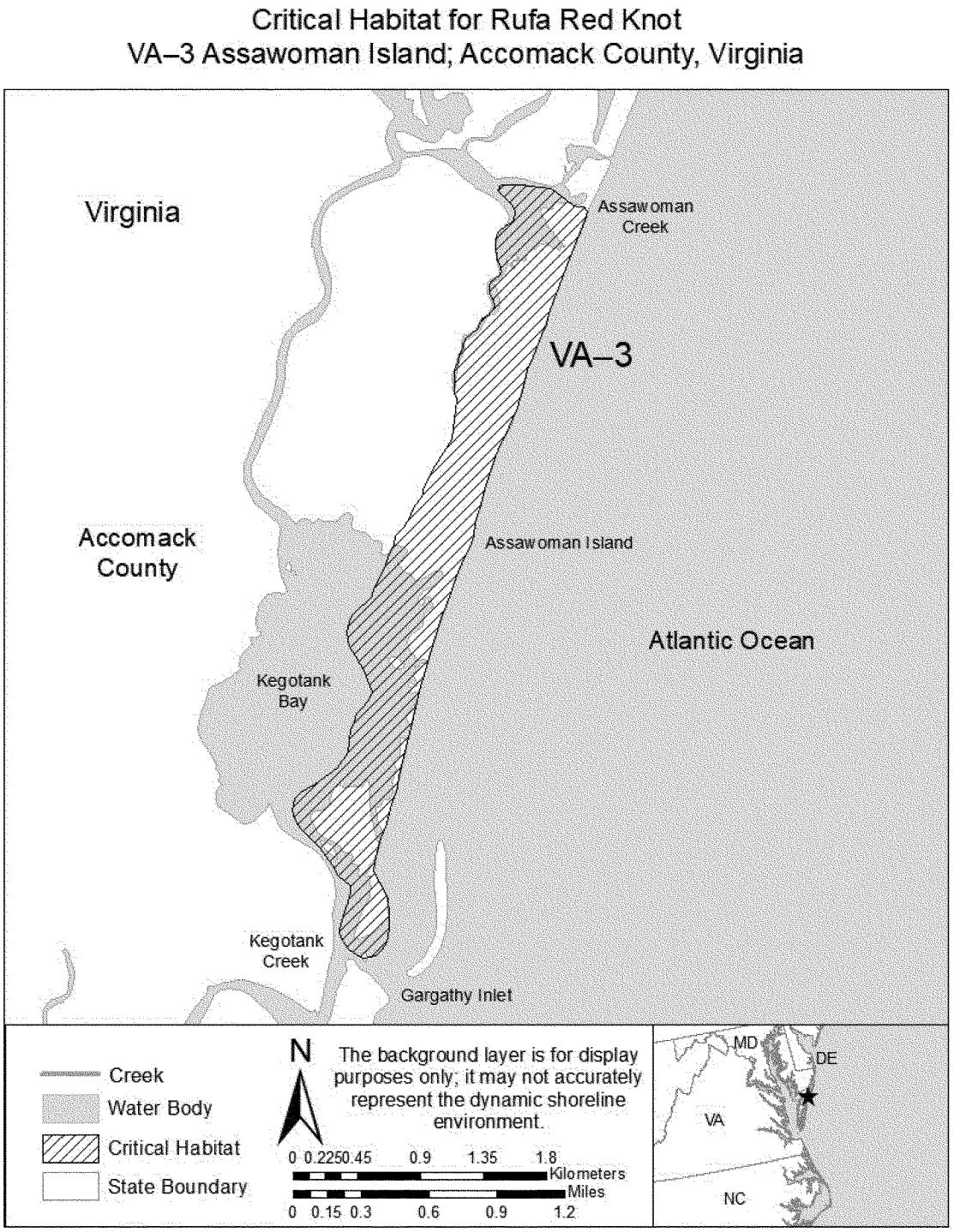
(vi) Map of Subunit VA–2B is presented at paragraph (27)(ii) of this entry.

(28) Unit VA–3: Assawoman Island, Virginia.

(i) Unit VA–3 consists of approximately 633 ac (256 ha) of occupied habitat in Accomack County consisting of beach shoreline and dynamic intertidal areas. The unit is from Assawoman Creek in the north to Kegotank Creek and Gargathy Inlet in the south, extending east past the MLLW line including dynamic intertidal areas that are covered at high tide and uncovered at low tide, as well as shoaling areas that are inundated with less than 3 in (7.6 cm) of water). The western boundary is formed by Houseboat Creek, a section of Egg Marsh, and Kegotank Bay. All lands within this unit are federally owned by Chincoteague NWR.

(ii) Map of Unit VA–3 follows:

Figure 22 to Rufa Red Knot paragraph (28)(ii)

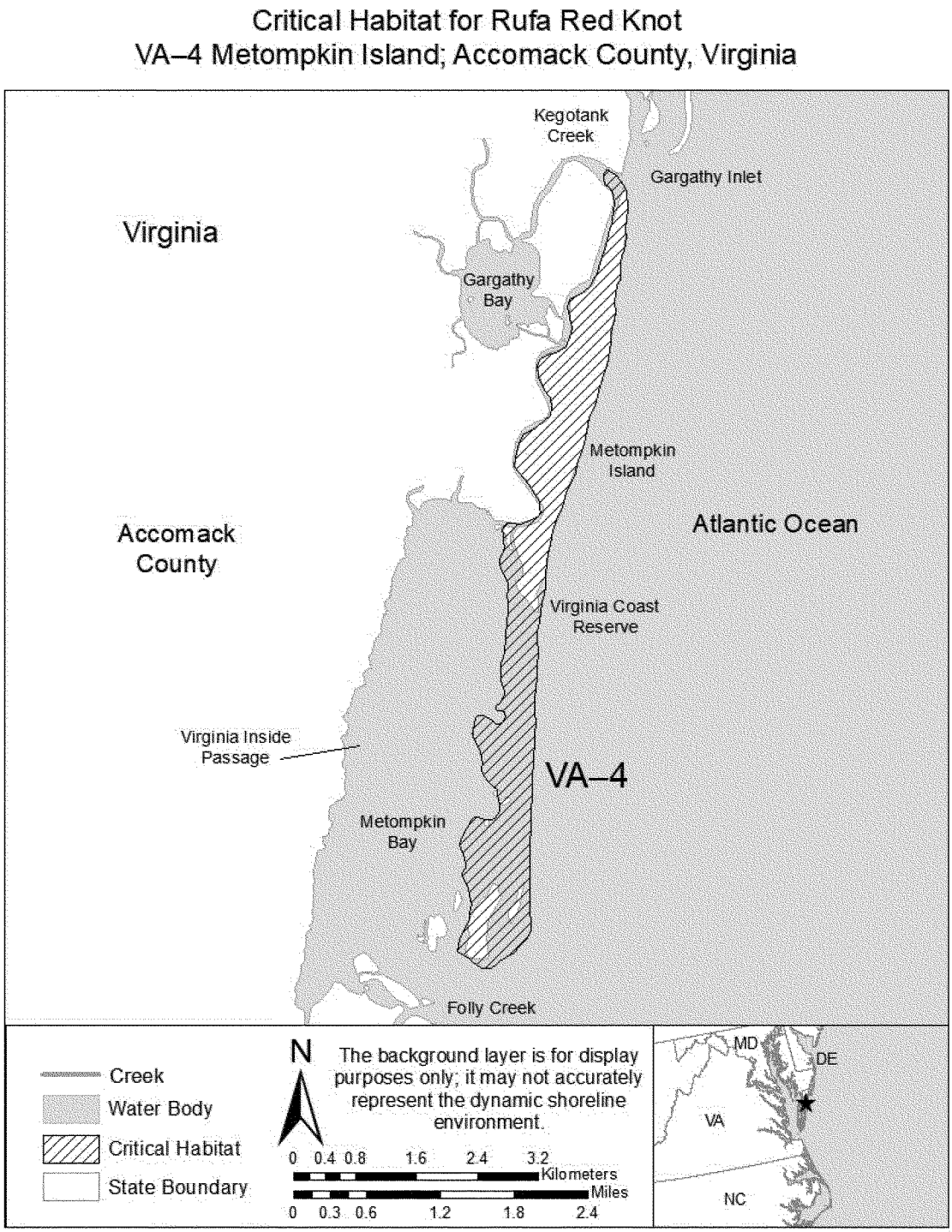


(29) Unit VA–4: Metompkin Island, Virginia.

(i) Unit VA–4 consists of approximately 1,468 ac (594 ha) of occupied habitat in Accomack County consisting of beach shoreline and dynamic intertidal areas. The unit extends from Kegotank Creek and Gargathy Inlet south to the mouth of Folly Creek. The western boundary is formed by the Virginia Inside Passage of the Intracoastal Waterway and Metompkin Bay and includes extensive areas of overwash and low marsh areas along the western boundary. The eastern boundary extends seaward past the MLLW line, including dynamic intertidal areas that are covered at high tide and uncovered at low tide, as well as shoaling areas that are inundated with less than 3 in (7.6 cm) of water. Lands within this unit include approximately 64 ac (26 ha) in Federal ownership (Chincoteague NWR), 56 ac (22 ha) in State ownership, and 1,239 ac (502 ha) in private/other ownership (TNC), and 110 ac (44 ha) that are uncategorized. This coastal area is part of the Virginia Coast Reserve.

(ii) Map of Unit VA–4 follows:

Figure 23 to Rufa Red Knot paragraph (29)(ii)

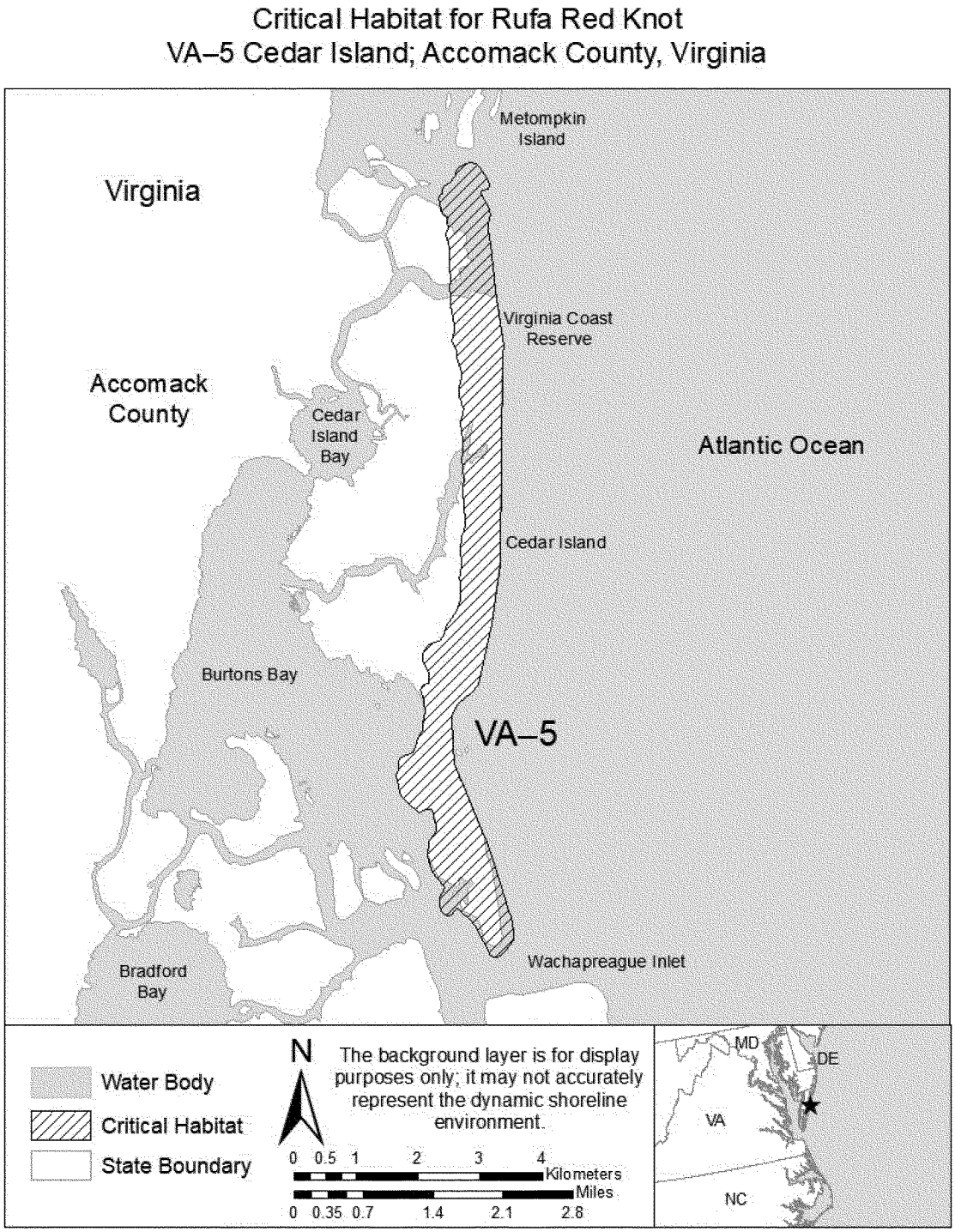


(30) Unit VA–5: Cedar Island, Virginia.

(i) Unit VA–5 consists of approximately 2,274 ac (920 ha) of occupied habitat in Accomack County consisting of beach shoreline and dynamic intertidal areas. The unit extends from an inlet between Cedar Island and the southern end of Metompkin Island south to Wachapreague Inlet. The western boundary is along the marsh line where the habitat changes from lightly vegetated sandy beach and exposed peat with little vegetation to densely vegetated marshland, peat banks, or densely vegetated forested or herbaceous vegetation landward of the beach and primary dune, or open water including Burtons Bay. The eastern boundary extends seaward past the MLLW line, including dynamic intertidal areas that are covered at high tide and uncovered at low tide, as well as shoaling areas that are inundated with less than 3 in (7.6 cm) of water. Lands within this unit include approximately 203 ac (82 ha) in Federal ownership, 77 ac (31 ha) in State ownership, 920 ac (372 ha) in private/other ownership, and 1,074 ac (434 ha) that are uncategorized. This coastal area is part of the Virginia Coast Reserve.

(ii) Map of Unit VA–5 follows:

Figure 24 to Rufa Red Knot paragraph (30)(ii)

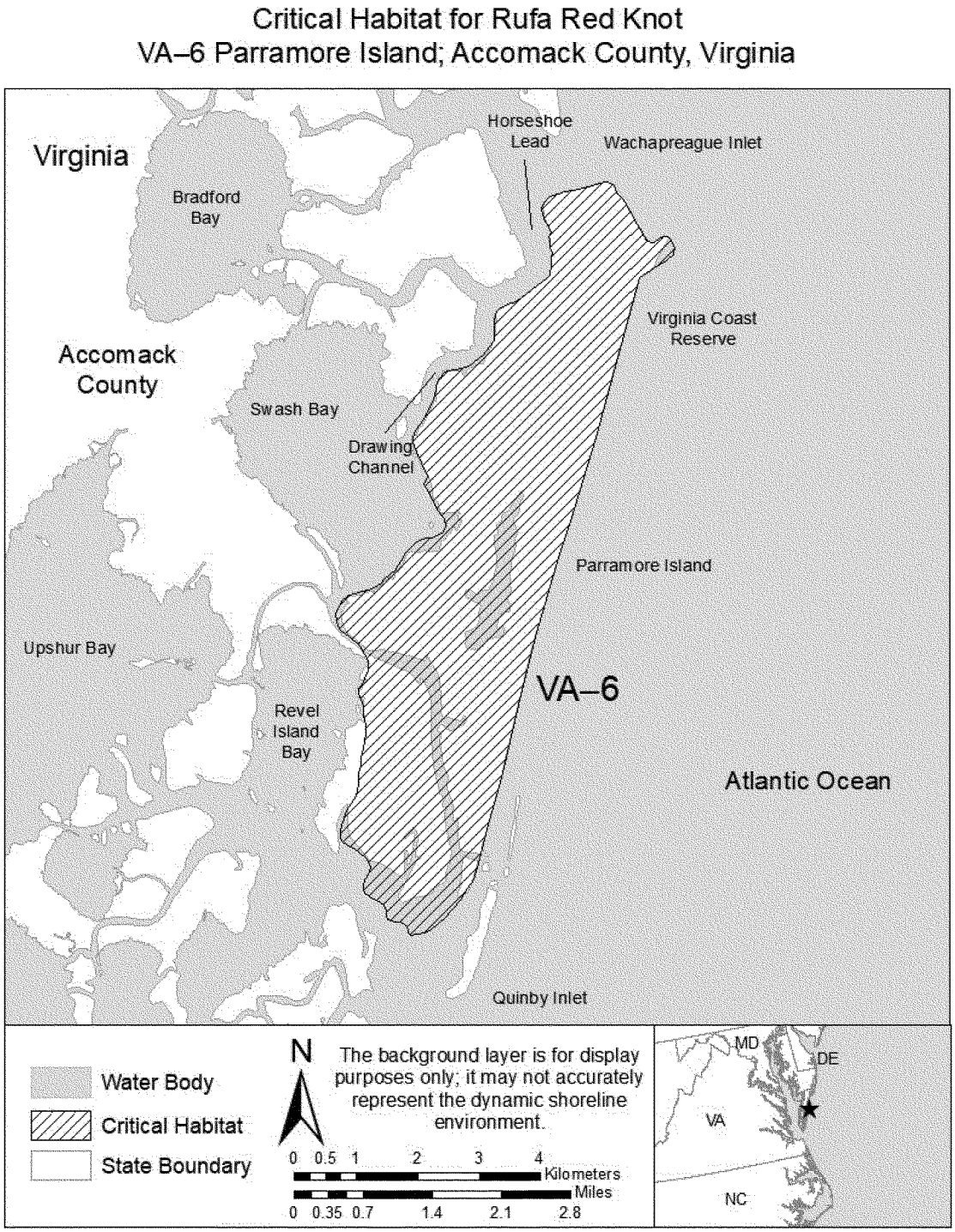


(31) Unit VA–6: Parramore Island, Virginia.

(i) Unit VA–6 consists of approximately 6,802 ac (2,753 ha) of occupied habitat in Accomack County consisting of beach shoreline and dynamic intertidal areas. The unit extends from Wachapreague Inlet south to Quinby Inlet. The western boundary is Horseshoe Lead, Drawing Channel, Swash Bay, and Revel Island Bay. The eastern boundary extends seaward past the MLLW line, including dynamic intertidal areas that are covered at high tide and uncovered at low tide, as well as shoaling areas that are inundated with less than 3 in (7.6 cm) of water. Lands within this unit include approximately 5,631 ac (2,280 ha) in private/other ownership (TNC) and 1,171 ac (473 ha) that are uncategorized. This coastal area is part of the Virginia Coast Reserve.

(ii) Map of Unit VA–6 follows:

Figure 25 to Rufa Red Knot paragraph (31)(ii)

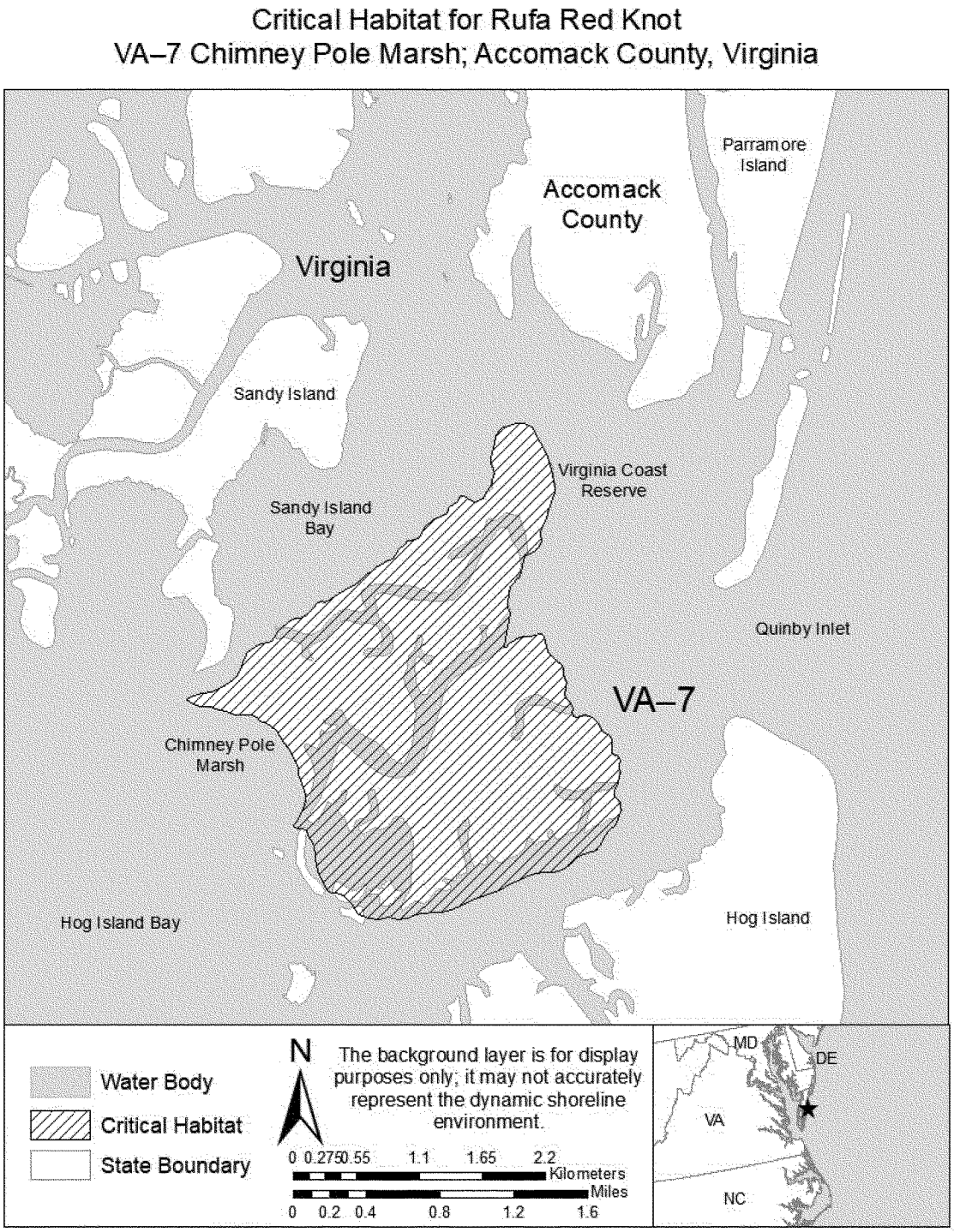


(32) Unit VA–7: Chimney Pole Marsh, Virginia.

(i) Unit VA–7 consists of approximately 2,004 ac (811 ha) of occupied habitat in Chimney Pole Marsh and the southern portion of Sandy Island in Accomack County consisting of mud flats, low marsh, sandy beaches, overwash areas, and tidal channels. The boundary of the marsh on all sides extends seaward past the MLLW line, including dynamic intertidal areas that are covered at high tide and uncovered at low tide, as well as shoaling areas that are inundated with less than 3 in (7.6 cm) of water. Lands within this unit include approximately 1,224 ac (496 ha) in State ownership, 285 ac (116 ha) in private/other ownership (TNC), and 495 ac (200 ha) that are uncategorized.

(ii) Map of Unit VA–7 follows:

Figure 26 to Rufa Red Knot paragraph (32)(ii)

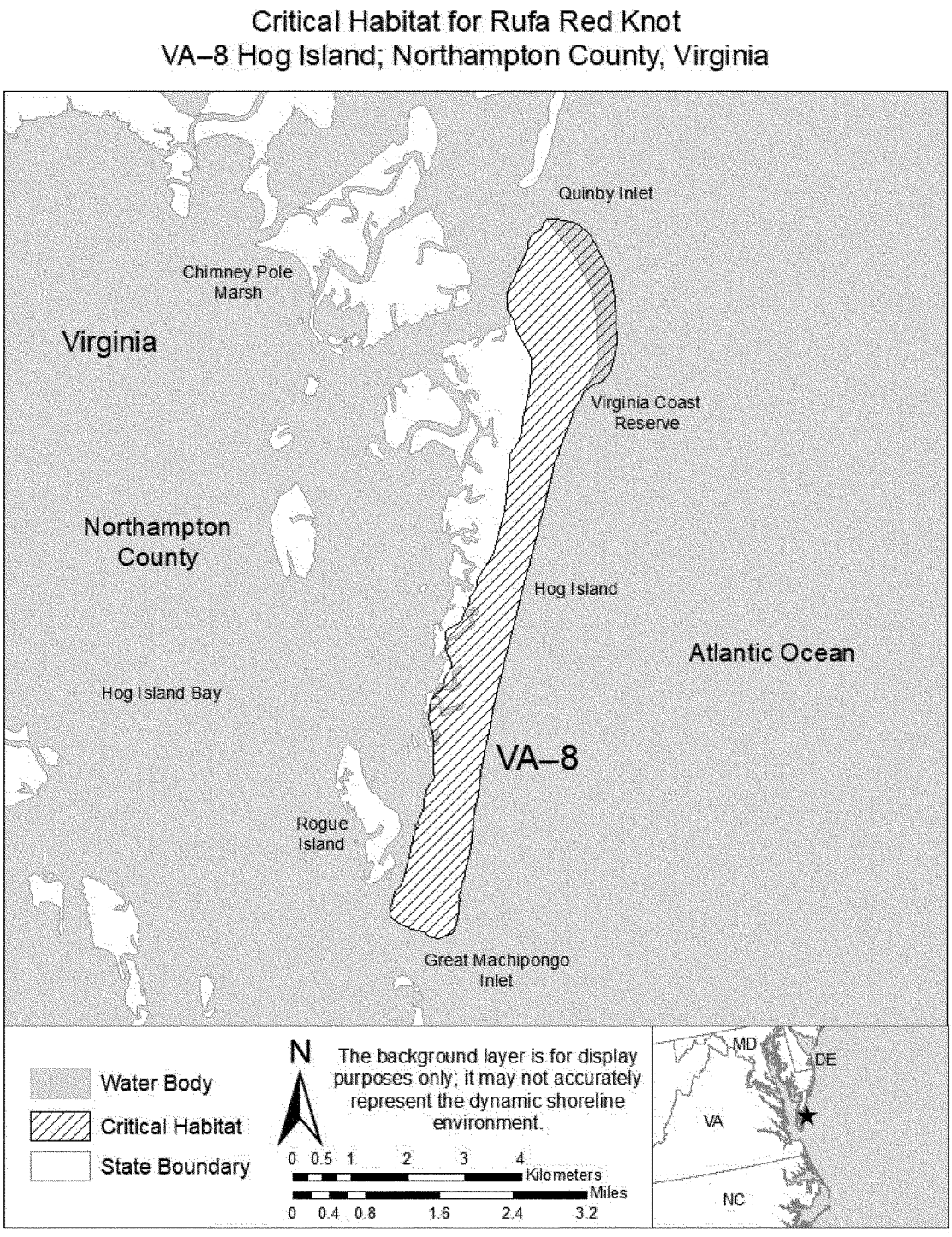


(33) Unit VA–8: Hog Island, Virginia.

(i) Unit VA–8 consists of approximately 3,235 ac (1,309 ha) of occupied habitat in Northampton County consisting of shoreline habitat. The unit is bounded by the Quinby Inlet to the north and Great Machipongo Inlet to the south. The western boundary is along the marsh line where the habitat changes from lightly vegetated sandy beach and exposed peat with little vegetation to densely vegetated marshland, peat banks, or densely vegetated forested or herbaceous vegetation landward of the beach and primary dune, or open water including Hog Island Bay. The eastern boundary extends seaward past the MLLW line, including dynamic intertidal areas that are covered at high tide and uncovered at low tide, as well as shoaling areas that are inundated with less than 3 in (7.6 cm) of water. Lands within this unit include approximately 16 ac (7 ha) in State ownership, 2,966 ac (1,201 ha) in private/other ownership, and 253 ac (101 ha) that is uncategorized. This coastal area is part of the Virginia Coast Reserve.

(ii) Map of Unit VA–8 follows:

Figure 27 to Rufa Red Knot paragraph (33)(ii)

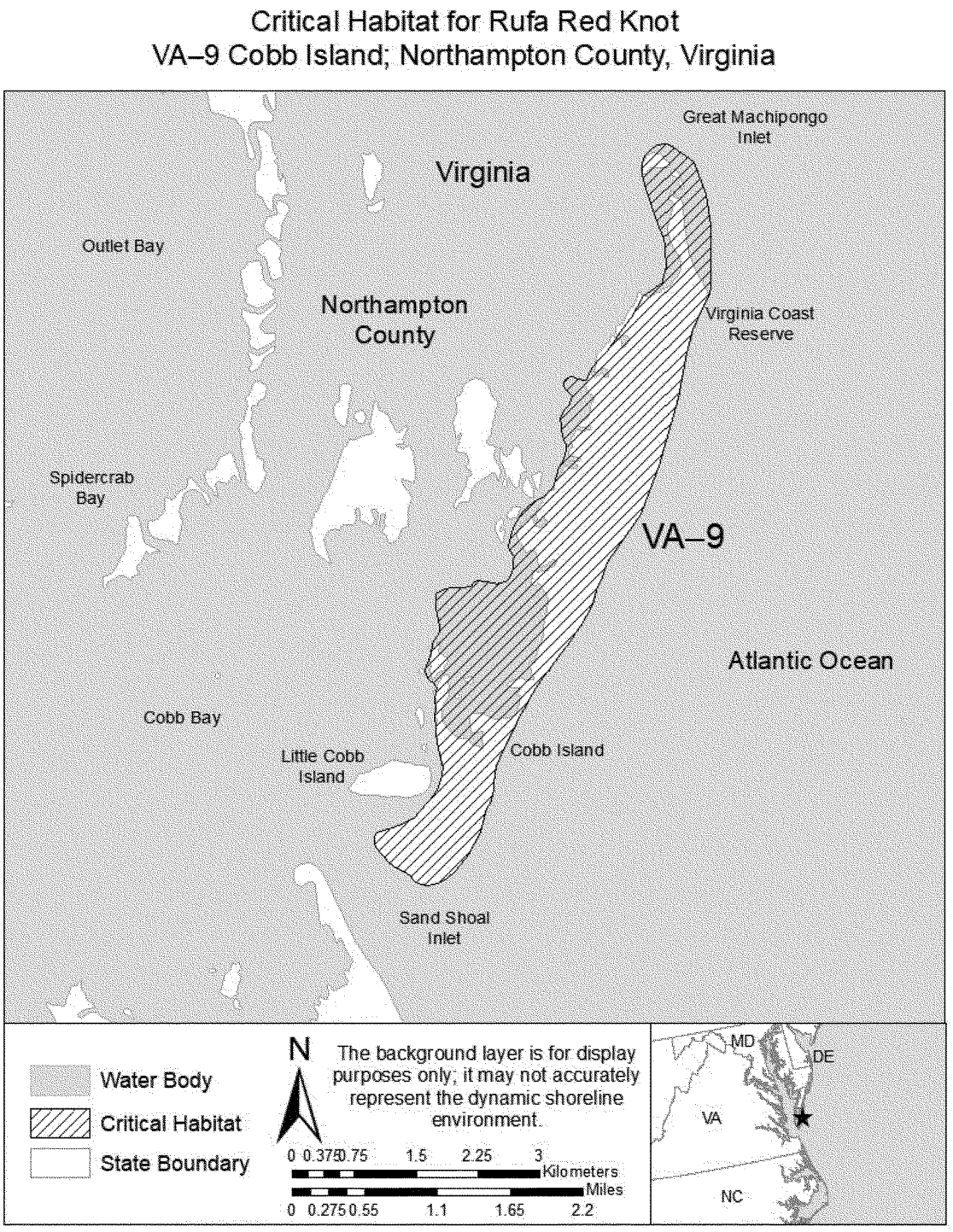


(34) Unit VA–9: Cobb Island, Virginia.

(i) Unit VA–9 consists of approximately 2,342 ac (948 ha) of occupied habitat in Northampton County consisting of shoreline habitat. The unit is bounded by Great Machipongo Inlet to the north and Sand Shoal Inlet to the south. The western boundary is formed by Hog Island Bay, Spidercrab Bay, and Cobb Bay. The eastern boundary extends seaward past the MLLW line, including dynamic intertidal areas that are covered at high tide and uncovered at low tide, as well as shoaling areas that are inundated with less than 3 in (7.6 cm) of water. Lands within this unit include approximately 16 ac (7 ha) in State ownership, 1,778 ac (720 ha) in private/other ownership, and 547 ac (221 ha) that are uncategorized. This coastal area is part of the Virginia Coast Reserve.

(ii) Map of Unit VA–9 follows:

Figure 28 to Rufa Red Knot paragraph (34)(ii)

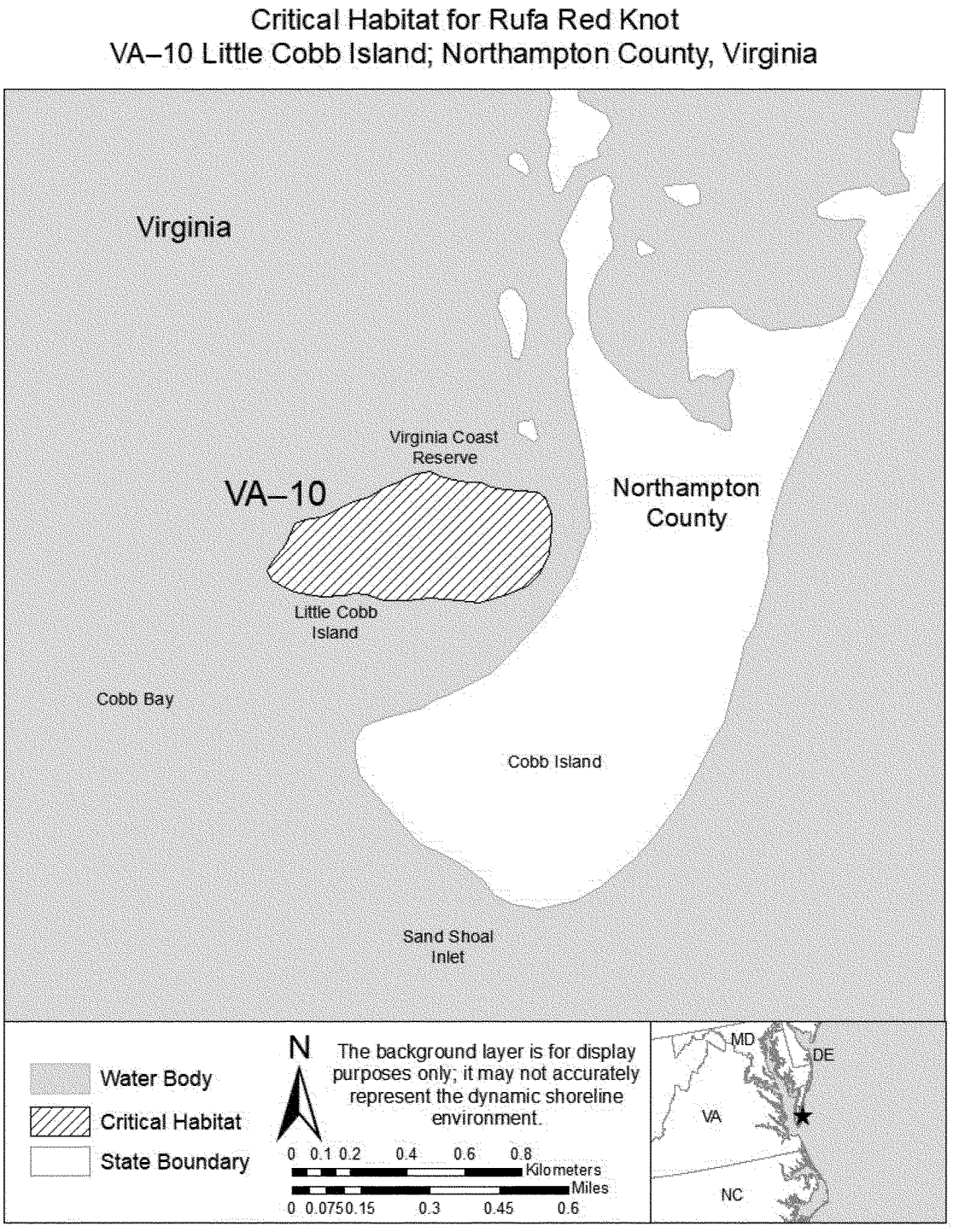


(35) Unit VA–10: Little Cobb Island, Virginia.

(i) Unit VA–10 consists of approximately 82 ac (33 ha) of occupied habitat in Northampton County consisting of shoreline habitat lying just west of the southern end of Cobb Island and within the waters of Cobb Bay. The boundary of this small island in all directions is the waters of Cobb Bay and the extent of the boundary seaward past the MLLW line, including dynamic intertidal areas that are covered at high tide and uncovered at low tide, as well as shoaling areas that are inundated with less than 3 in (7.6 cm) of water. All lands within this unit are in private/other ownership (TNC) and are part of the Virginia Coast Reserve.

(ii) Map of Unit VA–10 follows:

Figure 29 to Rufa Red Knot paragraph (35)(ii)

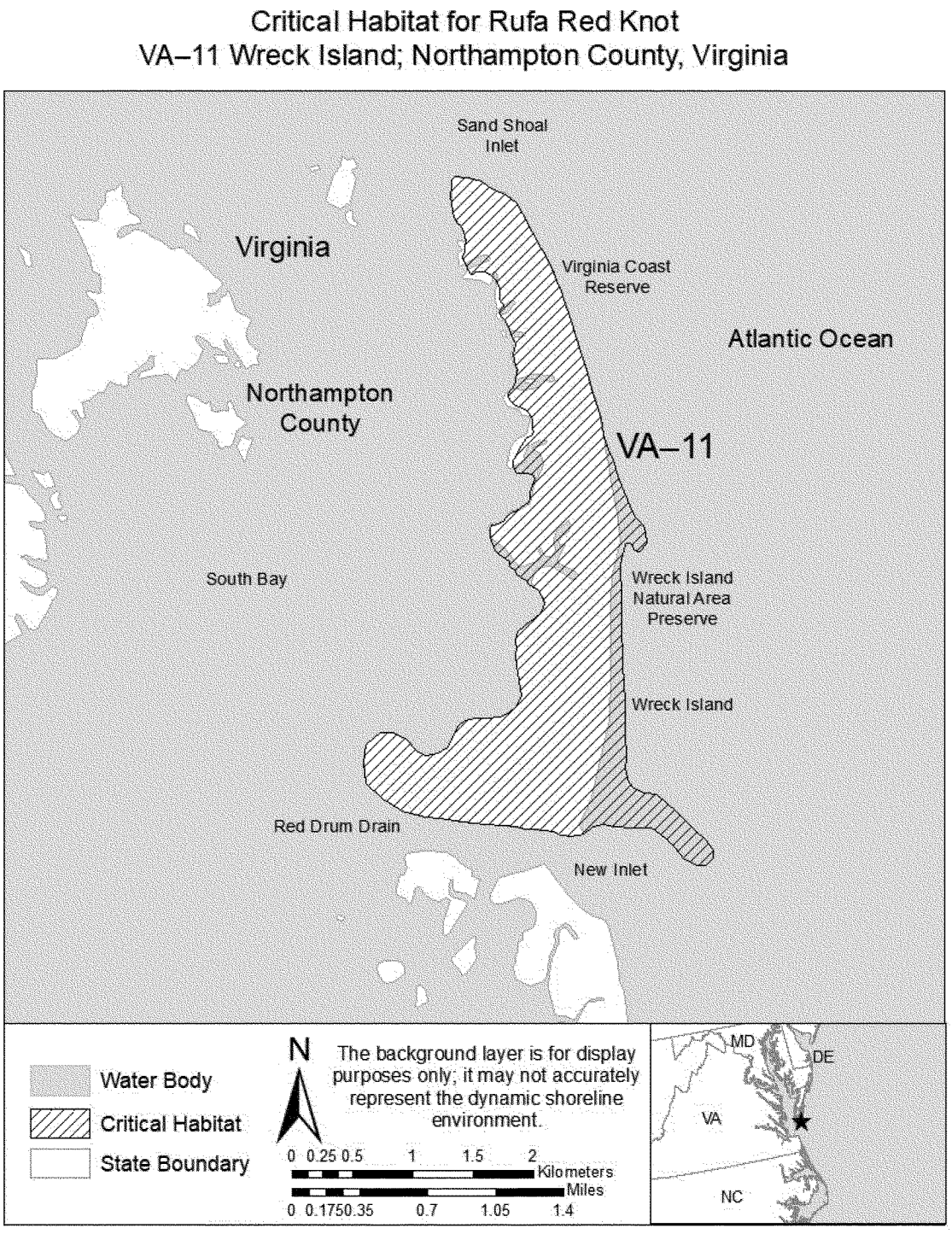


(36) Unit VA–11: Wreck Island, Virginia.

(i) Unit VA–11 consists of approximately 1,270 ac (514 ha) of occupied habitat in Northampton County consisting of shoreline habitat bounded to the north by Sand Shoal Inlet and Red Drum Drain and New Inlet to the south. The western boundary is South Bay. The eastern boundary extends seaward past the MLLW line, including dynamic intertidal areas that are covered at high tide and uncovered at low tide, as well as shoaling areas that are inundated with less than 3 in (7.6 cm) of water. All lands within this unit are State owned and managed as Wreck Island Natural Area Preserve.

(ii) Map of Unit VA–11 follows:

Figure 30 to Rufa Red Knot paragraph (36)(ii)

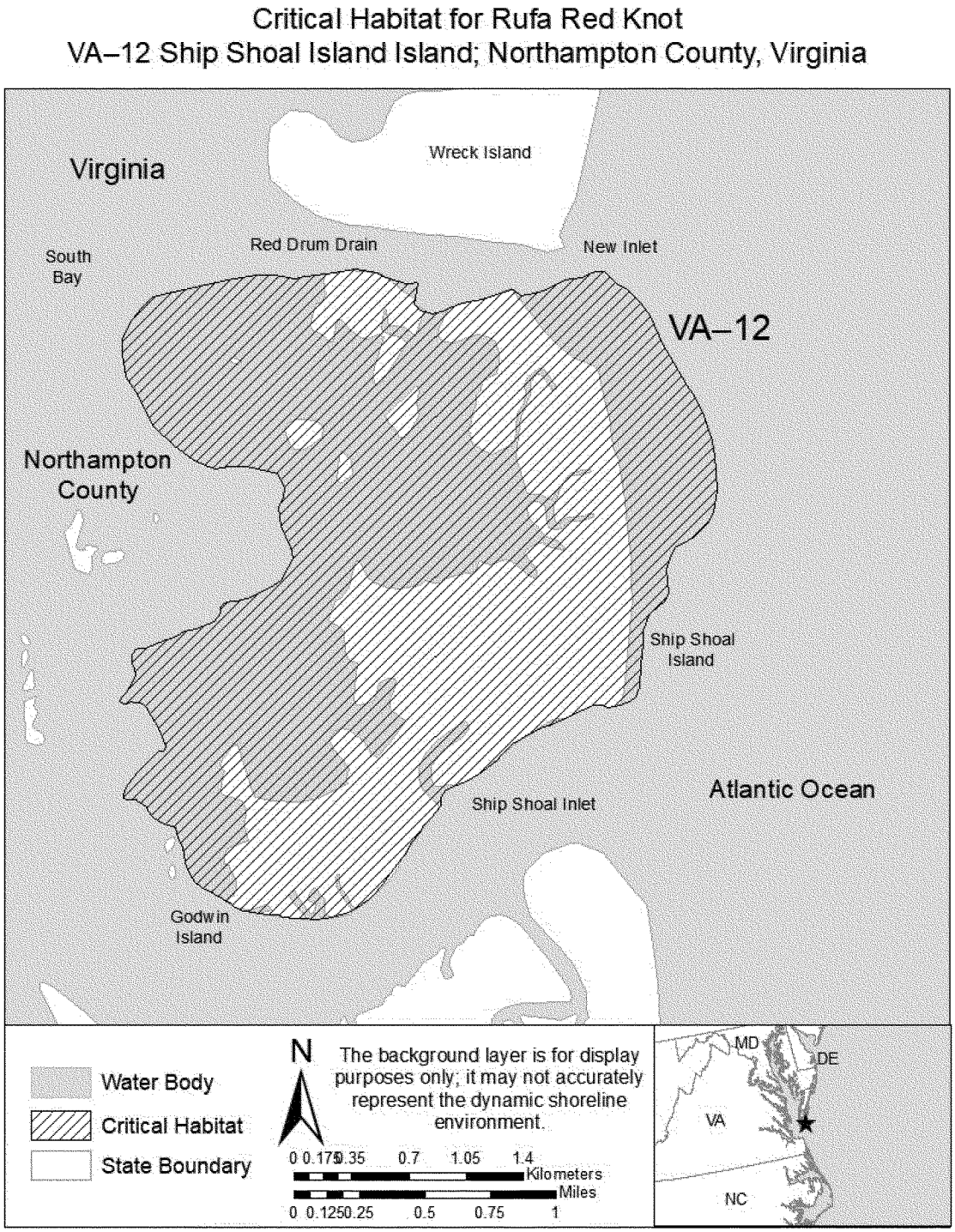


(37) VA–12: Ship Shoal Island, Virginia.

(i) Unit VA–12 consists of approximately 2,426 ac (982 ha) of occupied habitat in Northampton County, including both Ship Shoal Island and the area known as Godwin Island. The north boundary is Red Drum Drain and New Inlet, the south boundary is Ship Shoal Inlet, the west boundary is South Bay, and the east boundary is the Atlantic Ocean, including dynamic intertidal areas that are covered at high tide and uncovered at low tide, as well as shoaling areas that are inundated with less than 3 in (7.6 cm) of water. The majority of lands within this unit are owned and managed by TNC as part of the Virginia Coast Reserve. Lands within this unit include 426 ac (172 ha) in State ownership, 1,941 ac (785 ha) in private/other ownership, and 60 ac (24 ha) that are uncategorized.

(ii) Map of Unit VA–12 follows:

Figure 31 to Rufa Red Knot paragraph (37)(ii)

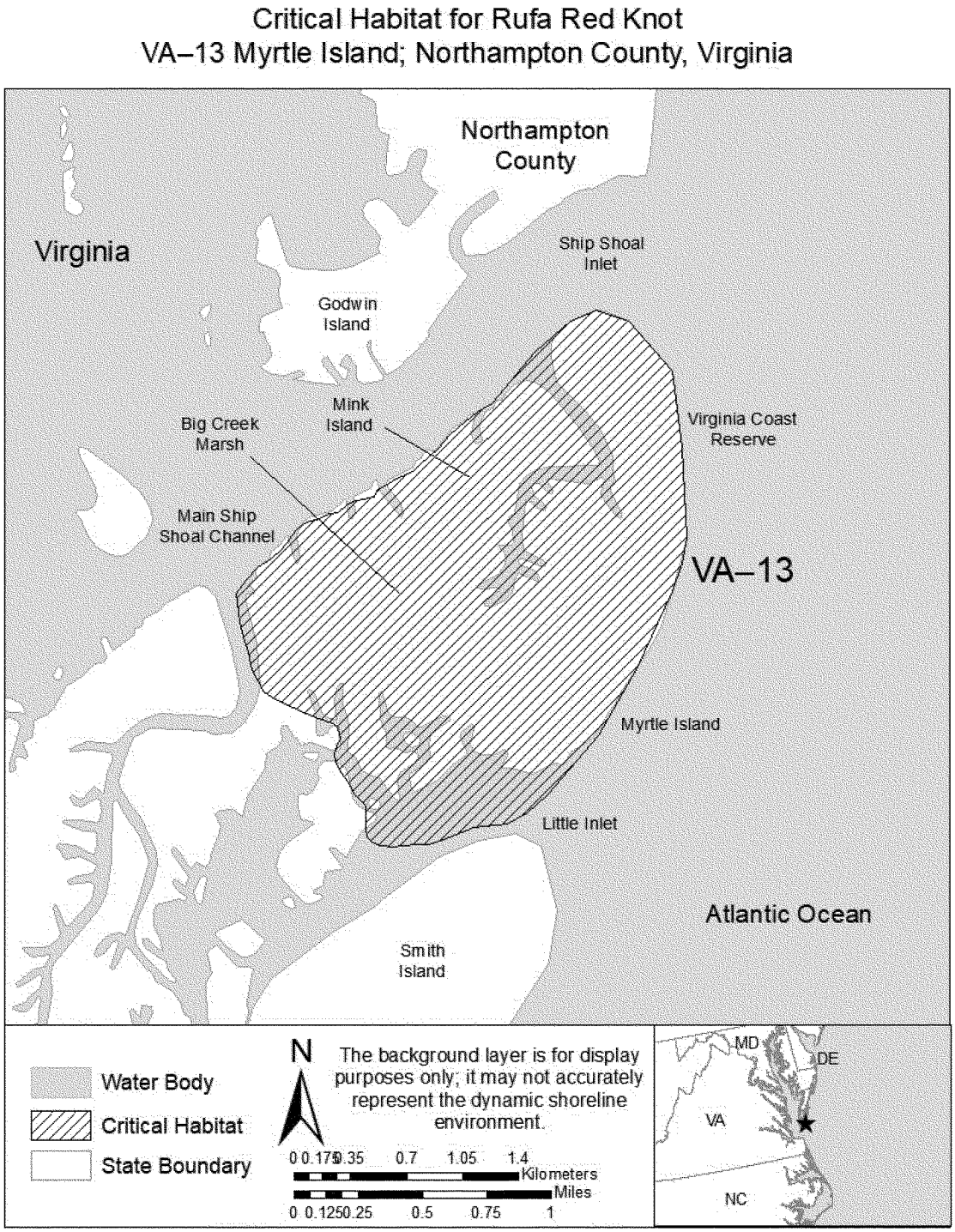


(38) Unit VA–13: Myrtle Island, Virginia.

(i) Unit VA–13 consists of approximately 1,416 ac (573 ha) of occupied habitat in Northampton County consisting of extensive mud flats, low marsh, sandy beaches, overwash areas, and tidal channels. The north boundary is Ship Shoal Inlet, the south boundary is Little Inlet, the west boundary is Main Ship Shoal Channel and Big Creek Marsh, and the east boundary is the Atlantic Ocean. The boundary for the island and marsh complex extends seaward past the MLLW line, including dynamic intertidal areas that are covered at high tide and uncovered at low tide, as well as shoaling areas that are inundated with less than 3 in (7.6 cm) of water. Lands within this unit include 1,028 ac (417 ha) that are in private/other ownership and 388 ac (156 ha) that are uncategorized. The island is owned and managed by TNC as part of the Virginia Coast Reserve.

(ii) Map of Unit VA–13 follows:

Figure 32 to Rufa Red Knot paragraph (38)(ii)

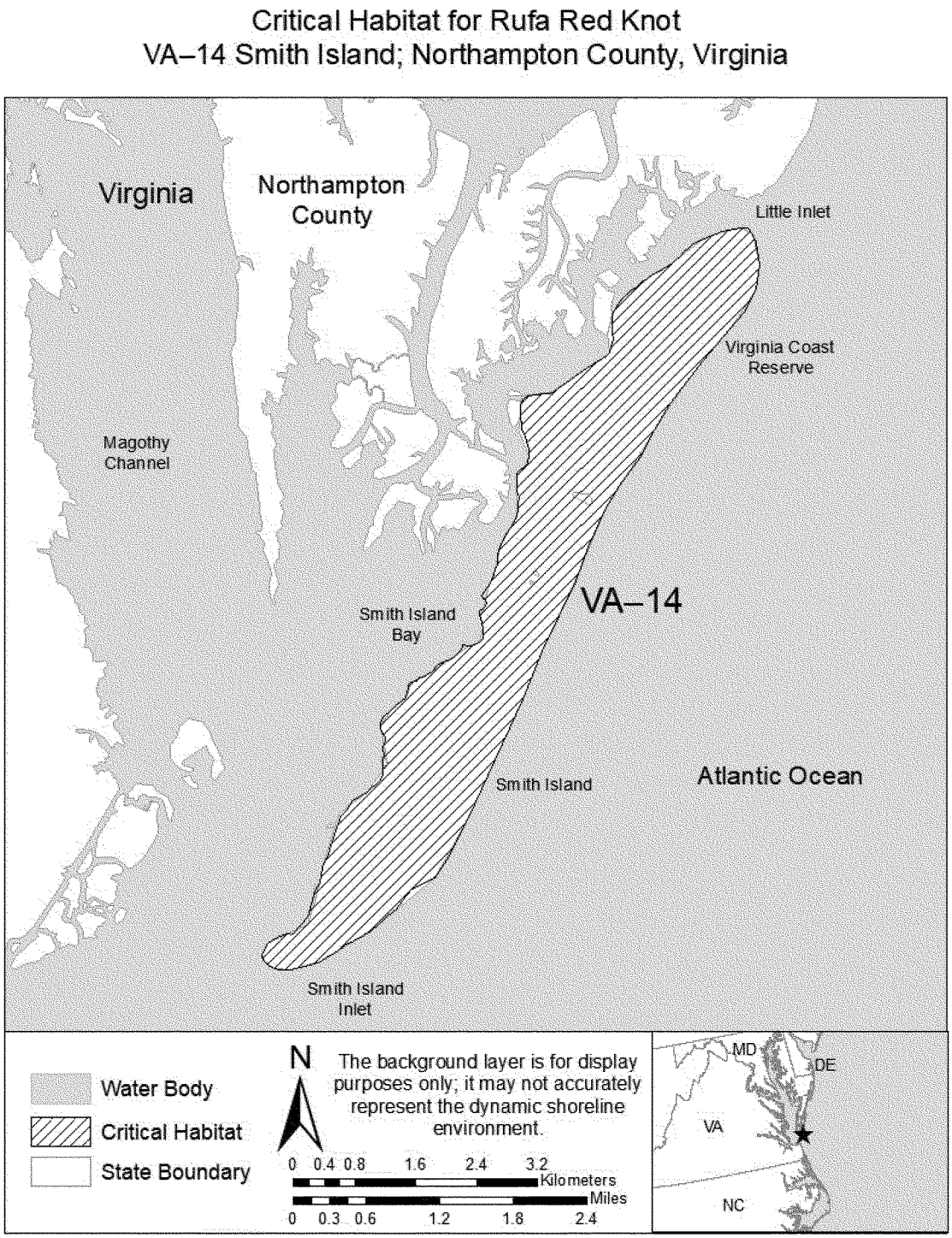


(39) Unit VA–14: Smith Island, Virginia.

(i) Unit VA–14 consists of approximately 3,258 ac (1,319 ha) of occupied habitat in Northampton County consisting of shoreline habitat bounded to the north by Little Inlet, to the south by Smith Island Inlet, and to the west along the dune line where the habitat changes from sandy beach with little vegetation to densely vegetated dunes or marshland, as well as densely vegetated forested or herbaceous vegetation landward of the beach and primary dune, or open water including Magothy Bay. The eastern boundary extends seaward past the MLLW line, including dynamic intertidal areas that are covered at high tide and uncovered at low tide, as well as shoaling areas that are inundated with less than 3 in (7.6 cm) of water. All lands within this unit are in private/other ownership (TNC). The island is owned and managed by TNC as part of the Virginia Coast Reserve.

(ii) Map of Unit VA–14 follows:

Figure 33 to Rufa Red Knot paragraph (39)(ii)



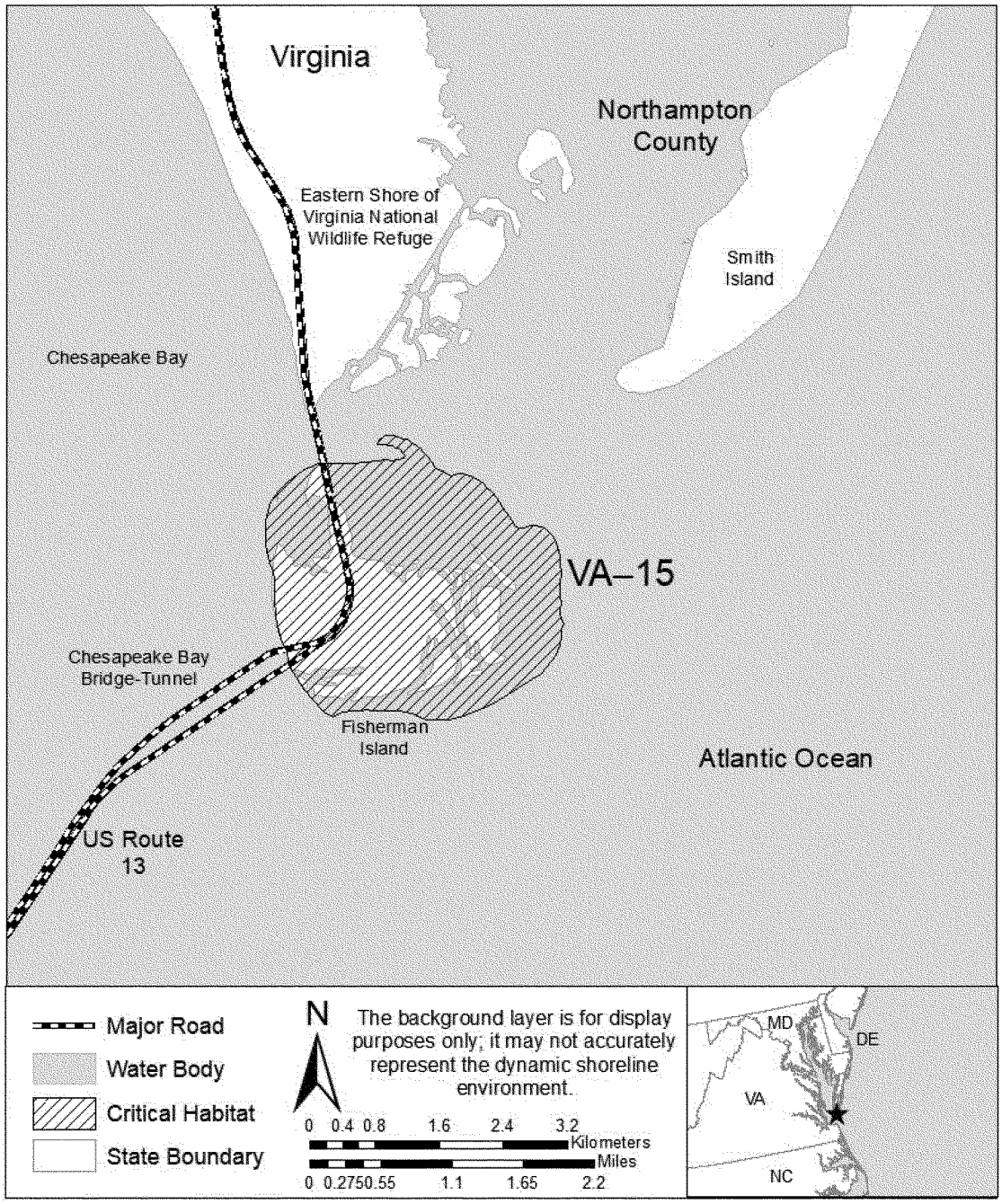
(40) Unit VA–15: Fisherman Island, Virginia.

(i) Unit VA–15 consists of approximately 2,413 ac (977 ha) of occupied habitat in Northampton County. The unit is an oval-shaped island located at the mouth of the Chesapeake Bay and just south of the tip of the Eastern Shore peninsula. The island is surrounded by the waters of the Chesapeake Bay and Atlantic Ocean. It is bisected by U.S. Route 13 and the Chesapeake Bay Bridge–Tunnel complex. The interior boundary is along the dune line where the habitat changes from sandy beach with little vegetation to densely vegetated dunes or marshland, as well as densely vegetated forested or herbaceous vegetation landward of the beach and primary dune. The unit extends seaward past the MLLW line and includes areas that are slightly inundated with less than 3 in (7.6 cm) of water. The unit is federally owned by the Service's Eastern Shore of Virginia NWR.

(ii) Map of Unit VA–15 follows:

Figure 34 to Rufa Red Knot paragraph (40)(ii)

Critical Habitat for Rufa Red Knot
VA–15 Fisherman Island; Northampton County, Virginia



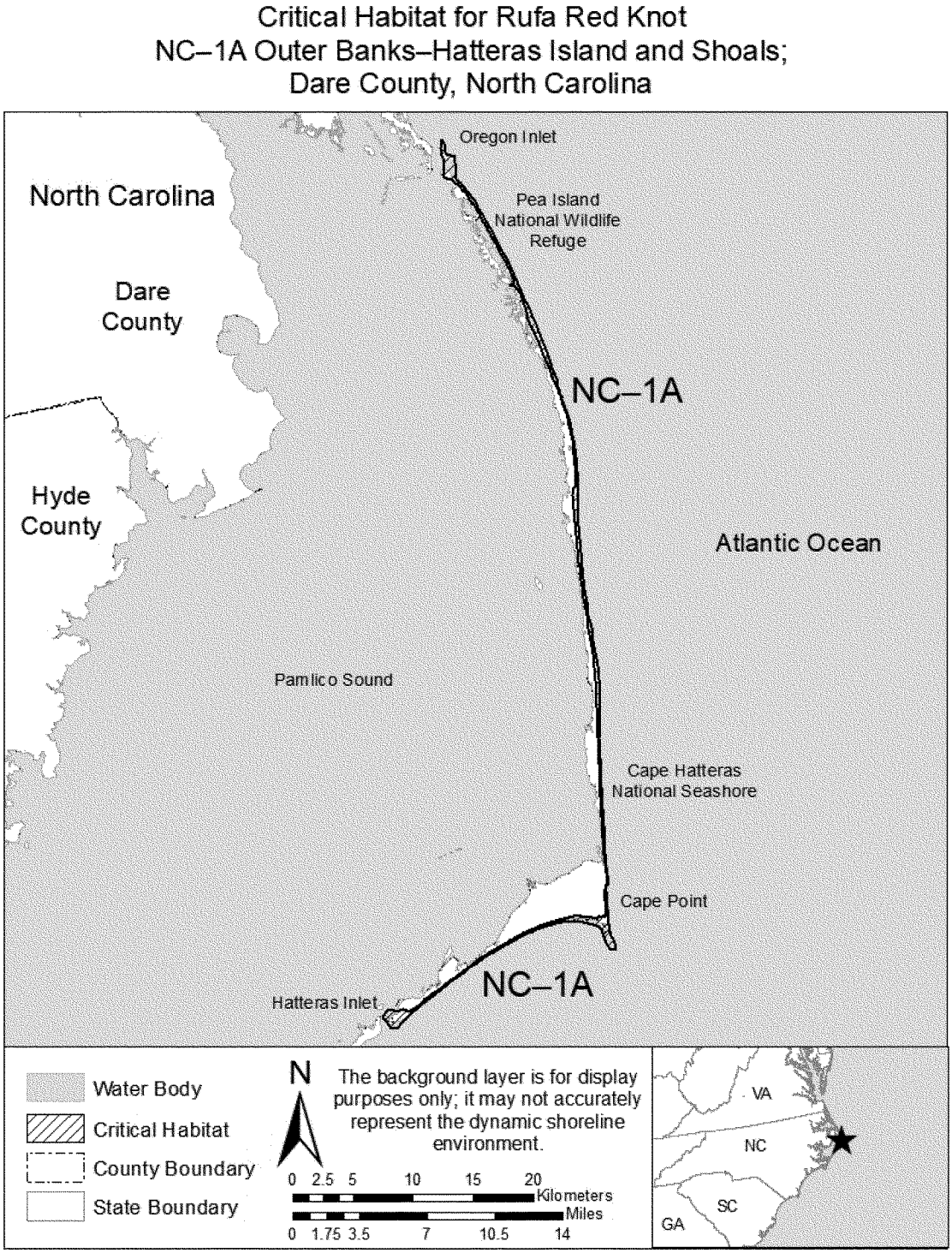
(41) Unit NC–1: Outer Banks, North Carolina.

(i) Unit NC–1 consists of two subunits comprising 11,367 ac (4,600 ha) of occupied habitat in Dare and Hyde Counties. This unit consists of Federal lands owned by the National Park Service (NPS) and Service, and lands owned by the State of North Carolina.

(ii) Subunit NC–1A (Hatteras Island and Shoals) consists of approximately 5,754 ac (2,329 ha) of occupied habitat in Dare County consisting of beach shoreline from the southeast side of Oregon Inlet, south along the ocean-facing side of the island (including Pea Island NWR) to Cape Point in Cape Hatteras National Seashore. From Cape Point, the subunit stretches along the ocean side of the island about 13.25 mi (21 km) west to the east side of Hatteras Inlet. This subunit includes from MLLW (*i.e.,* the highly dynamic beach and emergent sand shoals that are covered at high tide and uncovered at low tide, that are associated with the northeast side of Hatteras Inlet's navigable channel) to the toe of the dunes or where densely vegetated habitat, not used by the rufa red knot, begins. Lands within this subunit include approximately 4,940 ac (1,999 ha) in Federal ownership (Cape Hatteras National Seashore) and 814 ac (329 ha) that are uncategorized.

(iii) Map of Subunit NC–1A follows:

Figure 35 to Rufa Red Knot paragraph (41)(iii)

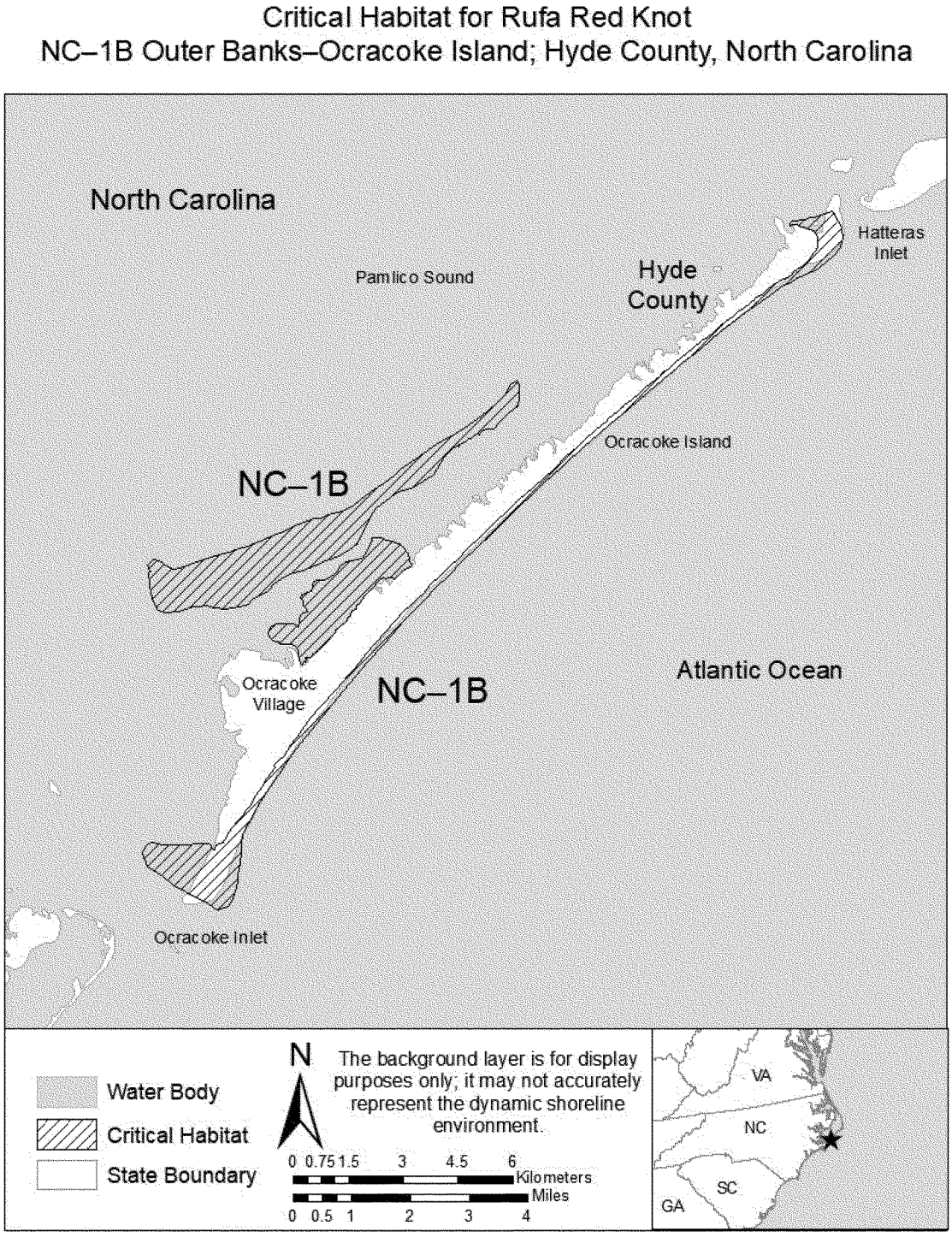


(iv) Subunit NC–1B (Ocracoke Island) consists of approximately 5,613 ac (2,271 ha) of occupied habitat in Hyde County consisting of beach shoreline from the southwest side of Hatteras Inlet along the ocean-facing side of the island to the northeast side of Ocracoke Inlet. This subunit also encompasses shallow areas and mudflats within Pamlico Sound on the west side of Ocracoke Island near Ocracoke Village. This subunit includes from MLLW (*i.e.,* the highly dynamic beach and emergent sand shoals that are covered at high tide and uncovered at low tide) to the toe of the dunes or where densely vegetated habitat, not used by the rufa red knot, begins, including the flood-tidal and ebb-tidal deltas associated with the southwest side of Hatteras Inlet and the northeast side of Ocracoke Inlet, and the

sand and mud islands identified in Pamlico Sound northeast of Ocracoke Village. Lands within this subunit include approximately 1,427 ac (577 ha) in Federal ownership (*i.e.,* the entire ocean-facing side of the Ocracoke Island, which is part of Cape Hatteras National Seashore), 3,612 ac (1,462 ha) in State ownership, and 575 ac (233 ha) that are uncategorized.

(v) Map of Subunit NC–1B follows:

Figure 36 to Rufa Red Knot paragraph (41)(v)



(42) Unit NC–2: Core Banks, North Carolina.

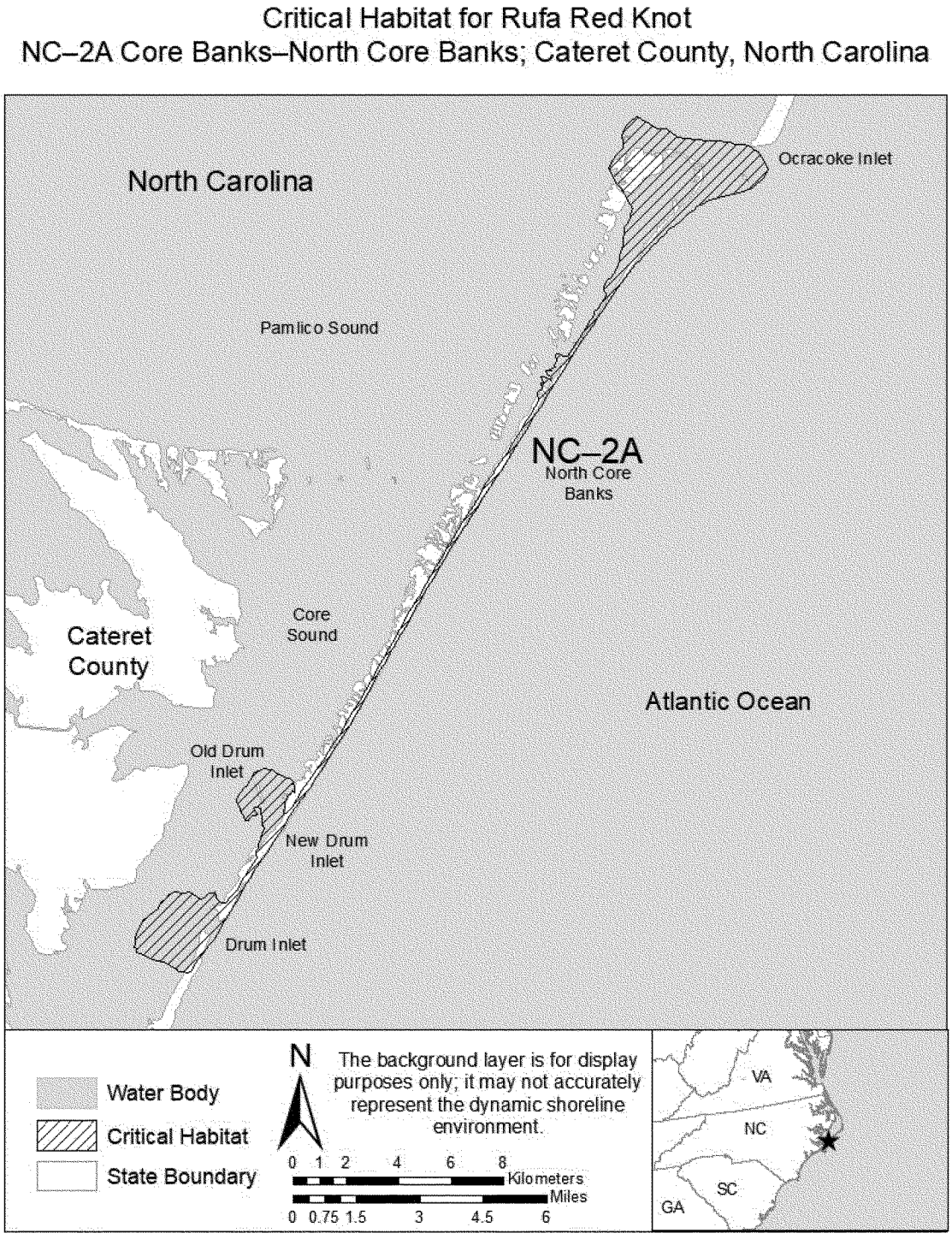
(i) Unit NC–2 consists of two subunits comprising 11,281 ac (4,565 ha) of occupied habitat in Carteret County. This unit consists of Federal lands owned by the NPS (Cape Lookout National Seashore).

(ii) Subunit NC–2A (North Core Banks) consists of approximately 8,187 ac (3,313 ha) of occupied habitat in Carteret County consisting of beach shoreline from the North Core Banks side of the Ocracoke Inlet channel south to the North Core Banks side of the New

Drum Inlet channel. The west boundary is the toe of the primary dune or dense vegetation line (where the physical or biological features do not occur), and the east boundary is MLLW on the Atlantic Ocean (*i.e.,* the highly dynamic beach and emergent sand shoals that are covered at high tide and uncovered at low tide). This subunit also includes MLLW on Core Sound to the MLLW on the Atlantic Ocean in washover areas associated with Old Drum Inlet, all emergent sand shoals within the flood-tidal and ebb-tidal deltas associated with the North Core Banks side of the Ocracoke Inlet channel, and the emergent sand shoals within the flood-tidal and ebb-tidal deltas associated with the North Core Banks side of the New Drum Inlet channel. Lands within this subunit include 6,534 ac (2,644 ha) that are in Federal ownership (Cape Lookout National Seashore) and 1,654 ac (669 ha) that are uncategorized.

(iii) Map of Subunit NC–2A follows:

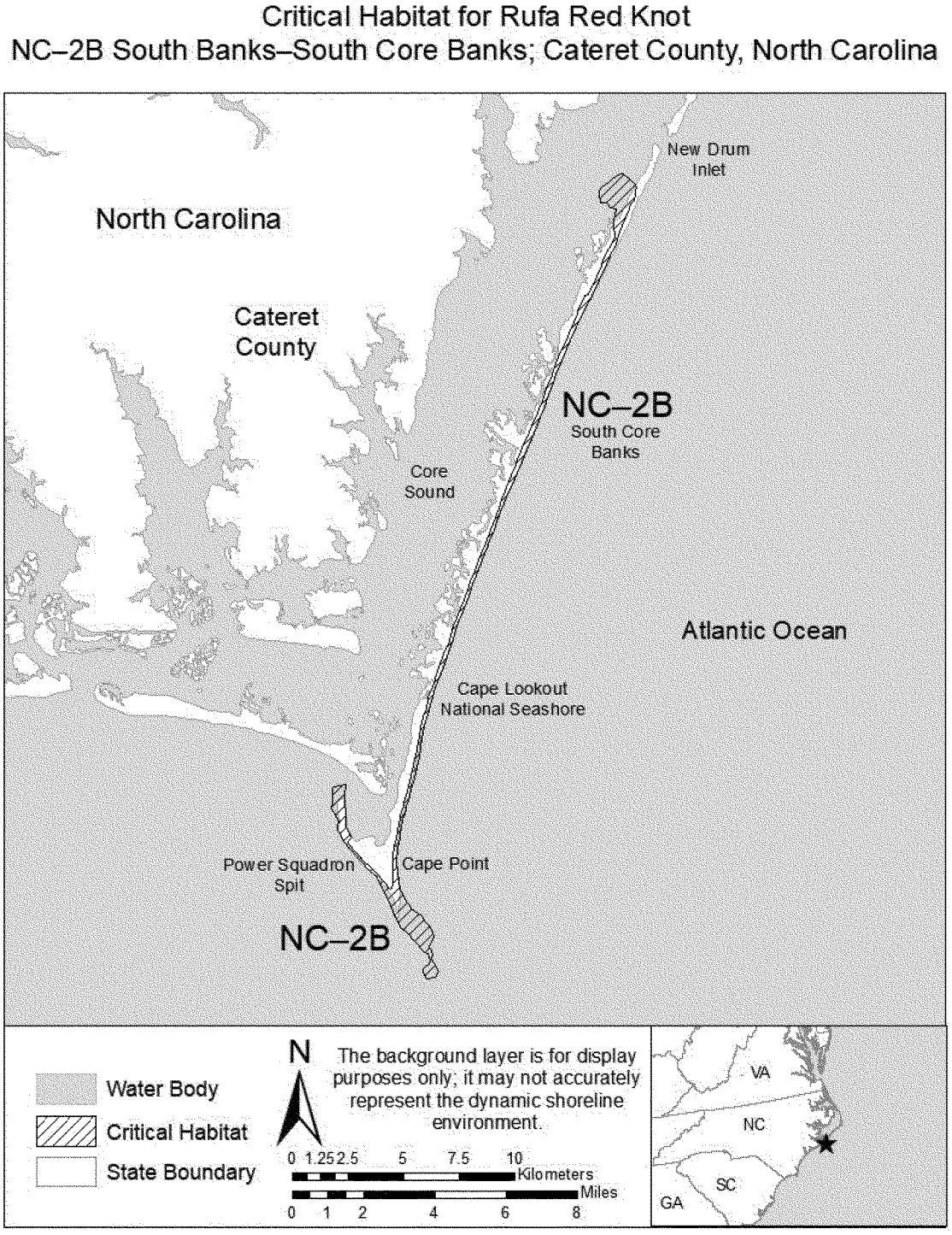
Figure 37 to Rufa Red Knot paragraph (42)(iii)



(iv) Subunit NC–2B (South Core Banks) consists of approximately 3,094 ac (1,252 ha) of occupied habitat in Carteret County consisting of beach shoreline from the South Core Banks side of the New Drum Inlet Channel south to the Power Squadron Spit excluding the jetty. The west boundary is at the toe of the primary dune or dense vegetation line where the physical or biological features do not occur, and the east boundary is MLLW on the Atlantic Ocean (*i.e.,* the highly dynamic beach and emergent sand shoals that are covered at high tide and uncovered at low tide). This subunit also includes MLLW on Core Sound to the MLLW on the Atlantic Ocean in emergent sand shoals within the flood-tidal and ebb-tidal deltas associated with the South Core Banks side of the New Drum Inlet channel, and all emergent sand shoals associated with Cape Point. All of the lands within this subunit are under Federal ownership (Cape Lookout National Seashore).

(v) Map of Subunit NC–2B follows:

Figure 38 to Rufa Red Knot paragraph (42)(v)

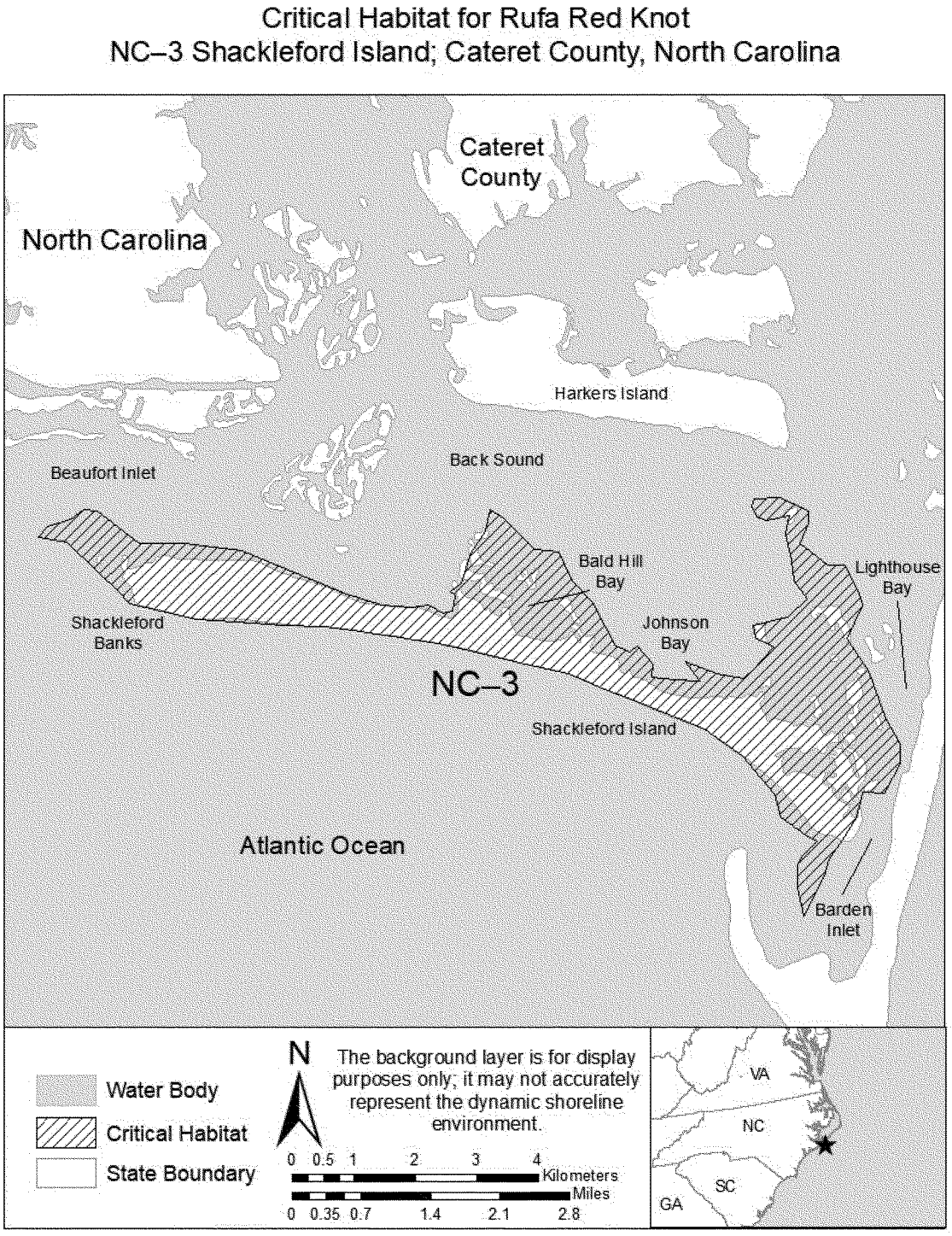


(43) Unit NC–3: Shackleford Island, North Carolina.

(i) Unit NC–3 consists of approximately 4,972 ac (2,012 ha) of occupied habitat in Carteret County consisting of shoreline habitat bounded to the north by the MLLW along Back Sound and Bald Hill, Johnson, and Lighthouse Bays south to dense vegetation where the physical or biological features do not occur. The east boundary is the Shackleford Island side of Barden Inlet channel, the south boundary is MLLW on the Atlantic Ocean, and the west boundary is the Shackleford Island side of Beaufort Inlet Channel. This unit includes emergent sand shoals within the flood-tidal and ebb-tidal deltas associated with the Shackleford Island side of the Barden Inlet channel, and the emergent sand shoals within the flood-tidal and ebb-tidal deltas associated with the west side of the Beaufort Inlet channel (*i.e.,* the highly dynamic beach and emergent sand shoals that are covered at high tide and uncovered at low tide). All lands within this unit are in Federal ownership (Cape Lookout National Seashore).

(ii) Map of Unit NC–3 follows:

Figure 39 to Rufa Red Knot paragraph (43)(ii)

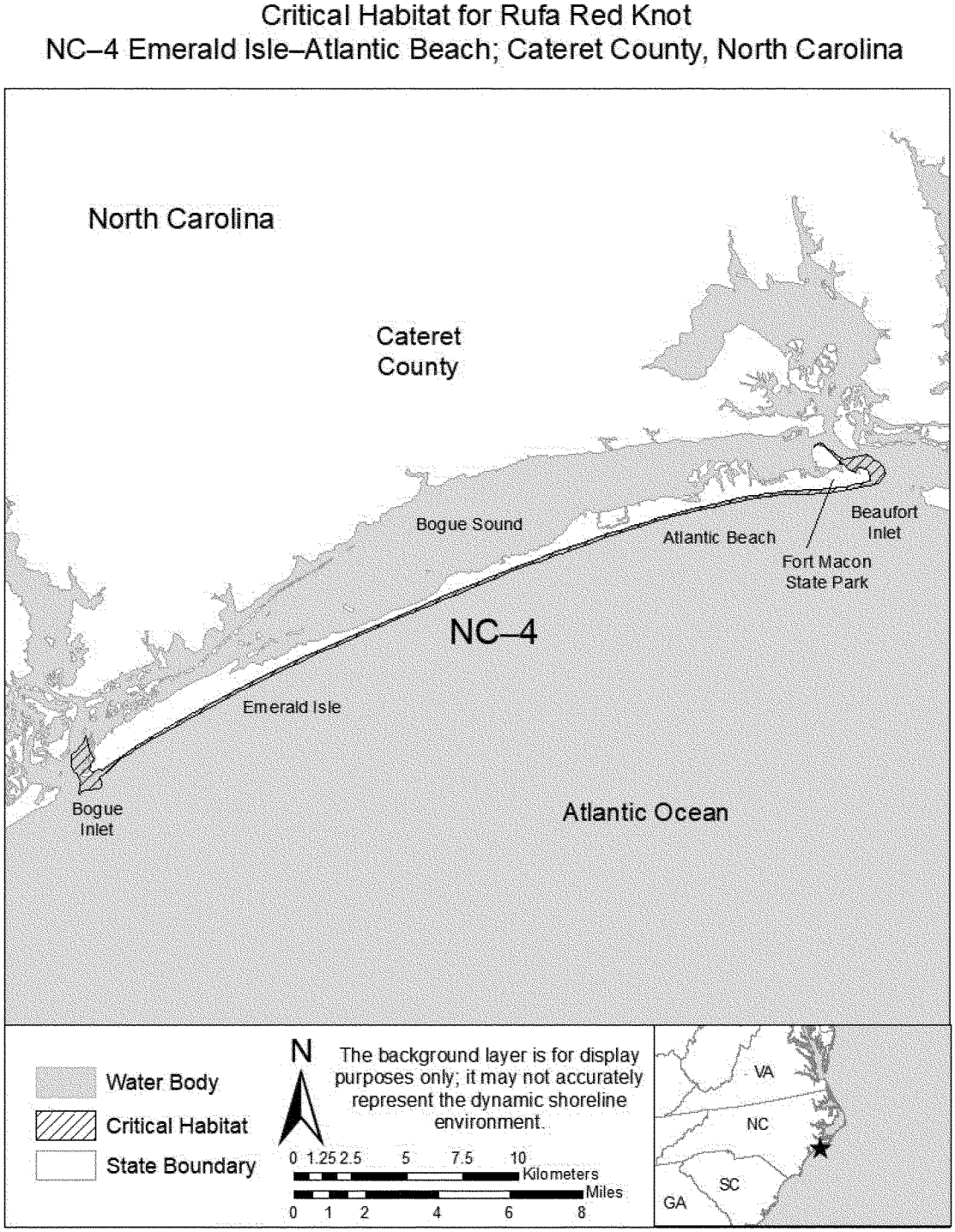


(44) Unit NC–4: Emerald Isle–Atlantic Beach, North Carolina.

(i) Unit NC–4 consists of approximately 2,030 ac (822 ha) of occupied habitat in Carteret County consisting of shoreline habitat that stretches about 23 mi (37 km) from the Beaufort Inlet channel and Fort Macon State Park west to the eastern side of the Bogue Inlet channel. Unit NC–4 includes from MLLW to the toe of the dunes or where densely vegetated habitat, not used by the rufa red knot, begins and where the physical or biological features no longer occur. This unit also includes the emergent sand shoals within the flood-tidal and ebb-tidal deltas associated with the west side of the Beaufort Inlet channel, not including the jetty, as well as the emergent sand shoals within the flood-tidal and ebb-tidal deltas on the east side of the Bogue Inlet channel. Lands within this unit include approximately 1,908 ac (772 ha) in State ownership and 122 ac (50 ha) in private/other ownership (which includes 1 ac (0.5 ha) in local government ownership and 121 ac (49 ha) in private ownership).

(ii) Map of Unit NC–4 follows:

Figure 40 to Rufa Red Knot paragraph (44)(ii)

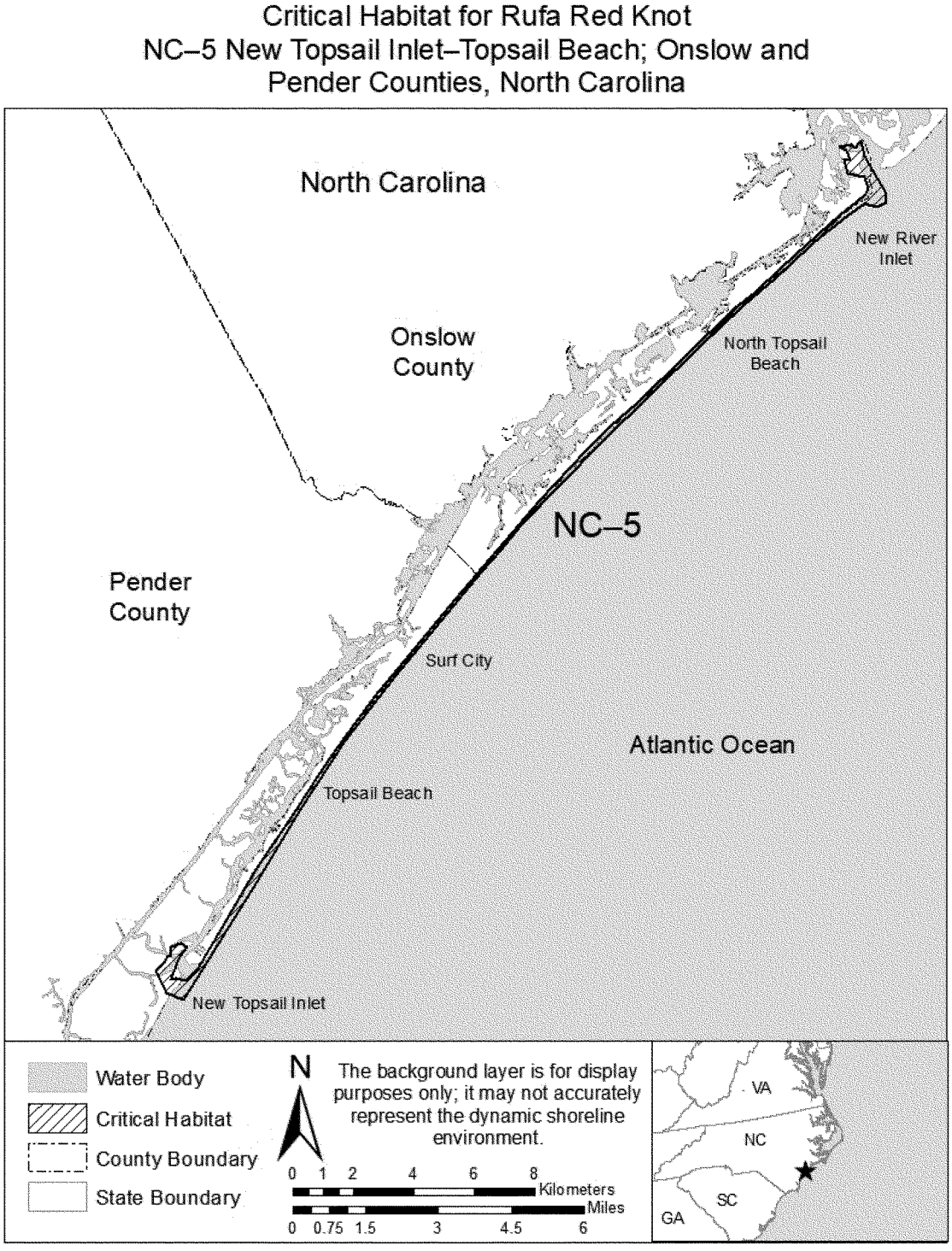


(45) Unit NC–5: New Topsail Inlet–Topsail Beach, North Carolina.

(i) Unit NC–5 consists of approximately 1,612 ac (652 ha) of occupied habitat in Onslow and Pender Counties consisting of shoreline habitat that stretches about 23 mi (37 km) from the west side of the New River Inlet channel west to the east side of the New Topsail Inlet channel. This unit includes from MLLW to the toe of the dunes or where densely vegetated habitat, not used by the rufa red knot, begins and where the physical or biological features no longer occur. This unit also includes the emergent sand shoals within the flood-tidal and ebb-tidal deltas associated with the west side of the New River Inlet channel, as well as the emergent sand shoals within the flood-tidal and ebb-tidal deltas on the east side of the New Topsail Inlet channel. All lands within this unit are in private/other ownership.

(ii) Map of Unit NC–5 follows:

Figure 41 to Rufa Red Knot paragraph (45)(ii)

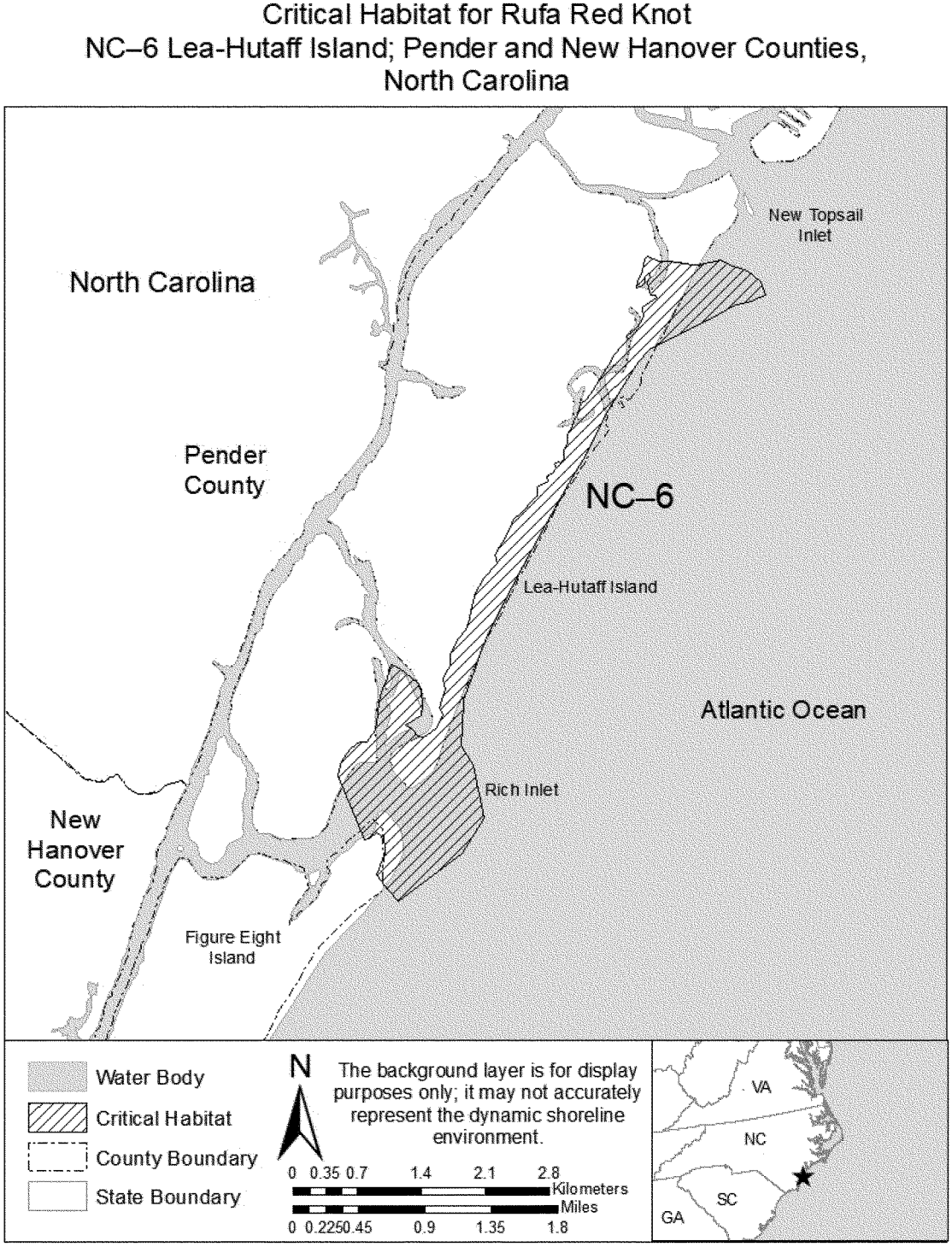


(46) Unit NC–6: Lea-Hutaff Island, North Carolina.

(i) Unit NC–6 consists of approximately 1,085 ac (439 ha) of occupied habitat on Lea-Hutaff Island in Pender and New Hanover Counties consisting of shoreline habitat that stretches about 4.8 mi (7.7 km) from the west side of the New Topsail Inlet channel west across the Rich Inlet channel to the toe of the primary dune or dense vegetation line on the northeast end of Wrightsville Beach. This unit includes from MLLW to the toe of the dunes or where densely vegetated habitat, not used by the rufa red knot, begins and where the physical or biological features no longer occur. This unit also includes the emergent sand shoals within the flood-tidal and ebb-tidal deltas associated with the west side of the New Topsail Inlet channel, and the emergent sand shoals within the flood-tidal and ebb-tidal deltas on the west side of Rich Inlet channel. Lands within this unit include approximately 72 ac (29 ha) in State ownership, 427 ac (173 ha) in private/other ownership, and 586 ac (237 ha) that are uncategorized.

(ii) Map of Unit NC–6 follows:

Figure 42 to Rufa Red Knot paragraph (46)(ii)

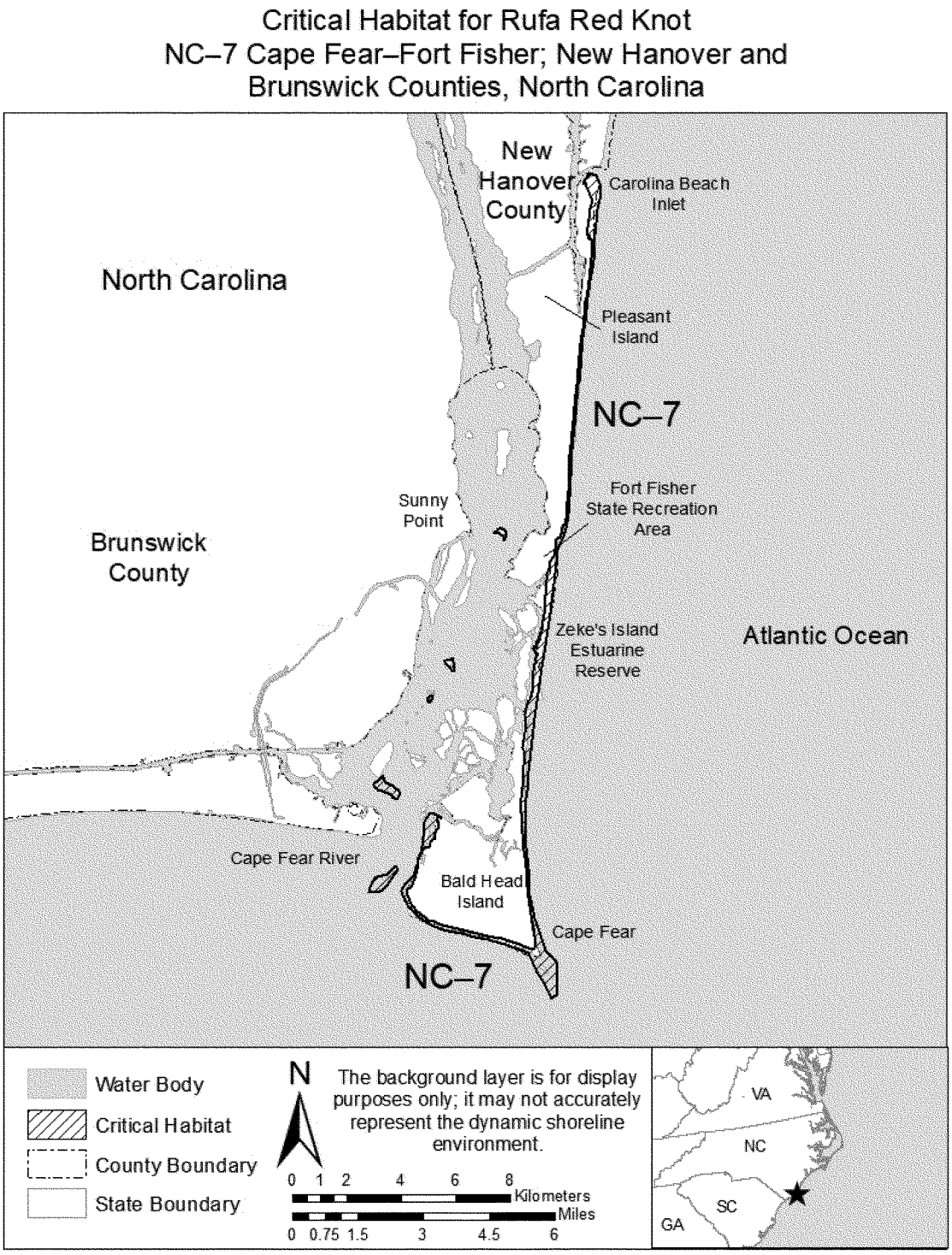


(47) Unit NC–7: Cape Fear–Fort Fisher, North Carolina.

(i) Unit NC–7 consists of approximately 1,986 ac (804 ha) of occupied coastal barrier island from Carolina Beach Inlet in New Hanover County, North Carolina, to the mouth of the Cape Fear River in Brunswick County, North Carolina. The north boundary of this unit is the northeast tip of Pleasure Island south of Carolina Beach Inlet, and the south boundary extends from the tip of Cape Fear west approximately 3.4 mi (5 km) to the mouth of the Cape Fear River. The west boundary is the toe of the primary dune or where densely vegetated habitat, not used by the rufa red knot, begins and where the physical or biological features no longer occur. The east boundary is MLLW on the Atlantic Ocean excluding groins and jetties. This unit also includes all emergent sand shoals associated with the tip of Cape Fear, the Cape Fear River south of Military Ocean Terminal Sunny Point, and the emergent sand shoals within the flood-tidal and ebb-tidal deltas associated with the southwest side of Carolina Beach Inlet channel and the southwest tip of Bald Head Island. Lands within this unit include approximately 1,713 ac (693 ha) in State ownership and 274 ac (111 ha) in private/other ownership. State lands in this unit contain parts of Fort Fisher State Recreation Area and Zeke's Island Estuarine Reserve.

(ii) Map of Unit NC–7 follows:

Figure 43 to Rufa Red Knot paragraph (47)(ii)

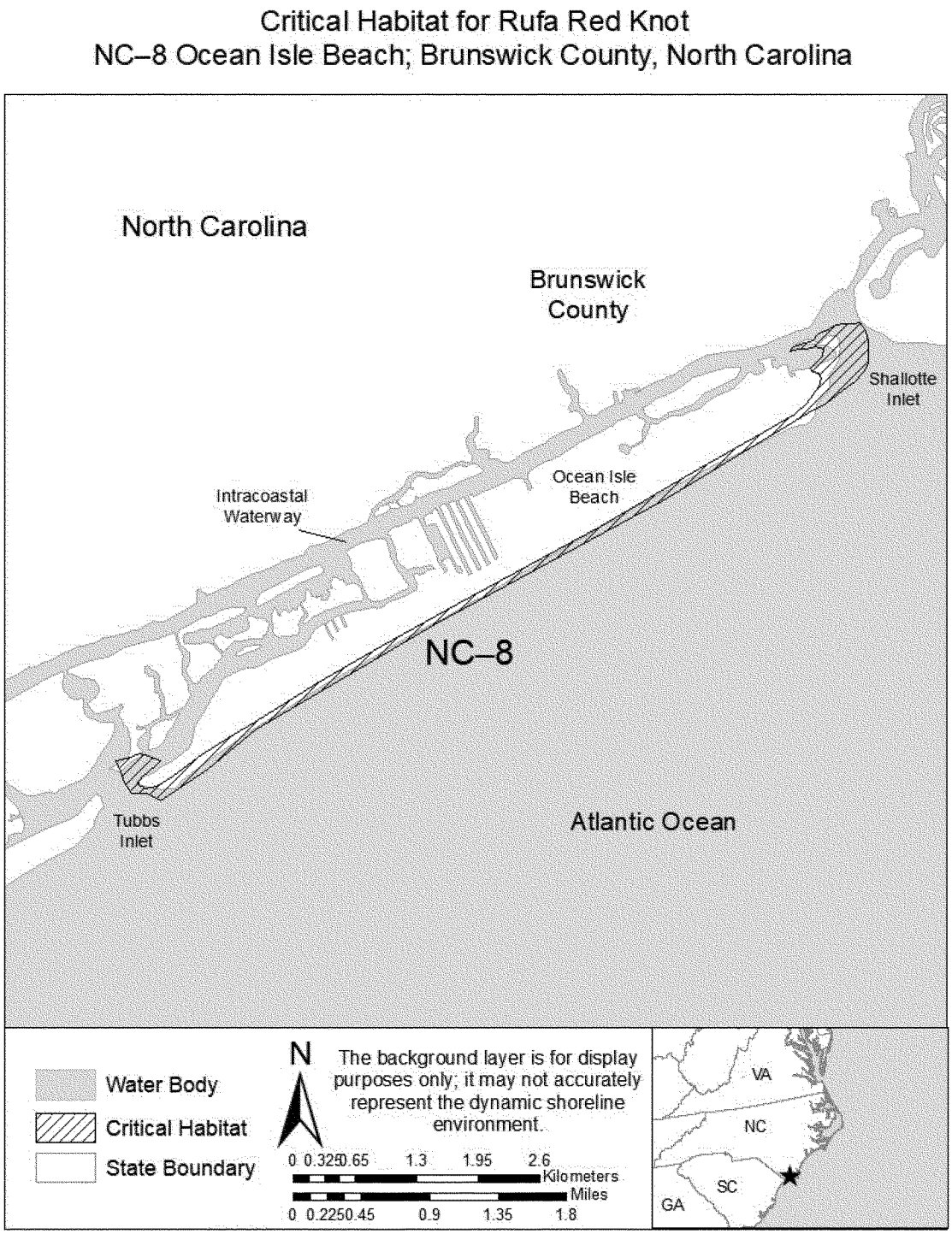


(48) Unit NC–8: Ocean Isle Beach, North Carolina.

(i) Unit NC–8 consists of approximately 298 ac (120 ha) of occupied coastal barrier island in Brunswick County, stretching about 6 mi (10 km) from the west side of Shallotte Inlet to the east side of Tubbs Inlet. The east boundary of this unit is the west side of Shallotte Inlet. The south boundary is the MLLW on the Atlantic Ocean, the west boundary is the east side of Tubbs Inlet, and the north boundary is the toe of the primary dune or where densely vegetated habitat, not used by the rufa red knot, begins and where the physical or biological features no longer occur. This unit also includes the emergent sand shoals within the flood-tidal and ebb-tidal deltas associated with the west side of the Shallotte Inlet channel, as well as the emergent sand shoals within the flood-tidal and ebb-tidal deltas on the east side of the Tubbs Inlet channel. Lands within this unit include approximately 182 ac (73 ha) in State ownership and 116 ac (47 ha) in private/other (municipal) ownership.

(ii) Map of Unit NC–8 follows:

Figure 44 to Rufa Red Knot paragraph (48)(ii)

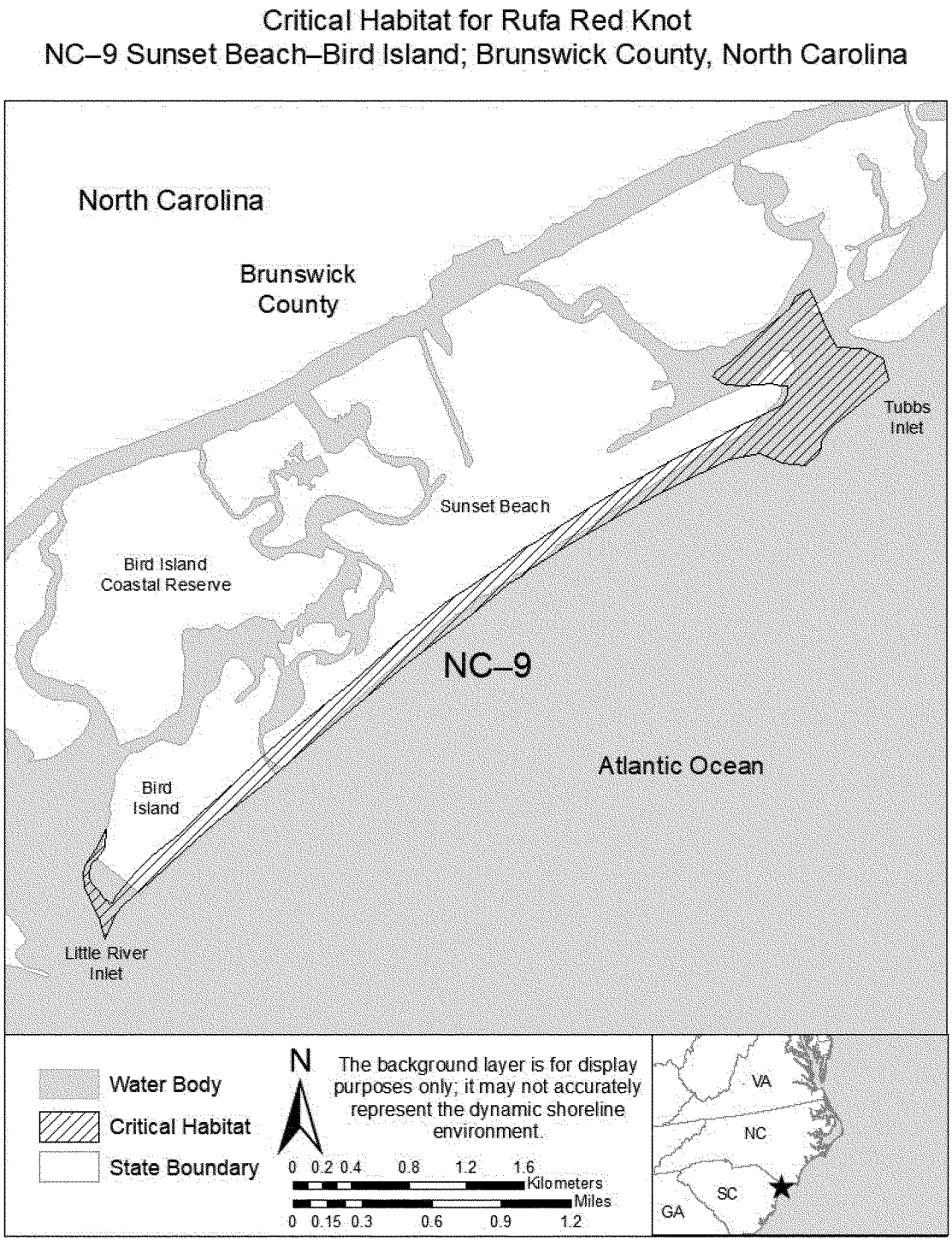


(49) Unit NC–9: Sunset Beach–Bird Island, North Carolina.

(i) Unit NC–9 consists of approximately 384 ac (155 ha) of occupied coastal barrier island in Brunswick County, stretching about 4.1 mi (6.6 km) from the west side of Tubbs Inlet to the east side of Little River Inlet. The east boundary of this unit is the west side of Tubbs Inlet. The south boundary is the MLLW on the Atlantic Ocean, the west boundary is the east side of Little River Inlet, and the north boundary is the toe of the primary dune or where densely vegetated habitat, not used by the rufa red knot, begins and where the physical or biological features no longer occur. This unit also includes the emergent sand shoals within the flood-tidal and ebb-tidal deltas associated with the west side of the Tubbs Inlet channel, as well as the emergent sand shoals within the flood-tidal and ebb-tidal deltas on the east side of the Little River Inlet channel, excluding the jetty. Lands within this unit include approximately 345 ac (139 ha) in State ownership (part of the North Carolina Coastal Reserve) and 39 ac (16 ha) in private/other ownership.

(ii) Map of Unit NC–9 follows:

Figure 45 to Rufa Red Knot paragraph (49)(ii)

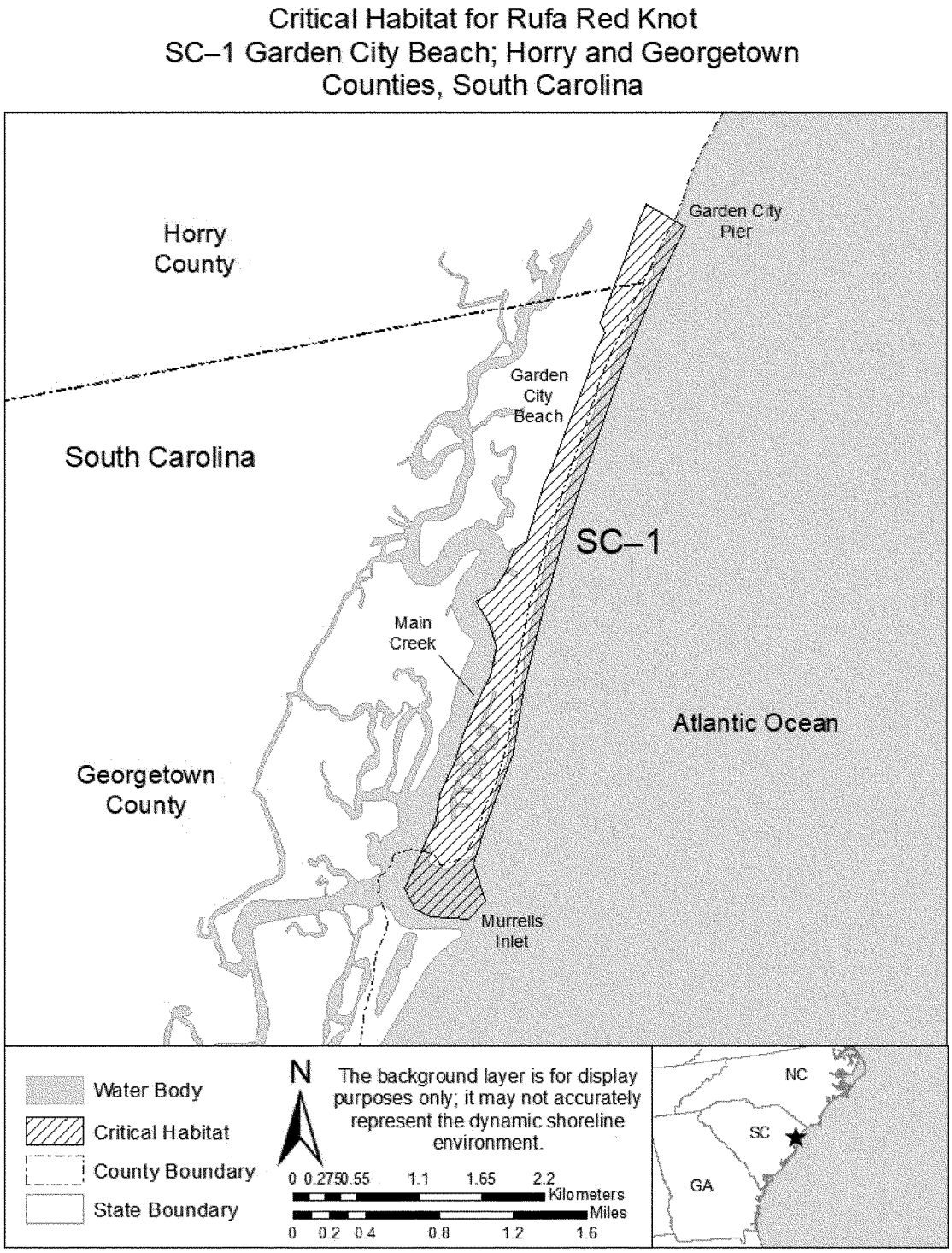


(50) Unit SC–1: Garden City Beach, South Carolina.

(i) Unit SC–1 consists of approximately 616 ac (249 ha) of occupied coastal shoreline habitat in Georgetown and Horry Counties. The northern boundary of the unit begins at the Garden City pier in Horry County and extends southwest to the northern side of Murrells Inlet in Georgetown County. The unit includes all emergent land from MLLW (which includes the highly dynamic shoreline and sandy intertidal zone that is covered at high tide and uncovered at low tide) to the toe of the dunes or where densely vegetated habitat, not used by the rufa red knot, begins. This unit also includes the ephemeral, emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the northeastern side of Murrells Inlet's navigable channel. Lands within this unit include approximately 267 ac (108 ha) in State ownership and 349 ac (141 ha) in private/other ownership.

(ii) Map of Unit SC–1 follows:

Figure 46 to Rufa Red Knot paragraph (50)(ii)

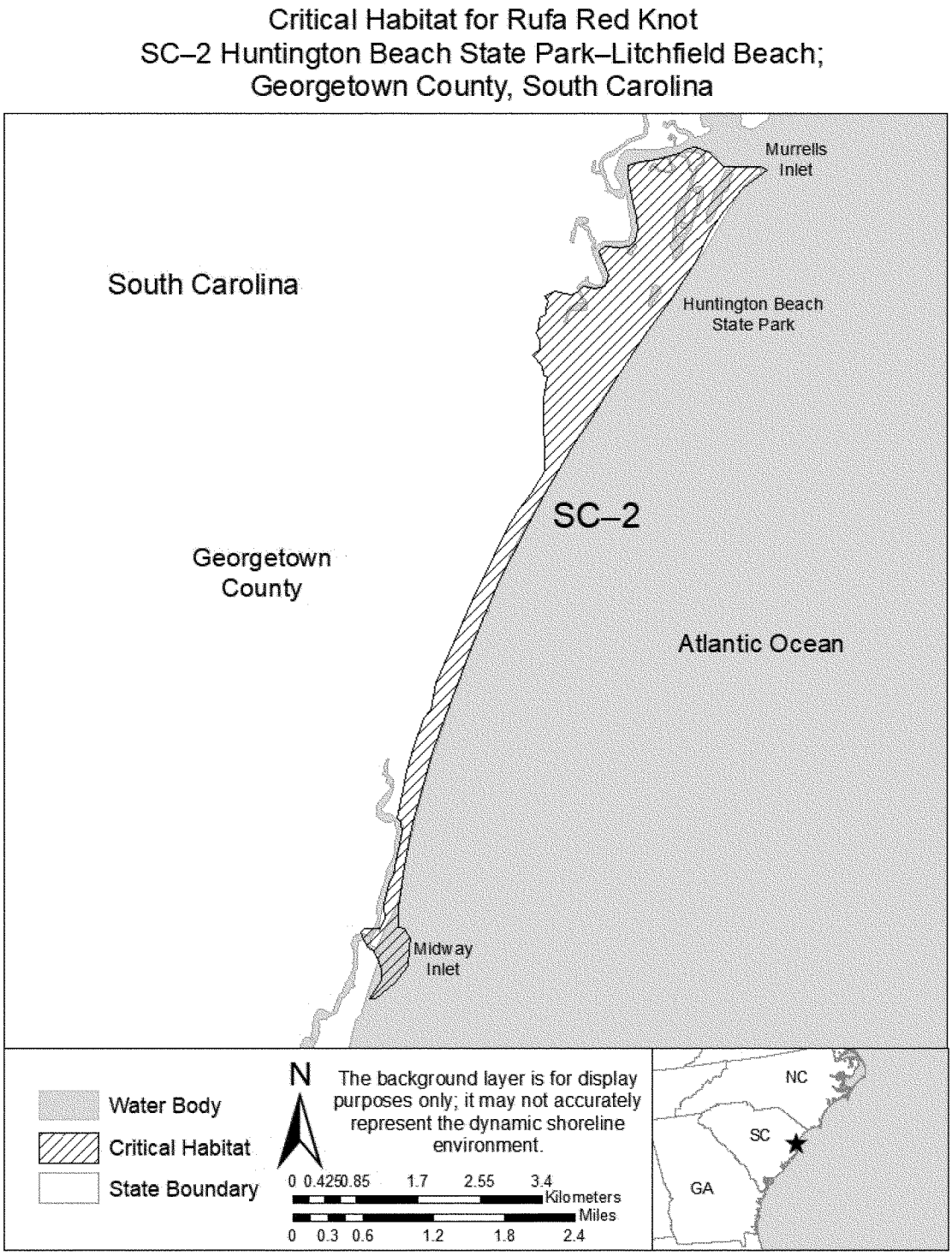


(51) Unit SC–2: Huntington Beach State Park–Litchfield Beach, South Carolina.

(i) Unit SC–2 consists of approximately 1,634 ac (661 ha) of occupied coastal shoreline habitat in Georgetown County. The unit boundary begins on the southern side of Murrells Inlet southwest and extends southwest to the northern side of Midway Inlet. The unit includes all emergent land from MLLW (which includes the highly dynamic shoreline and sandy intertidal zone that is covered at high tide and uncovered at low tide) to the toe of the dunes or where densely vegetated habitat, not used by the rufa red knot, begins. This unit also includes the ephemeral, emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the southwestern side of Murrells Inlet's navigable channel and the northeastern side of Midway Inlet's navigable channel. Lands within this unit include approximately 80 ac (32 ha) in State ownership, which includes Huntington Beach State Park, and 1,554 ac (629 ha) in private/other ownership.

(ii) Map of Unit SC–2 follows:

Figure 47 to Rufa Red Knot paragraph (51)(ii)

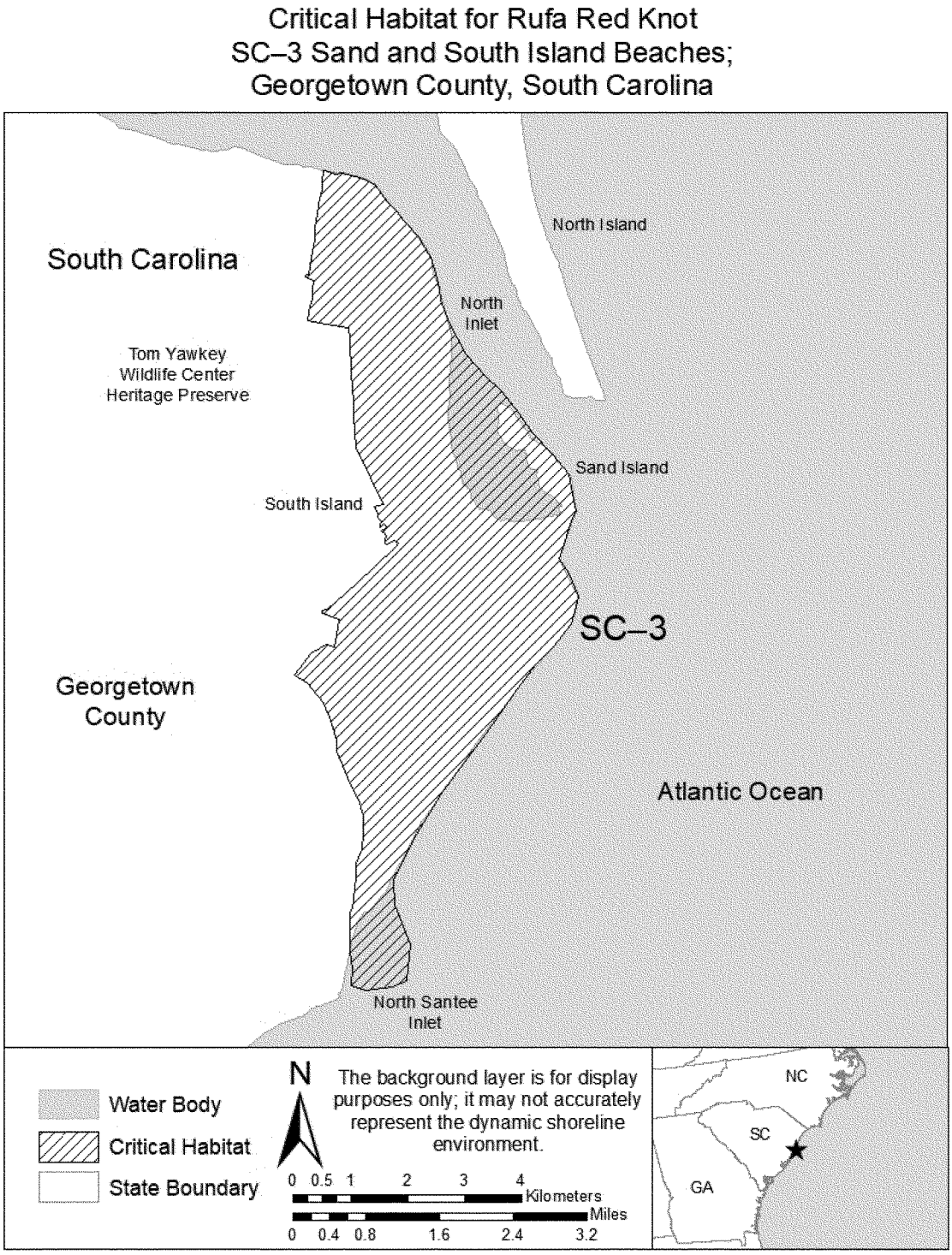


(52) Unit SC–3: Sand and South Island Beaches, South Carolina.

(i) Unit SC–3 consists of approximately 8,256 ac (3,341 ha) of occupied coastal shoreline habitat on Sand and South Islands, barrier islands off the coast of Georgetown County. The unit boundary begins on the northeastern edge of South Island in North Inlet behind North Island following the shoreline to include Sand Island and continuing southwest to the southern tip of South Island. The unit includes all emergent land from MLLW (which includes the highly dynamic shoreline and sandy intertidal zone that is covered at high tide and uncovered at low tide) to the toe of the dunes or where densely vegetated habitat, not used by the rufa red knot, begins. This unit also includes the ephemeral, emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the unnamed inlet between Sand and South Islands and the northeastern side of North Santee River Inlet's navigable channel. Lands within this unit include approximately 7,843 ac (3,174 ha) in State ownership (including the Tom Yawkey Wildlife Center Heritage Preserve), 129 ac (52 ha) in private/other ownership, and 283 ac (115 ha) that are uncategorized.

(ii) Map of Unit SC–3 follows:

Figure 48 to Rufa Red Knot paragraph (52)(ii)



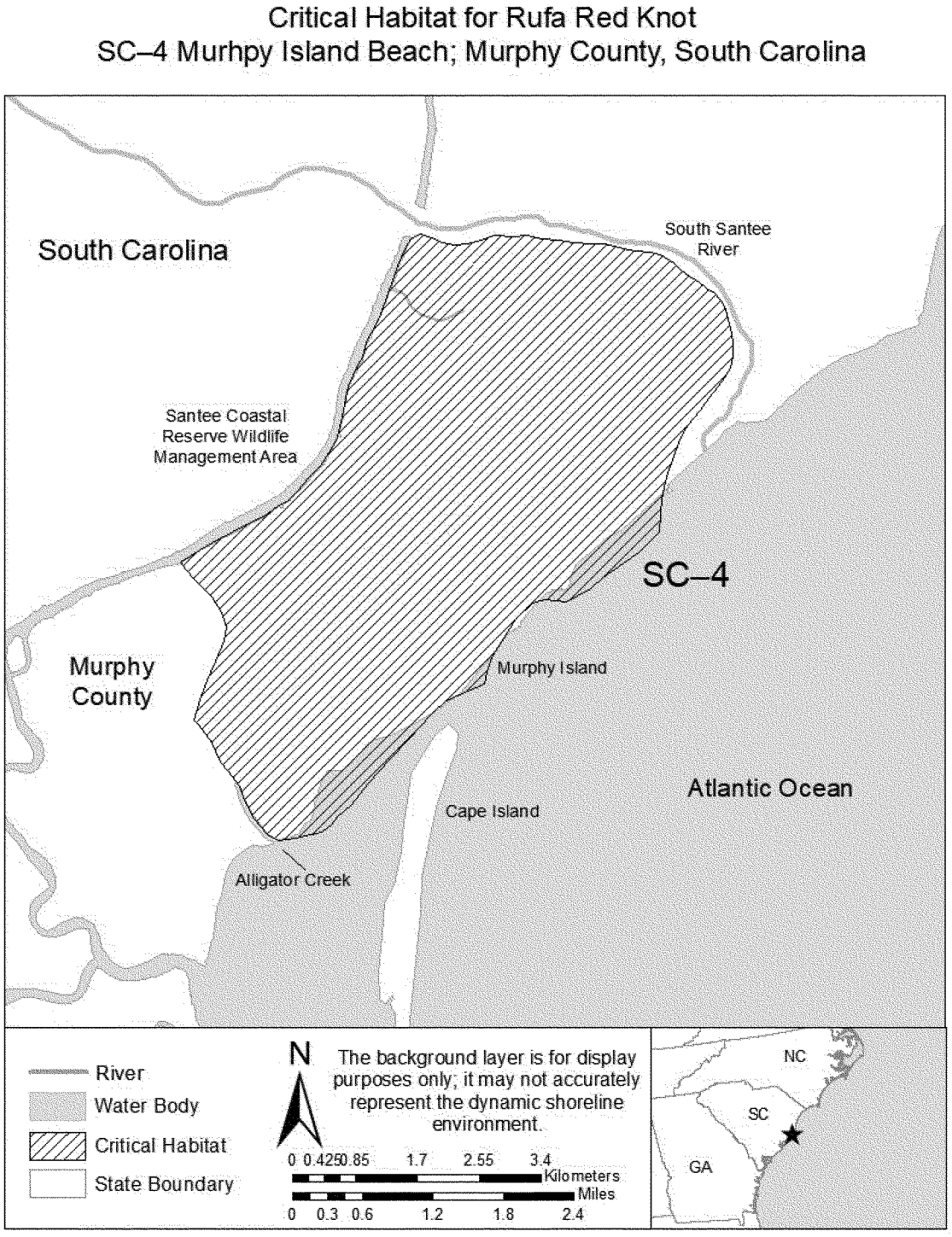
(53) Unit SC–4: Murphy Island Beach, South Carolina.

(i) Unit SC–4 consists of approximately 8,312 ac (3,364 ha) of occupied coastal shoreline habitat on all of Murphy Island, a barrier island off the coast of Charleston County. The unit boundary begins on the South Santee River shoreline of Murphy Island and extends to the Alligator Creek shoreline. The unit includes all emergent land from MLLW (which includes the highly dynamic shoreline and sandy intertidal zone that is covered at high tide and uncovered at low tide) to the toe of the dunes or where densely vegetated habitat, not used by the rufa red knot, begins. This unit also includes the ephemeral, emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the unnamed

inlets along the shoreline of Murphy Island. Lands within this unit are entirely in State ownership; the South Carolina Department of Natural Resources manages Murphy Island as part of the Santee Coastal Reserve Wildlife Management Area.

(ii) Map of Unit SC–4 follows:

Figure 49 to Rufa Red Knot paragraph (53)(ii)



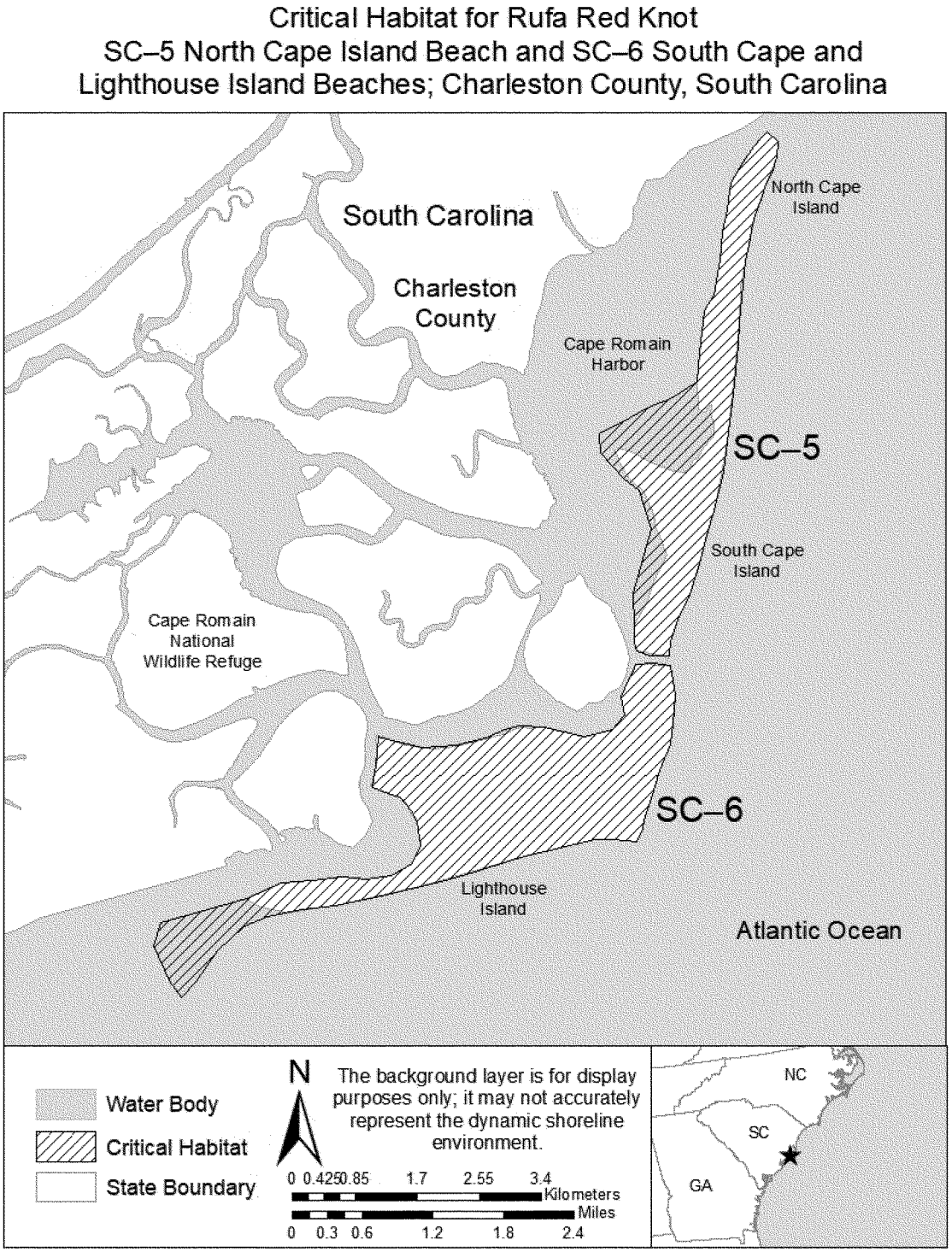
(54) Unit SC–5: North Cape Island Beach, South Carolina.

(i) Unit SC–5 consists of approximately 1,270 ac (514 ha) of occupied coastal shoreline habitat on the northern portion of Cape Island, a barrier island off the coast of Charleston County. The unit boundary begins on the Cape Romain Harbor shoreline of Cape Island and extends south to the shoreline along the unnamed inlet between South Cape Island and Lighthouse Island. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone

that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the northern side of the navigable channel of the unnamed inlet between South Cape Island and Lighthouse Island. Lands within this unit include approximately 775 ac (313 ha) in Federal ownership (Cape Romain NWR) and 495 ac (200 ha) in State ownership.

(ii) Map of Unit SC–5 follows:

Figure 50 to Rufa Red Knot paragraph (54)(ii)



(55) Unit SC–6: South Cape and Lighthouse Island Beaches, South Carolina.

(i) Unit SC–6 consists of approximately 2,037 ac (824 ha) of occupied coastal shoreline habitat along the entire southern portion of Cape Island and all of Lighthouse Island, barrier islands off the coast, in Charleston County. The unit boundary begins at the unnamed inlet between

South Cape Island and Lighthouse Island and extends to the western tip of Lighthouse Island in Key Inlet. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the southern side of the navigable channel of the unnamed inlet between North Cape Island and South Cape Island and the emergent sand shoals associated with Key Inlet. Lands within this unit include approximately 1,552 ac (628 ha) in Federal ownership (Cape Romain NWR) and 485 ac (196 ha) in State ownership.

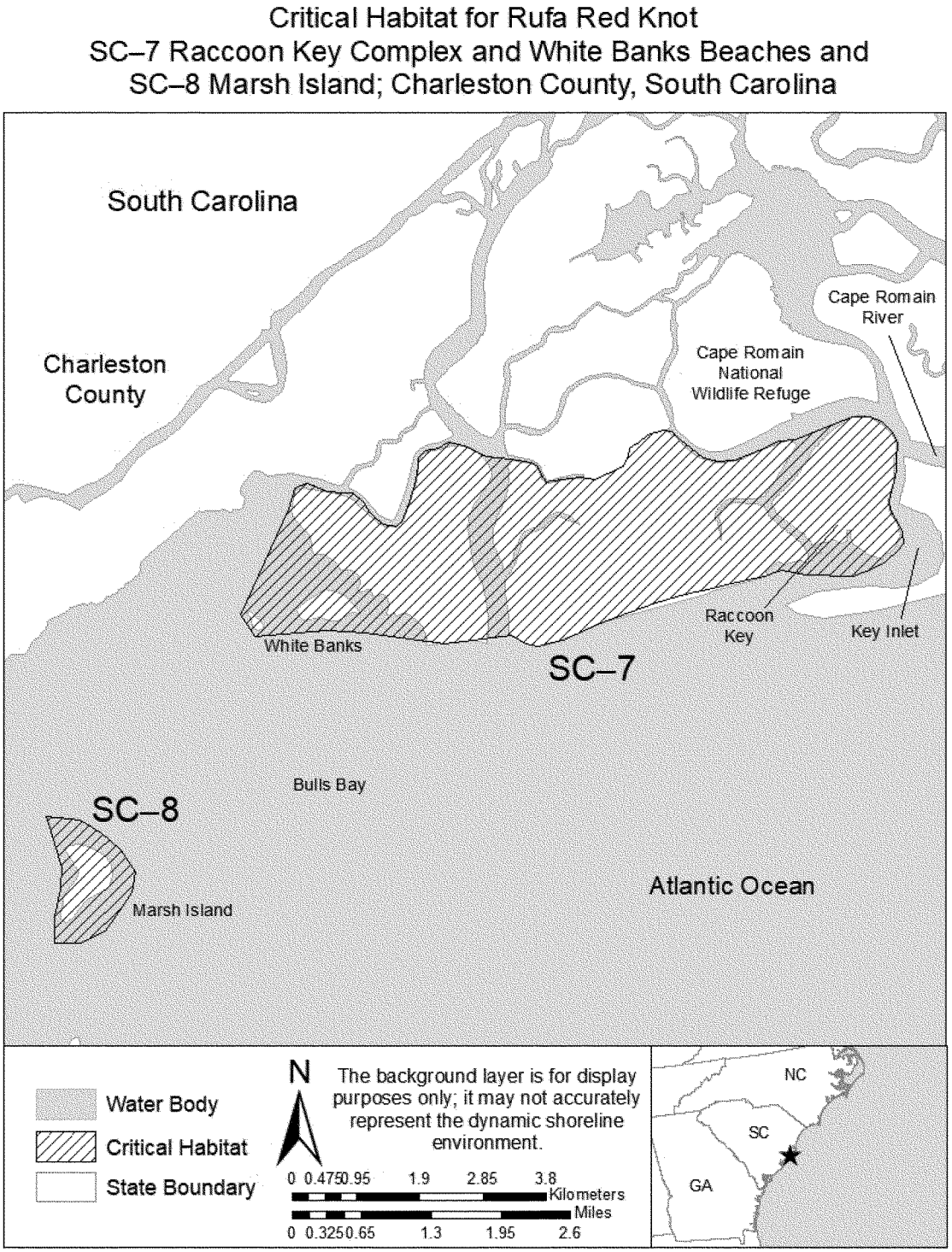
(ii) Map of Unit SC–6 is presented at paragraph (54)(ii) of this entry.

(56) Unit SC–7: Raccoon Key Complex and White Banks Beaches, South Carolina.

(i) Unit SC–7 consists of approximately 5,324 ac (2,154 ha) of occupied coastal shoreline habitat along the entire Raccoon Key complex and White Banks, islands off the coast, in Charleston County. The unit boundary begins at the intersection of the Romain River and Key Inlet side of Raccoon Key and extends to the western edge of White Banks in Bulls Bay. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the unnamed inlets in the Raccoon Key complex. Lands within this unit are all in Federal ownership (Cape Romain NWR).

(ii) Map of Unit SC–7 follows:

Figure 51 to Rufa Red Knot paragraph (56)(ii)



(57) Unit SC–8: Marsh Island, South Carolina.

(i) Unit SC–8 consists of approximately 415 ac (168 ha) of occupied habitat across the entirety of Marsh Island, which is an island in Bulls Bay, Charleston County. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with Marsh Island. Lands within this unit are all in Federal ownership (Cape Romain NWR).

(ii) Map of Unit SC–8 is presented at paragraph (56)(ii) of this entry.

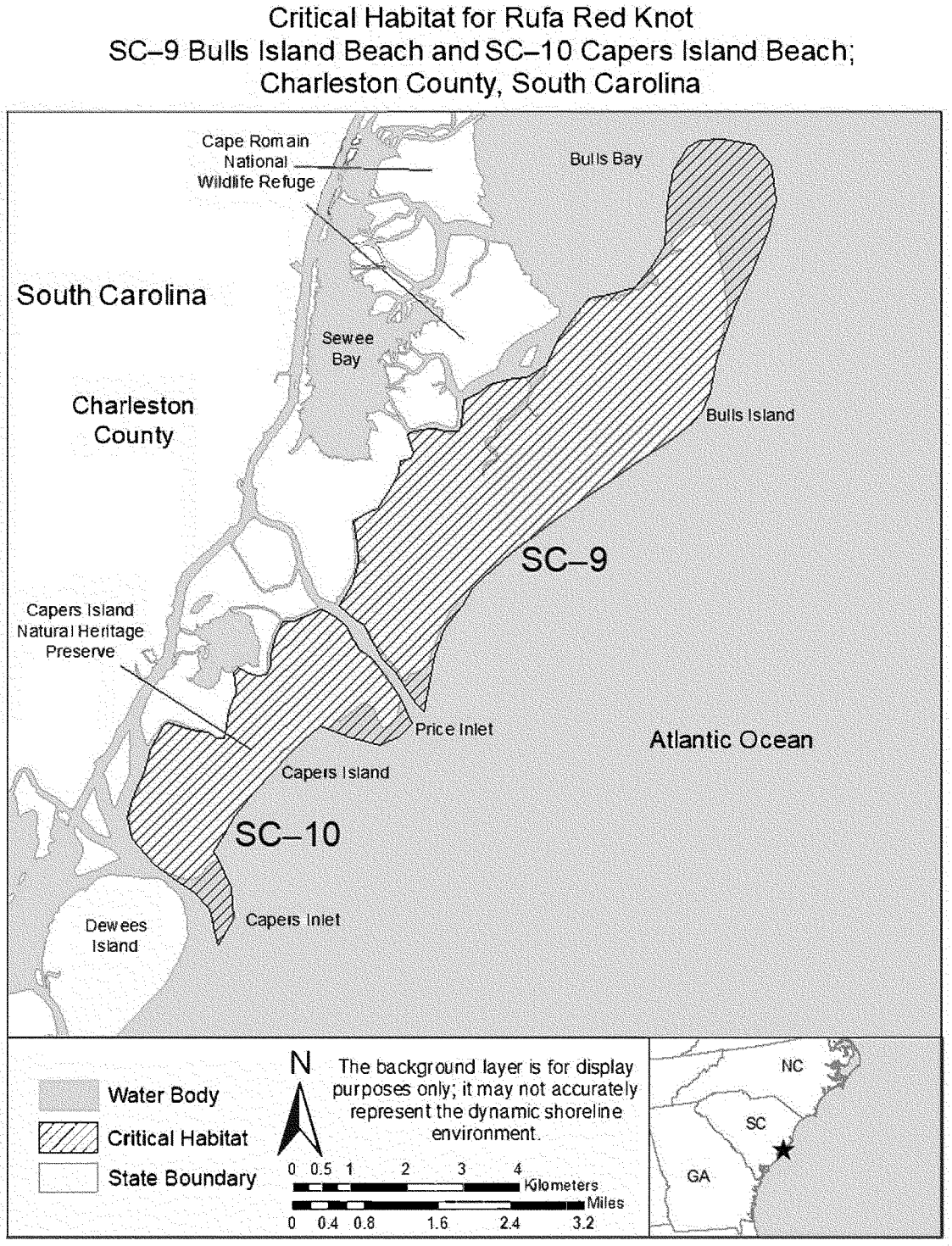
(58) Unit SC–9: Bulls Island Beach, South Carolina.

(i) Unit SC–9 consists of approximately 6,141 ac (2,485 ha) of occupied habitat across the entirety of Bulls Island, which is a barrier island along the coast of Charleston County. The unit boundary begins on the Bulls Bay shoreline of Bulls Island and extends southwest to the Price Inlet shoreline. The unit includes all

emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the northeastern side of Price Inlet's navigable channel. Lands within this unit include approximately 5,200 ac (2,104 ha) in Federal ownership (Cape Romain NWR) and 941 ac (381 ha) in State ownership.

(ii) Map of Unit SC–9 follows:

Figure 52 to Rufa Red Knot paragraph (58)(ii)



(59) Unit SC–10: Capers Island Beach, South Carolina.

(i) Unit SC–10 consists of approximately 2,534 ac (1,026 ha) of occupied habitat across the entirety of Capers Island, which is a barrier island off the coast of Charleston County. The unit boundary begins on the Price Inlet shoreline of Capers Island and extends southwest to the Capers Inlet shoreline. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the southwestern side of Price Inlet's navigable channel and the northeastern side of Capers Inlet's navigable channel. Lands within this unit are entirely in State ownership (Capers Island Natural Heritage Preserve).

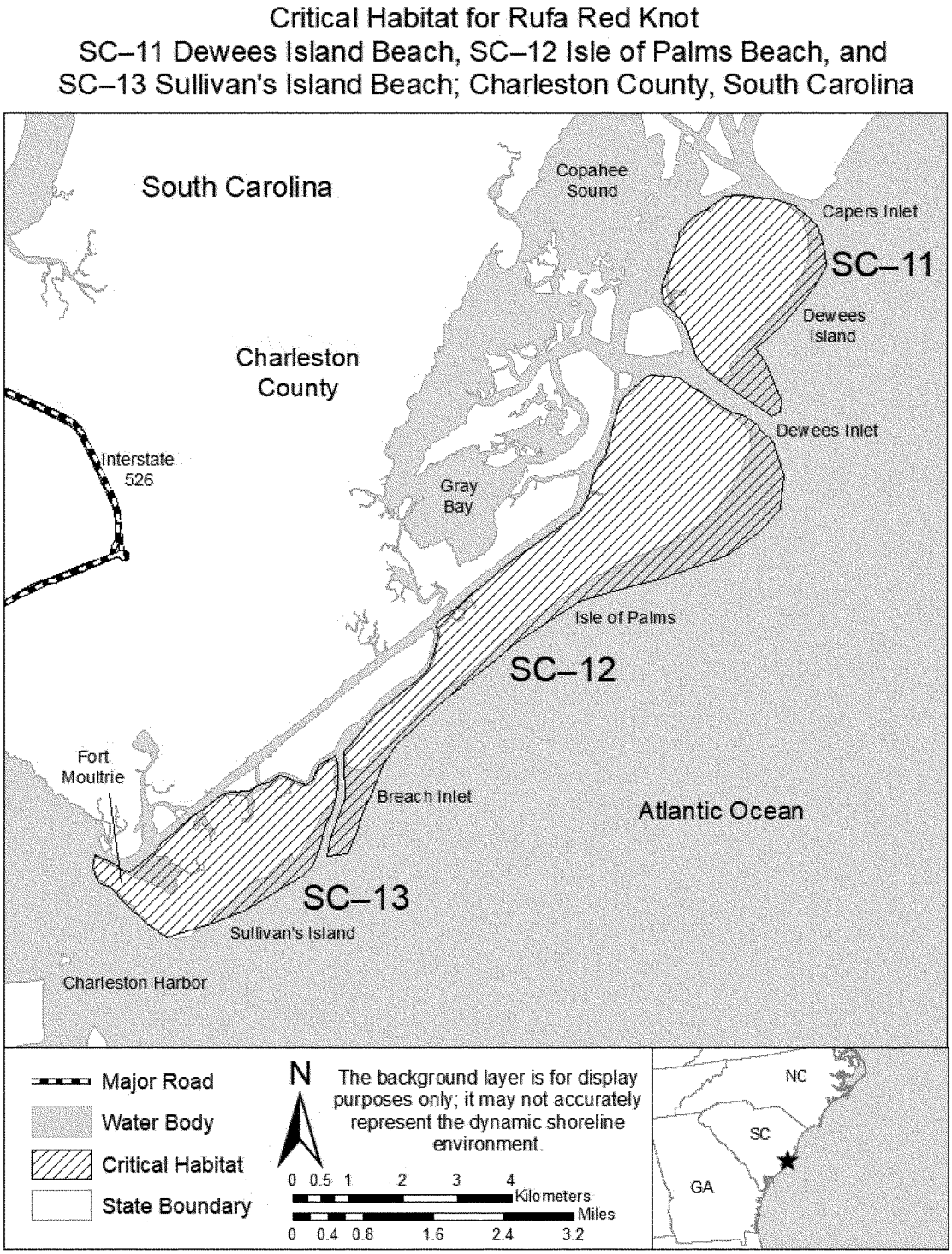
(ii) Map of Unit SC–10 is presented at paragraph (58)(ii) of this entry.

(60) Unit SC–11: Dewees Island Beach, South Carolina.

(i) Unit SC–11 consists of approximately 1,812 ac (733 ha) of occupied habitat across the entirety of Dewees Island, which is a barrier island off the coast of Charleston County. The unit boundary begins on the Capers Inlet shoreline of Dewees Island and extends to the Dewees Inlet shoreline. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the southwestern side of Capers Inlet's navigable channel and the northeastern side of Dewees Inlet's navigable channel. Lands within this unit include approximately 265 ac (107 ha) in State ownership and 1,547 ac (626 ha) in private/other ownership.

(ii) Map of Unit SC–11 follows:

Figure 53 to Rufa Red Knot paragraph (60)(ii)



(61) Unit SC–12: Isle of Palms Beach, South Carolina.

(i) Unit SC–12 consists of approximately 4,117 ac (1,666 ha) of occupied habitat across the entirety of Isle of Palms, which is a barrier island off the coast of Charleston County. The unit boundary begins at the Dewees Inlet shoreline of the Isle of Palms and extends southwest to the Breach Inlet shoreline. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the southwestern side of Dewees Inlet's navigable channel and the northeastern side of Breach Inlet's navigable channel. Lands within this unit include approximately 754 ac (305 ha) in State ownership and 3,363 ac (1,361 ha) in private/other ownership.

(ii) Map of Unit SC–12 is presented at paragraph (53)(ii) of this entry.

(62) Unit SC–13: Sullivan's Island Beach, South Carolina.

(i) Unit SC–13 consists of approximately 1,782 ac (721 ha) of occupied habitat across the entirety of Sullivan's Island, which is a barrier island off the coast of Charleston County. The unit boundary begins on the Breach Inlet shoreline of Sullivan's Island and extends southwest to the Charleston Harbor shoreline. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the southwestern side of Breach Inlet's navigable channel. Lands within this unit include approximately 83 ac (34 ha) in Federal ownership (Ft. Moultrie, which is part of Ft. Sumter National Monument), 694 ac (281 ha) in State ownership, and 1,005 ac (407 ha) in private/other ownership.

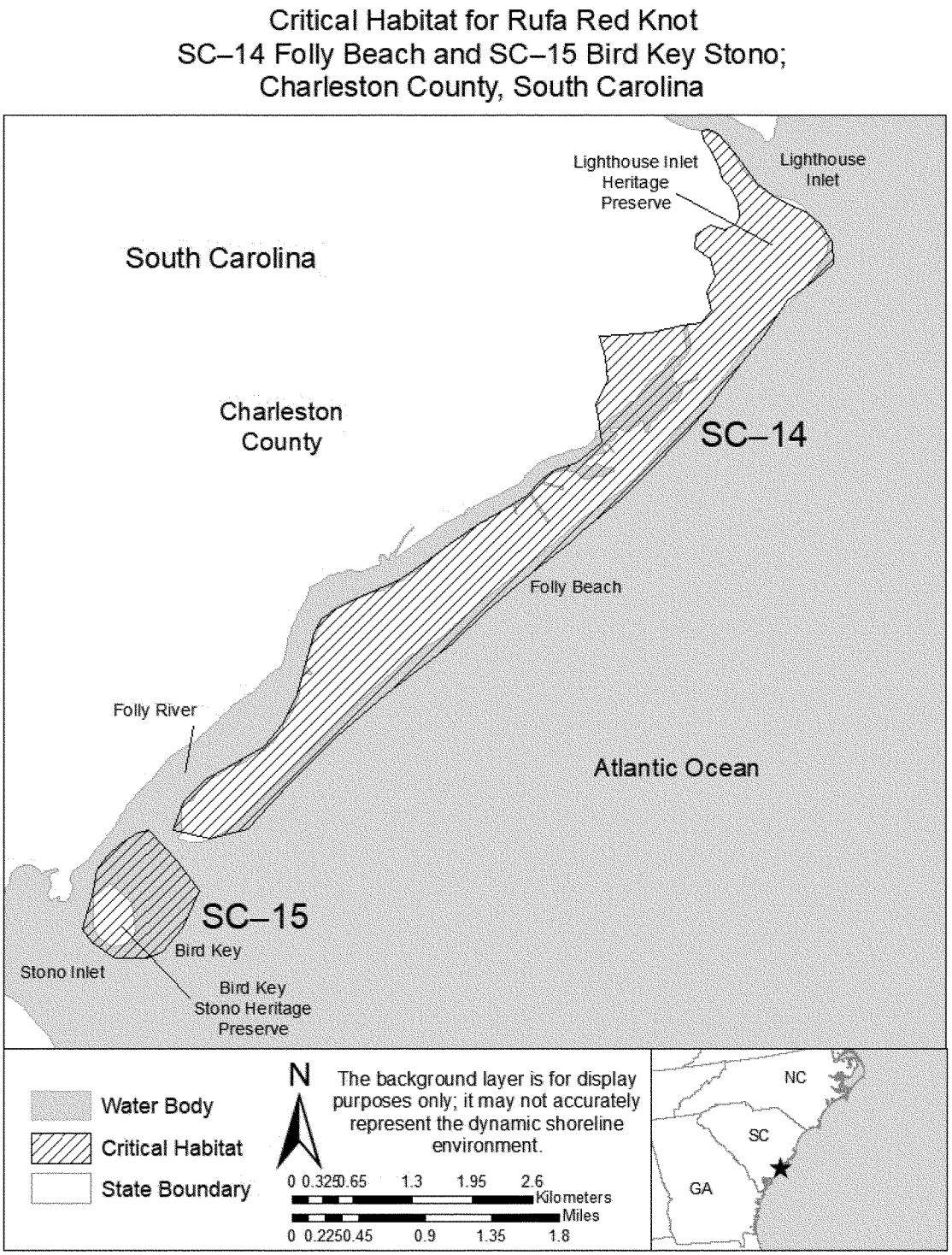
(ii) Map of Unit SC–13 is presented at paragraph (53)(ii) of this entry.

(63) Unit SC–14: Folly Beach, South Carolina.

(i) Unit SC–14 consists of approximately 1,989 ac (805 ha) of occupied habitat across the entirety of Folly Beach, which is a barrier island off the coast of Charleston County. The unit boundary begins on the Lighthouse Inlet shoreline of Folly Beach and extends southwest to the Folly River shoreline. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the southwestern side of Lighthouse Inlet's navigable channel and the Folly Beach side of the Folly River Inlet's navigable channel between Folly Beach and Bird Key. Lands within this unit are entirely in private/other land ownership within the city limits of the municipality of the City of Folly Beach.

(ii) Map of Unit SC–14 follows:

Figure 54 to Rufa Red Knot paragraph (63)(ii)



(64) Unit SC–15: Bird Key Stono, South Carolina.

(i) Unit SC–15 consists of approximately 294 ac (119 ha) of occupied habitat across the entirety of Bird Key Stono Heritage Preserve, an island in the mouth of the Stono Inlet in Charleston County. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the southwestern side of the Folly River Inlet. Lands within this unit are entirely in State ownership (managed as a State Seabird Sanctuary).

(ii) Map of Unit SC–15 is presented at paragraph (63)(ii) of this entry.

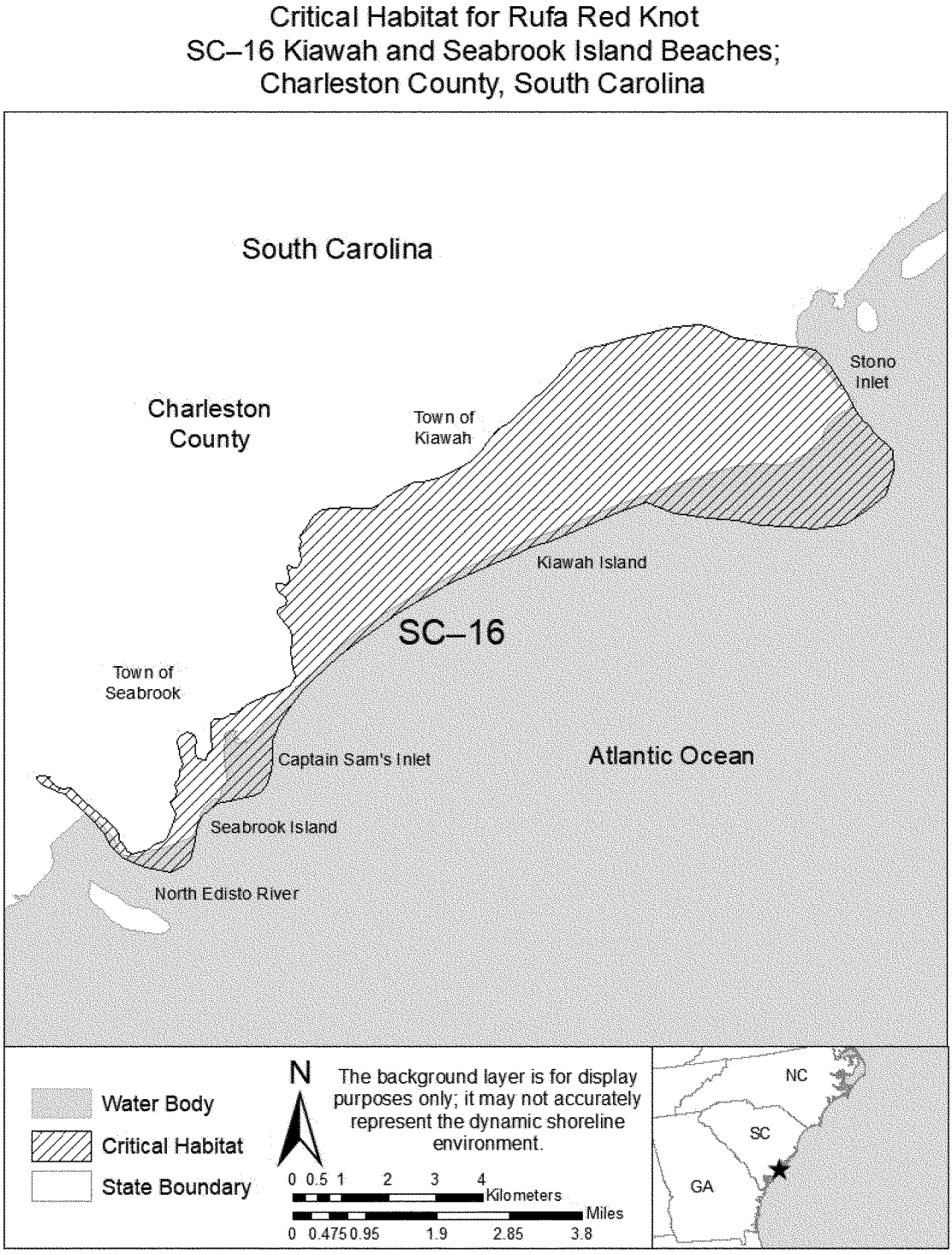
(65) Unit SC–16: Kiawah and Seabrook Island Beaches, South Carolina.

(i) Unit SC–16 consists of approximately 11,250 ac (4,553 ha) of occupied habitat across the entirety of Kiawah Island and a portion of Seabrook Island, which are barrier islands off the coast of Charleston

County. The unit boundary begins on the Stono Inlet shoreline of Kiawah Island and extends southwest to the tip of the Seabrook Island shoreline in the North Edisto River. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the western side of the Stono Inlet and all of Captain Sam's Inlet. Lands within this unit include approximately 1,399 ac (566 ha) in State ownership and 9,850 ac (3,986 ha) in private/other ownership within the Town limits of the Town of Kiawah Island and the Town of Seabrook Island.

(ii) Map of Unit SC–16 follows:

Figure 55 to Rufa Red Knot paragraph (65)(ii)

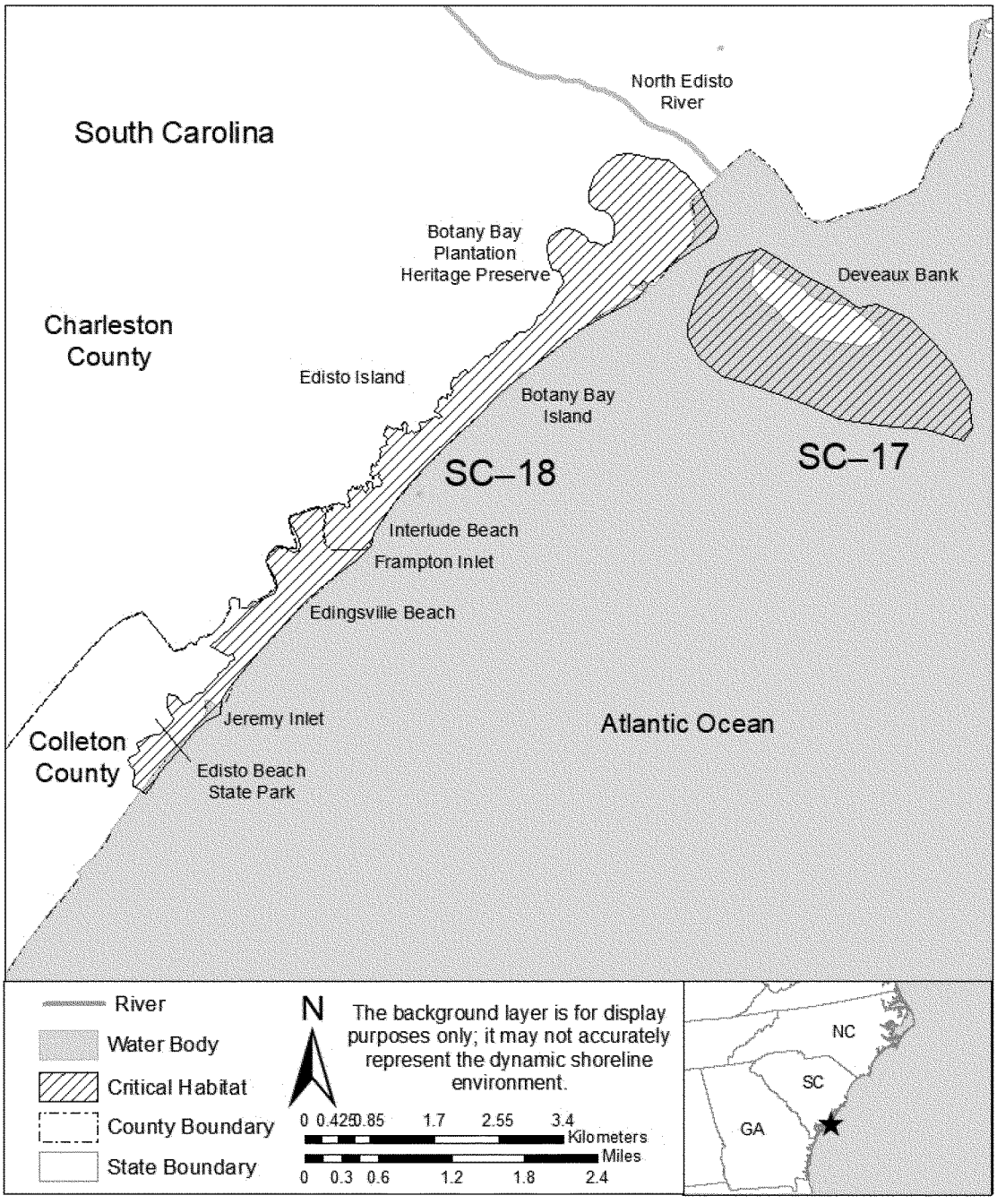


(66) Unit SC–17: Deveaux Bank, South Carolina.

(i) Unit SC–17 consists of approximately 1,328 ac (538 ha) of occupied habitat across the entirety of Deveaux Bank, an island in the mouth of the North Edisto River in Charleston County. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the mouth of the North Edisto River. Lands within this unit are entirely in State ownership (managed as a Seabird Sanctuary).

(ii) Map of Unit SC–17 follows:

Figure 56 to Rufa Red Knot paragraph (66)(ii)



(67) Unit SC–18: Edisto Island Beaches, South Carolina.

(i) Unit SC–18 consists of approximately 1,743 ac (705 ha) of occupied beach habitat on Edisto Island, a barrier island off the coast of Charleston and Colleton Counties. The unit includes all of Botany Bay Island, Botany Bay Plantation, Interlude Beach, and Edingsville Beach, and a portion of Edisto Beach State Park. The unit boundary begins on the North Edisto River shoreline of Botany Bay Island and extends southwest to the undeveloped eastern half of the beachfront portion of Edisto Beach State Park southwest of Jeremy Inlet. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with Frampton and Jeremy Inlets and the unnamed inlet separating Interlude Beach and Botany Bay Plantation. Lands within this unit include approximately 650 ac (263 ha) in State ownership (including Edisto Beach State Park and Botany Bay Heritage Preserve/Wildlife Management Area) and 1,093 ac (442 ha) in private/other ownership.

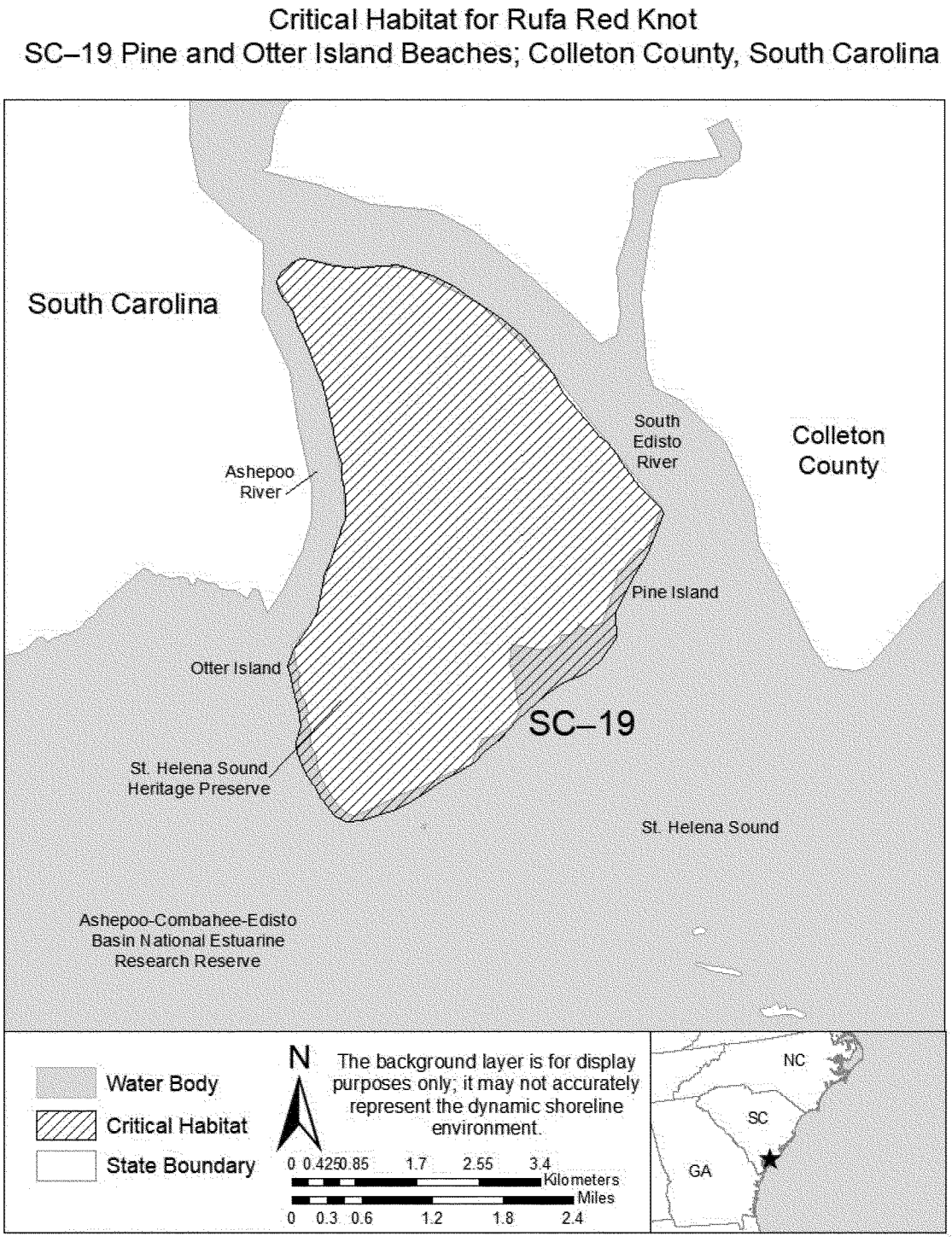
(ii) Map of Unit SC–18 is presented at paragraph (66)(ii) of this entry.

(68) Unit SC–19: Pine and Otter Island Beaches, South Carolina.

(i) Unit SC–19 consists of approximately 6,302 ac (2,550 ha) of occupied habitat across the entirety of Pine and Otter Islands, both of which are sea islands in St. Helena Sound in Colleton County. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with Fish Creek Inlet. Lands within this unit include approximately 6,296 ac (2,548 ha) in State ownership (including the Ashepoo-Combahee-Edisto Basin Preserve/Wildlife Management Area and the St. Helena Sound Heritage Preserve/Wildlife Management Area) and 6 ac (2 ha) in private/other ownership.

(ii) Map of Unit SC–19 follows:

Figure 57 to Rufa Red Knot paragraph (68)(ii)



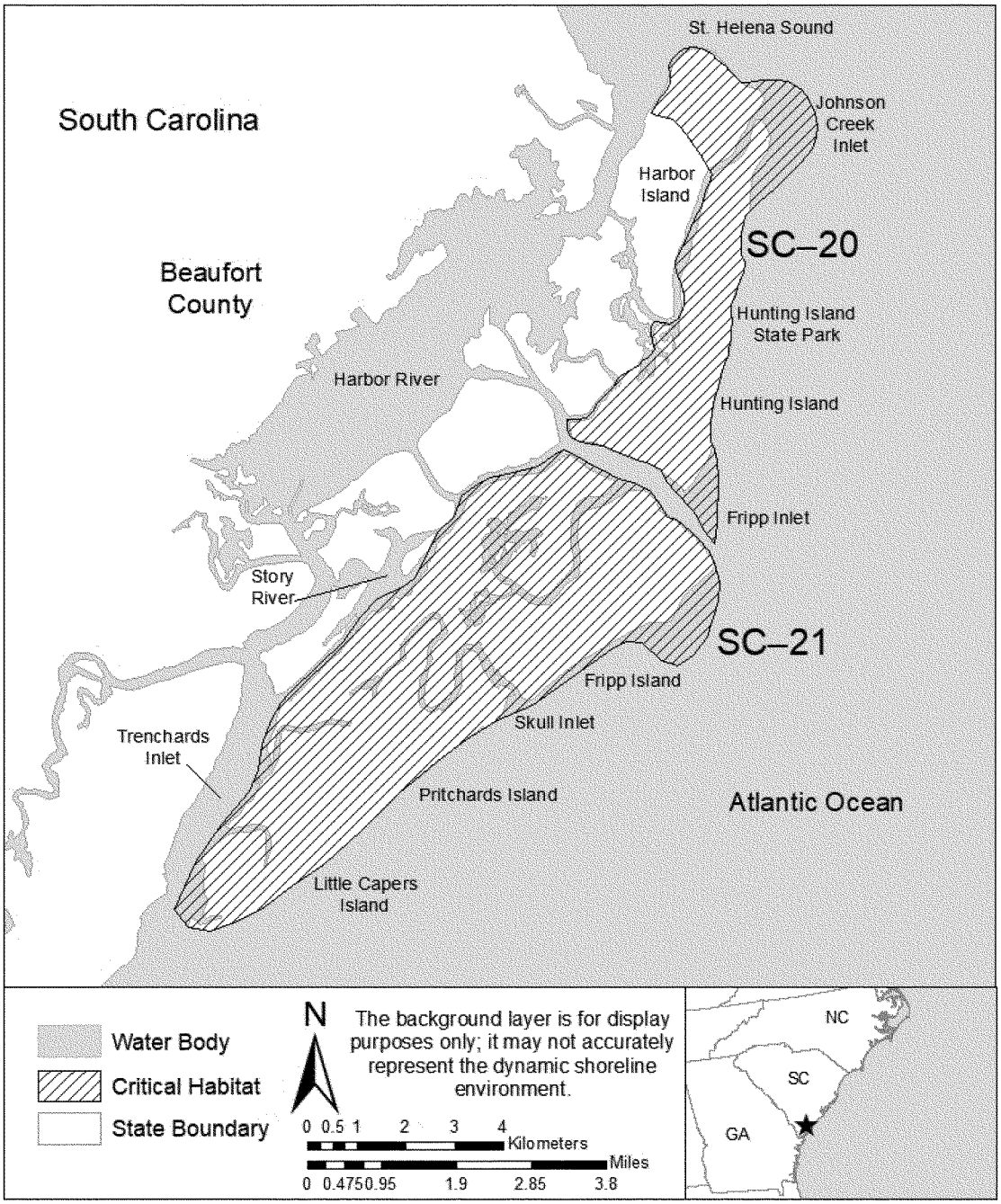
(69) Unit SC–20: Harbor and Hunting Island Beaches, South Carolina.

(i) Unit SC–20 consists of approximately 4,066 ac (1,645 ha) of occupied habitat on Harbor and Hunting Islands, both of which are barrier islands off the coast of Beaufort County. The unit boundary begins on the Harbor River shoreline of Harbor Island and extends southwest to the Fripp Inlet shoreline of Hunting Island. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with Johnson Creek Inlet. Lands within this unit include approximately 3,246 ac (1,313 ha) in State ownership (including Hunting Island State Park) and 820 ac (331 ha) in private/other ownership.

(ii) Map of Unit SC–20 follows:

Figure 58 to Rufa Red Knot paragraph (69)(ii)

Critical Habitat for Rufa Red Knot
SC–20 Harbor and Hunting Island Beaches and SC–21 Fripp, Pritchards and Little Capers Islands' Beaches; Beaufort County, South Carolina



(70) Unit SC–21: Fripp, Pritchards, and Little Capers Islands' Beaches, South Carolina.

(i) Unit SC–21 consists of approximately 10,178 ac (4,119 ha) of occupied habitat on Fripp Island, Pritchards Island, and Little Capers Island, barrier islands off the coast in Beaufort County. The unit boundary begins on the shoreline of Fripp Island on the south side of Fripp Inlet and extends southwest along the Atlantic Ocean shorelines of Fripp Island, Pritchards Island, and Little Capers Island to the eastern side of Trenchards Inlet where the boundary follows the southern shoreline of the Story River. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with Fripp, Skull, and Trenchards Inlets as well as the unnamed inlets along the Little Capers Island shoreline. Lands within this unit include approximately 4,055 ac (1,641

ha) in State ownership and 6,123 ac (2,478 ha) in private/other ownership.

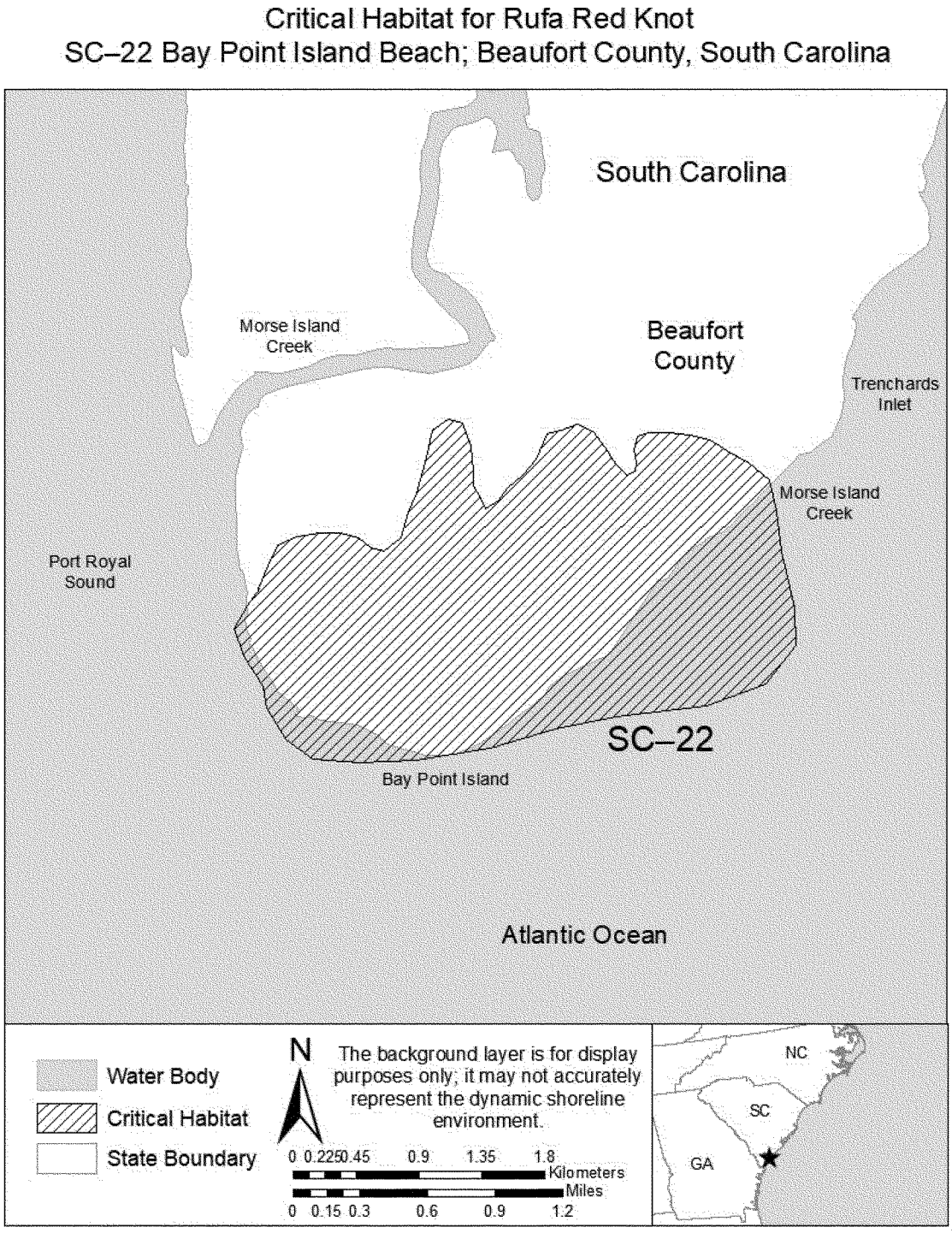
(ii) Map of Unit SC–21 is presented at paragraph (69)(ii) of this entry.

(71) Unit SC–22: Bay Point Island Beach, South Carolina.

(i) Unit SC–22 consists of approximately 1,698 ac (687 ha) of occupied habitat on Bay Point Island, a barrier island off the coast in Beaufort County. The unit boundary begins on the Trenchards Inlet shoreline at the entrance to Morse Island Creek and follows the Atlantic Ocean shoreline to the eastern shoreline of Port Royal Round to the western entrance to Morse Island Creek. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with Morse Creek and Trenchards Inlet within the unit boundary. Lands within this unit include approximately 553 ac (224 ha) in State ownership and 1,145 ac (464 ha) in private/other ownership.

(ii) Map of Unit SC–22 follows:

Figure 59 to Rufa Red Knot paragraph (71)(ii)

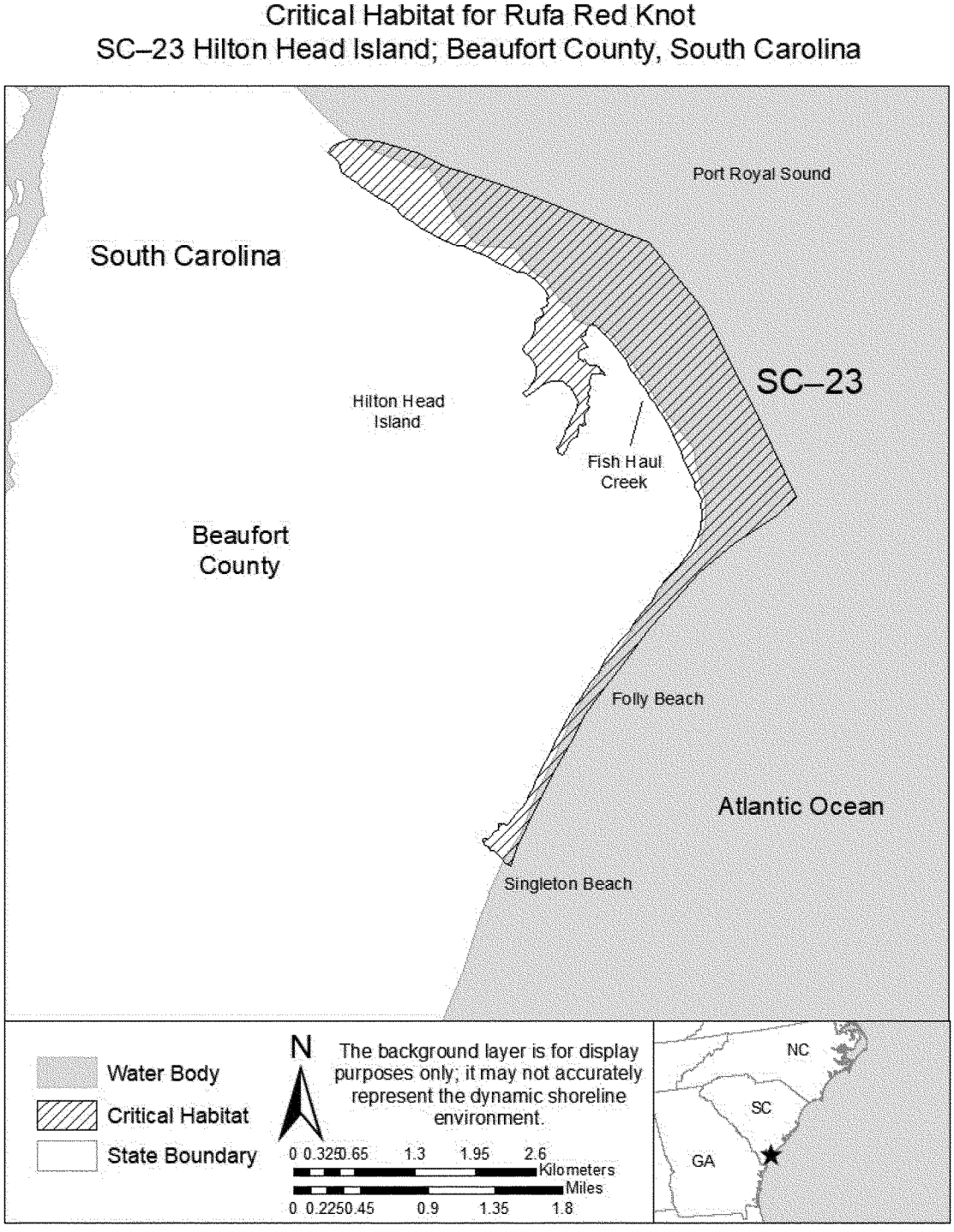


(72) Unit SC–23: Hilton Head Island Beach, South Carolina.

(i) Unit SC–23 consists of approximately 1,682 ac (681 ha) of occupied habitat on the heel of Hilton Head Island, a barrier island off the coast, in Beaufort County. The unit boundary begins on the Port Royal Sound shoreline beginning at Oyster Shell Lane, continues southeast then turns southwest along the Atlantic Ocean shoreline, and continues to the undeveloped portion of Singleton Beach southwest of the Folly Beach. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with Fish Haul Creek and unnamed inlets within the unit boundary. Lands within this unit include approximately 1,015 ac (411 ha) in State ownership and 667 ac (270 ha) in private/other ownership.

(ii) Map of Unit SC–23 follows:

Figure 60 to Rufa Red Knot paragraph (72)(ii)

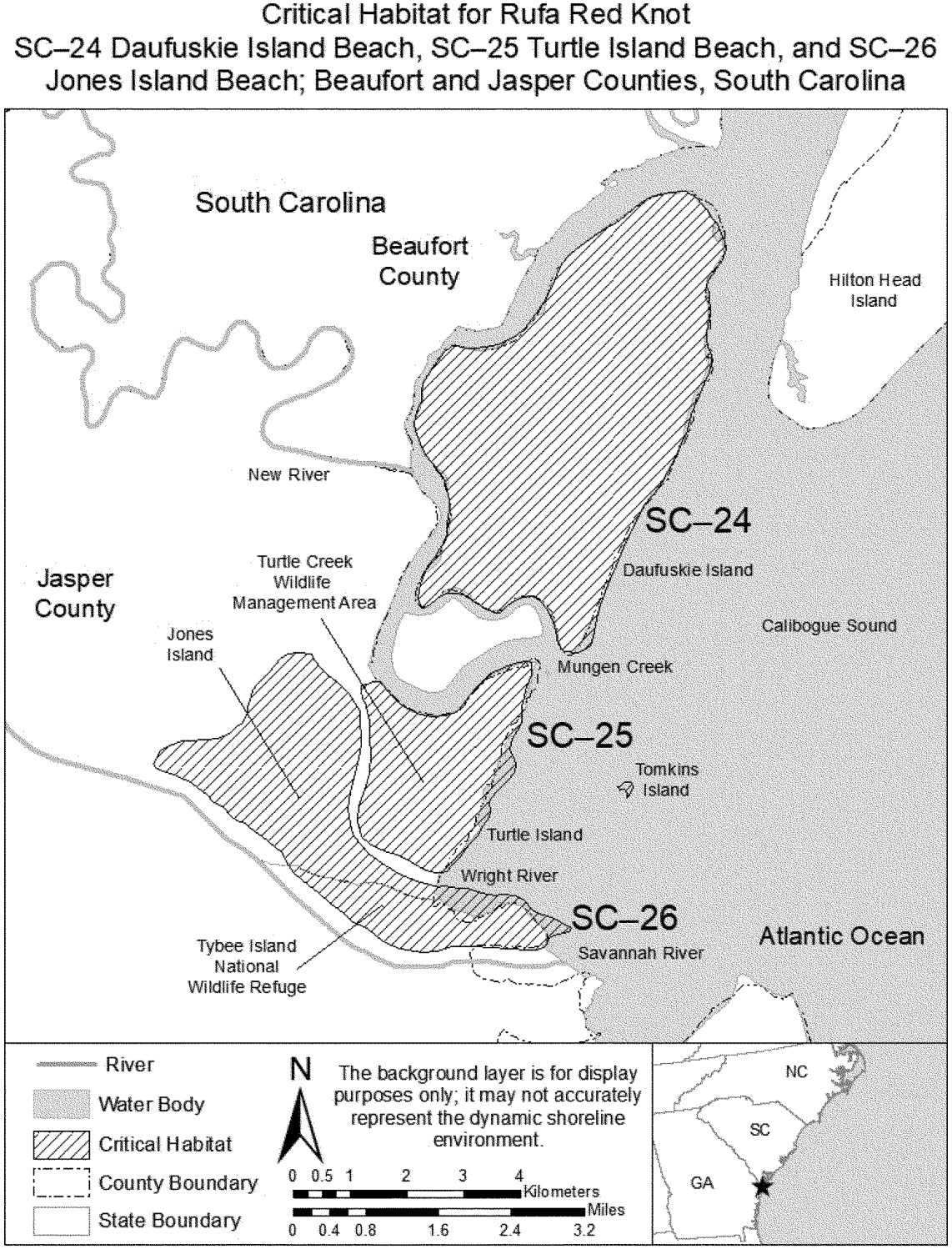


(73) Unit SC–24: Daufuskie Island Beach, South Carolina.

(i) Unit SC–24 consists of approximately 6,370 ac (2,578 ha) of occupied habitat across the entirety of Daufuskie Island, a sea island in Calibogue Sound, in Beaufort County. The unit boundary begins on the Calibogue Sound shoreline of Daufuskie Island and extends southwest to the Mungen Creek shoreline. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the unit boundary. All lands within this unit are in private/other ownership.

(ii) Map of Unit SC–24 follows:

Figure 61 to Rufa Red Knot paragraph (73)(ii)



(74) Unit SC–25: Turtle Island and Tomkins Island Beaches, South Carolina.

(i) Unit SC–25 consists of approximately 1,771 ac (717 ha) on Turtle Island (a sea island), and Tompkins Island (a human-made island) in Calibogue Sound in Jasper County. The unit boundary begins on the southern shoreline of the New River and extends southwest along the Calibogue Sound shoreline to the Wright River shoreline of Turtle Island. The unit boundary also includes the entire Calibogue Sound shoreline of Tompkins Island located east of Turtle Island. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the unnamed inlet in the center of the Turtle Island shoreline. Lands within this unit are entirely in State ownership as the South Carolina Department of Natural Resources (SCDNR) Turtle Island Wildlife Management Area and an SCDNR seabird sanctuary.

(ii) Map of Unit SC–25 is presented at paragraph (73)(ii) of this entry.

(75) Unit SC–26: Jones Island Beach, South Carolina.

(i) Unit SC–26 consists of approximately 3,025 ac (1,225 ha) of occupied habitat across the entirety of Jones Island, a sea island along the Savannah River and Calibogue Sound, in Jasper County. The unit boundary begins on the Wright River shoreline of Jones Island to the Savannah River shoreline. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with Wright River Inlet. Lands within this unit include approximately 785 ac (318 ha) in Federal ownership (Tybee Island NWR) and 2,240 ac (907 ha; 74 percent) in State ownership.

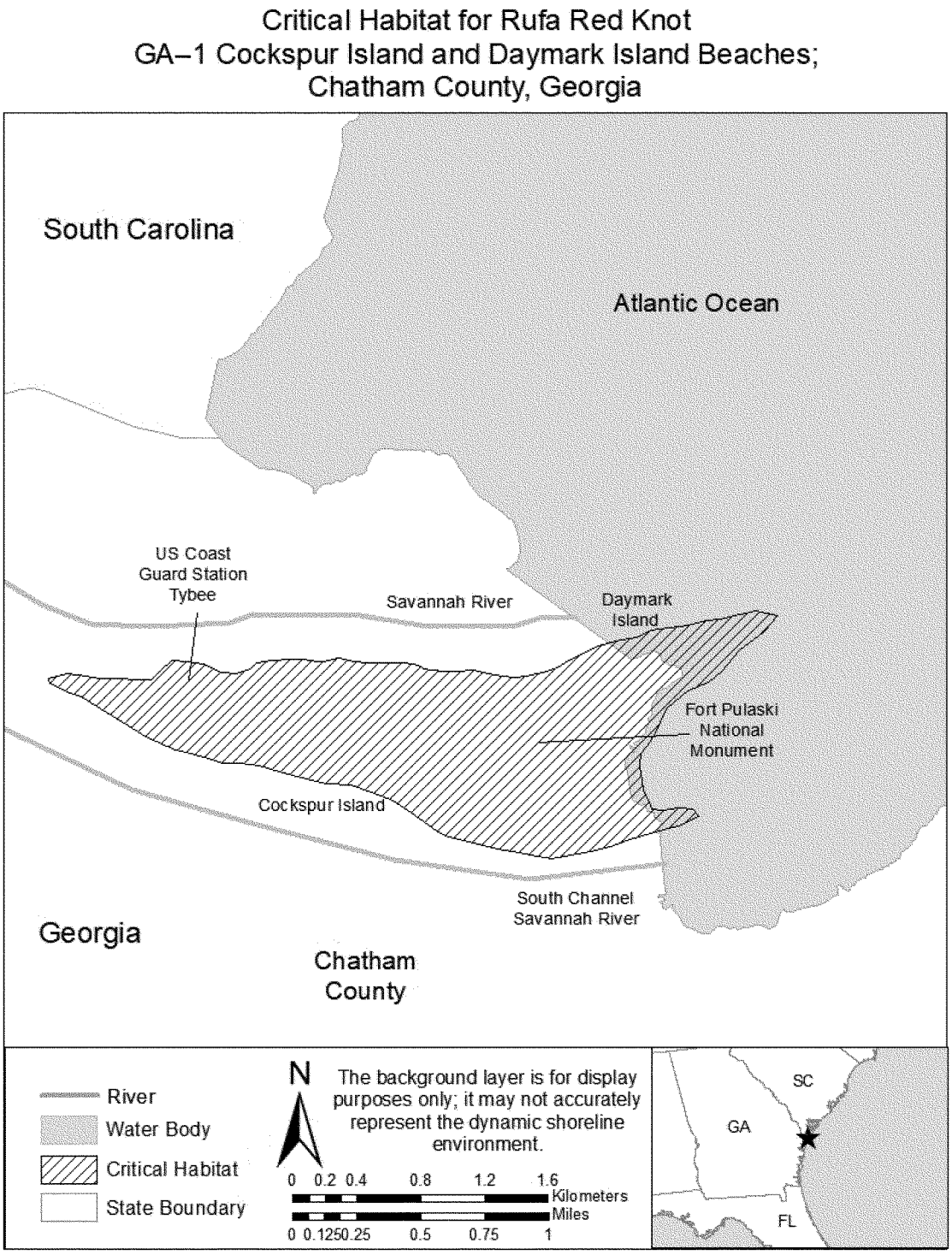
(ii) Map of Unit SC–26 is presented at paragraph (73)(ii) of this entry.

(76) Unit GA–1: Cockspur Island and Daymark Island Beaches, Georgia.

(i) Unit GA–1 consists of approximately 802 ac (325 ha) of occupied habitat on Cockspur and Daymark Islands in the mouth of the Savannah River in Chatham County. The unit boundary includes the entire Savannah River and South Channel of the Savannah River shorelines of Cockspur and Daymark Islands and includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and sandy intertidal zone that is covered at high tide and uncovered at low tide). Lands within this unit include approximately 708 ac (287) in Federal ownership as part of the U.S. Coast Guard's Station Tybee and NPS's Fort Pulaski National Monument, and 94 ac (38) in State ownership.

(ii) Map of Unit GA–1 follows:

Figure 62 to Rufa Red Knot paragraph (76)(ii)

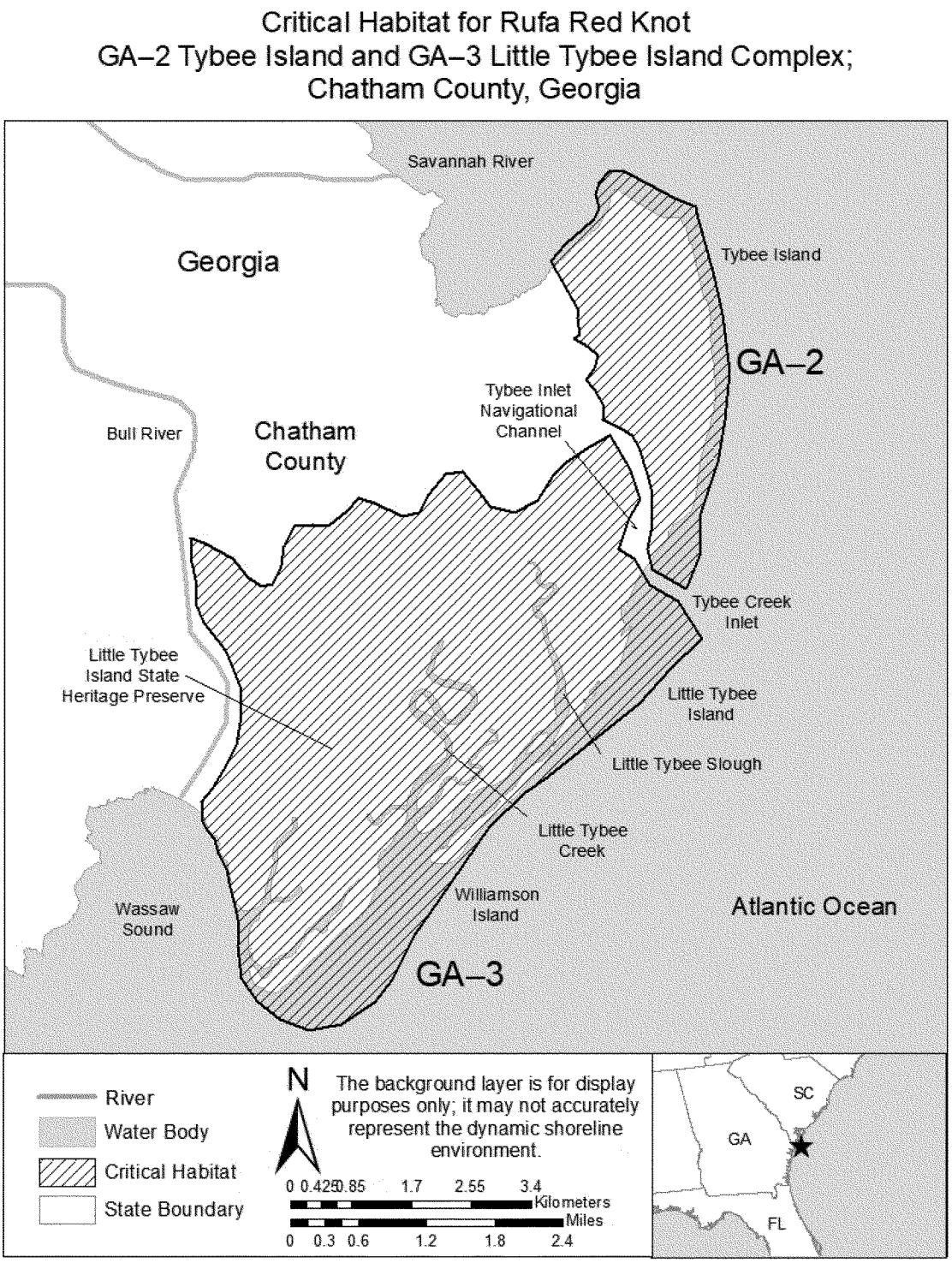


(77) Unit GA–2: Tybee Island Beach, Georgia.

(i) Unit GA–2 consists of approximately 2,046 ac (828 ha) of occupied habitat on Tybee Island (north, mid, and south beaches), a barrier island off the coast in Chatham County. The northern boundary of the unit begins at the Savannah River shoreline of Tybee Island and extends south to Tybee Creek Inlet, which separates Tybee Island from Little Tybee Island, and includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and sandy intertidal zone that is covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the eastern side of Tybee Inlet's navigable channel. Lands within this unit include approximately 6 ac (2 ha) in State ownership, 1,721 ac (697 ha) in private/other ownership, and 319 ac (129 ha) that are uncategorized.

(ii) Map of Unit GA–2 follows:

Figure 63 to Rufa Red Knot paragraph (77)(ii)



(78) Unit GA–3: Little Tybee Island Complex, Georgia.

(i) Unit GA–3 consists of approximately 8,265 ac (3,345 ha) of occupied habitat across the entirety of Little Tybee Island complex, a series of barrier islands off the coast of Chatham County. The unit boundary begins on the western side of Tybee Creek Inlet and extends southwest to Wassaw Sound and includes Little Tybee Island, Williamson Island, and all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the western side of Tybee Inlet's navigable channel, Little Tybee Slough, and Little Tybee Creek. All lands within this unit are in State ownership (Little Tybee Island State Heritage Preserve).

(ii) Map of Unit GA–3 is presented at paragraph (77)(ii) of this entry.

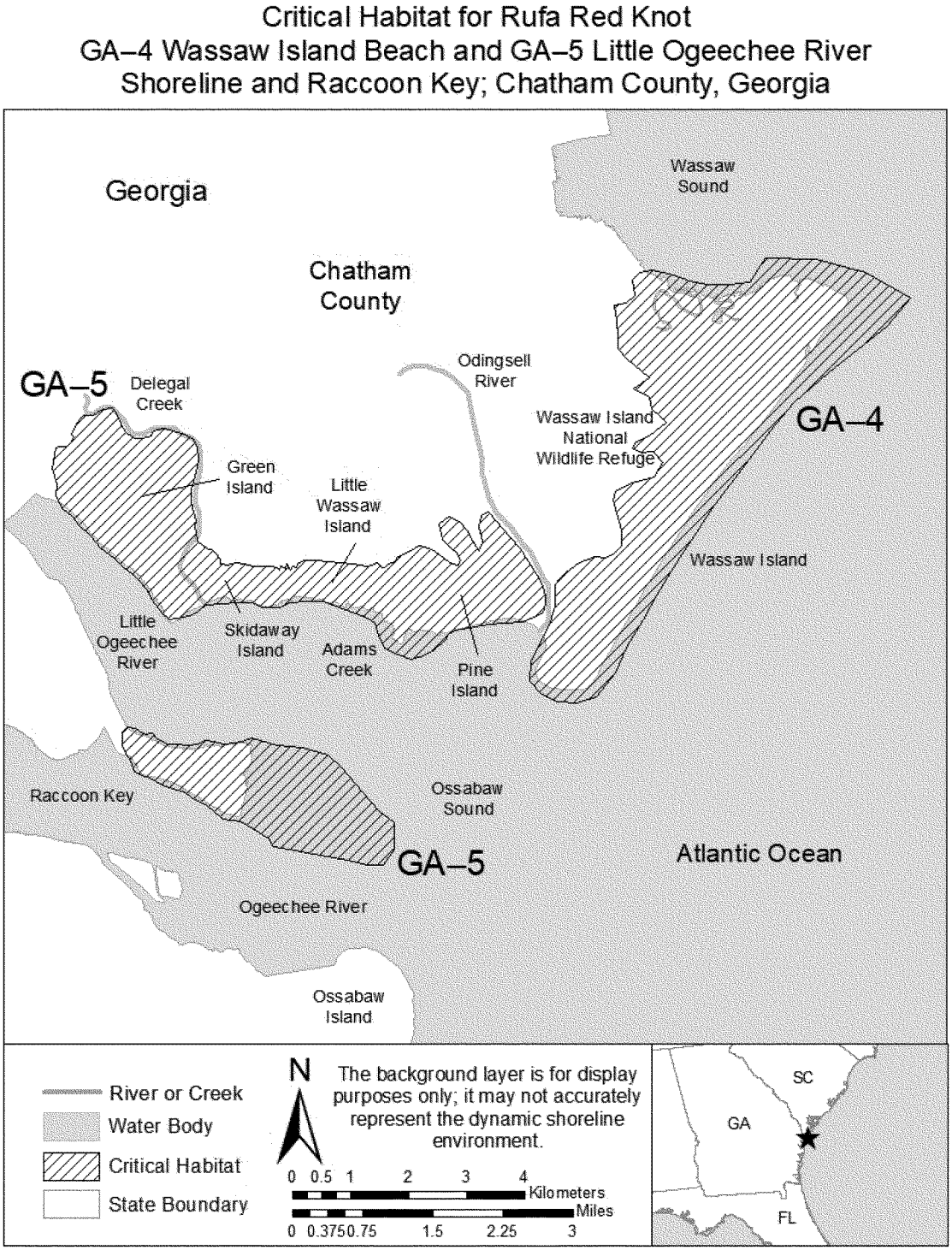
(79) Unit GA–4: Wassaw Island Beach, Georgia.

(i) Unit GA–4 consists of approximately 4,296 ac (1,738 ha) of

occupied habitat on Wassaw Island, a barrier island off the coast in Chatham County. The unit boundary begins on the southwestern side of Wassaw Sound off the northern tip of Wassaw Island and extends southwest to Ossabaw Sound shoreline. The unit includes all emergent land from MLLW (which includes the highly dynamic shoreline and sandy intertidal zone that is covered at high tide and uncovered at low tide) to the toe of the dunes or where densely vegetated habitat, not used by the rufa red knot, begins. This unit also includes the ephemeral, emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the southwestern side of Wassaw Sound off the northern tip of Wassaw Island. Lands within this unit include approximately 3,001 ac (1,215 ha) in Federal ownership (Wassaw Island NWR), 274 ac (111 ha) in private/other ownership, and 1,020 ac (412 ha) that are uncategorized.

(ii) Map of Unit GA–4 follows:

Figure 64 to Rufa Red Knot paragraph (79)(ii)



(80) Unit GA–5: Little Ogeechee River Shoreline and Raccoon Key, Georgia.

(i) Unit GA–5 consists of approximately 4,571 ac (1,850 ha) of occupied habitat of the Little Ogeechee River shoreline along Green Island, Little Wassaw Island, and Pine Island and all of Raccoon Key in Ossabaw Sound in Chatham County. The unit boundary begins at the Green Island shoreline of the Little Ogeechee River and continues east along the shorelines of Little Wassaw Island and Pine Island to the Odingsell River entrance behind Wassaw Island. The boundary continues north along the Pine Island and Little Wassaw Island shoreline of the Odingsell River and follows the Little Wassaw Island shoreline along Adams Creek through marshlands south of Skidaway Island to Delegal Creek behind Green Island. The unit includes all emergent land from MLLW to where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the Ossabaw entrance. Lands within this unit include approximately 3,136 ac (1,267 ha) in Federal ownership and 1,435 ac (581 ha) in State ownership.

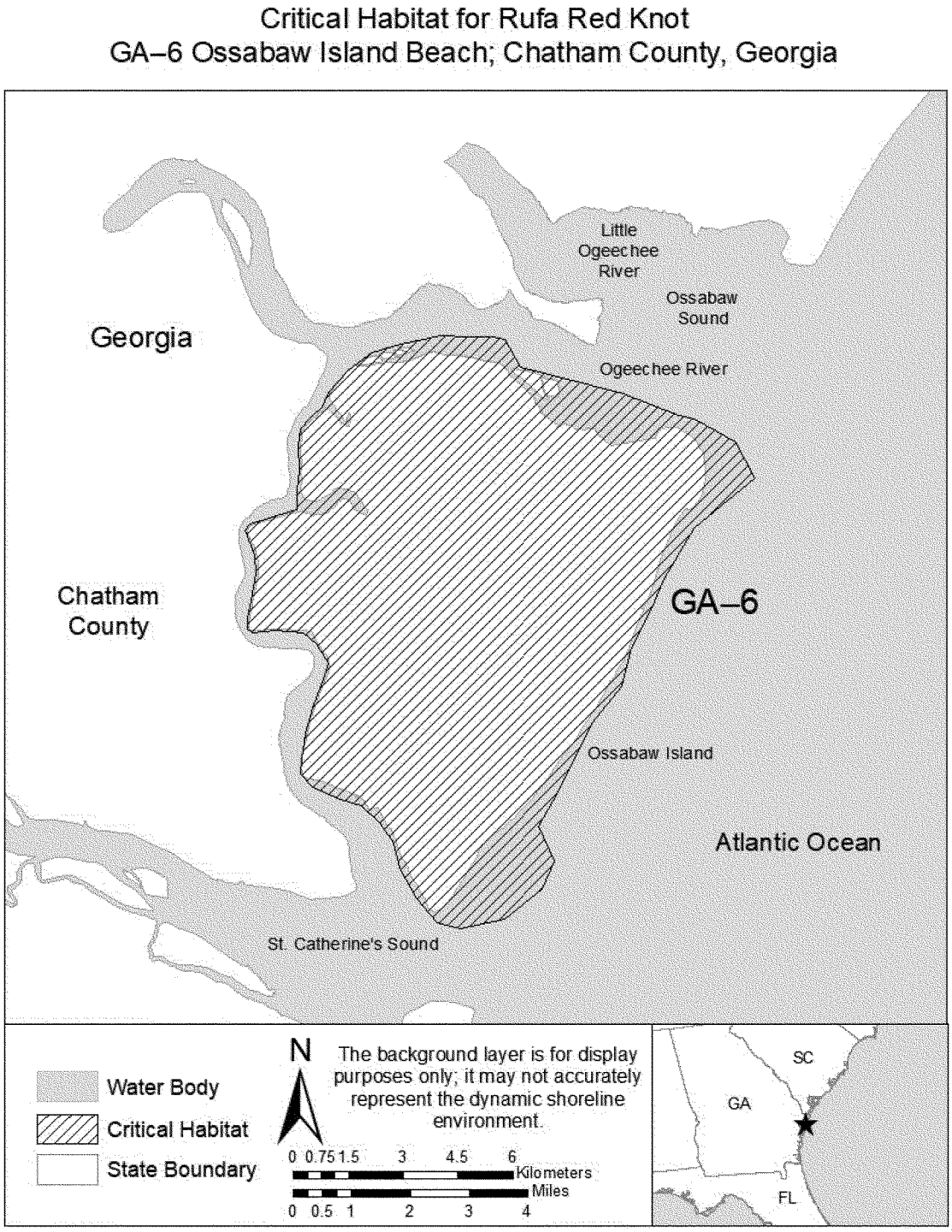
(ii) Map of Unit GA–5 is presented at paragraph (79)(ii) of this entry.

(81) Unit GA–6: Ossabaw Island Beach, Georgia.

(i) Unit GA–6 consists of approximately 32,357 ac (13,095 ha) of occupied habitat on Ossabaw Island, a barrier island off the coast in Chatham County. The unit boundary begins at the Ogeechee River shoreline of Ossabaw Island and extends southwest to the St. Catherine's Sound shoreline. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with Ossabaw Sound off the northeastern tip of the island and St. Catherine's Sound off the southwestern tip of the island. Lands within this unit include approximately 28,621 ac (11,582 ha) in State ownership and 3,736 ac (1,512 ha) that are uncategorized.

(ii) Map of Unit GA–6 follows:

Figure 65 to Rufa Red Knot paragraph (81)(ii)

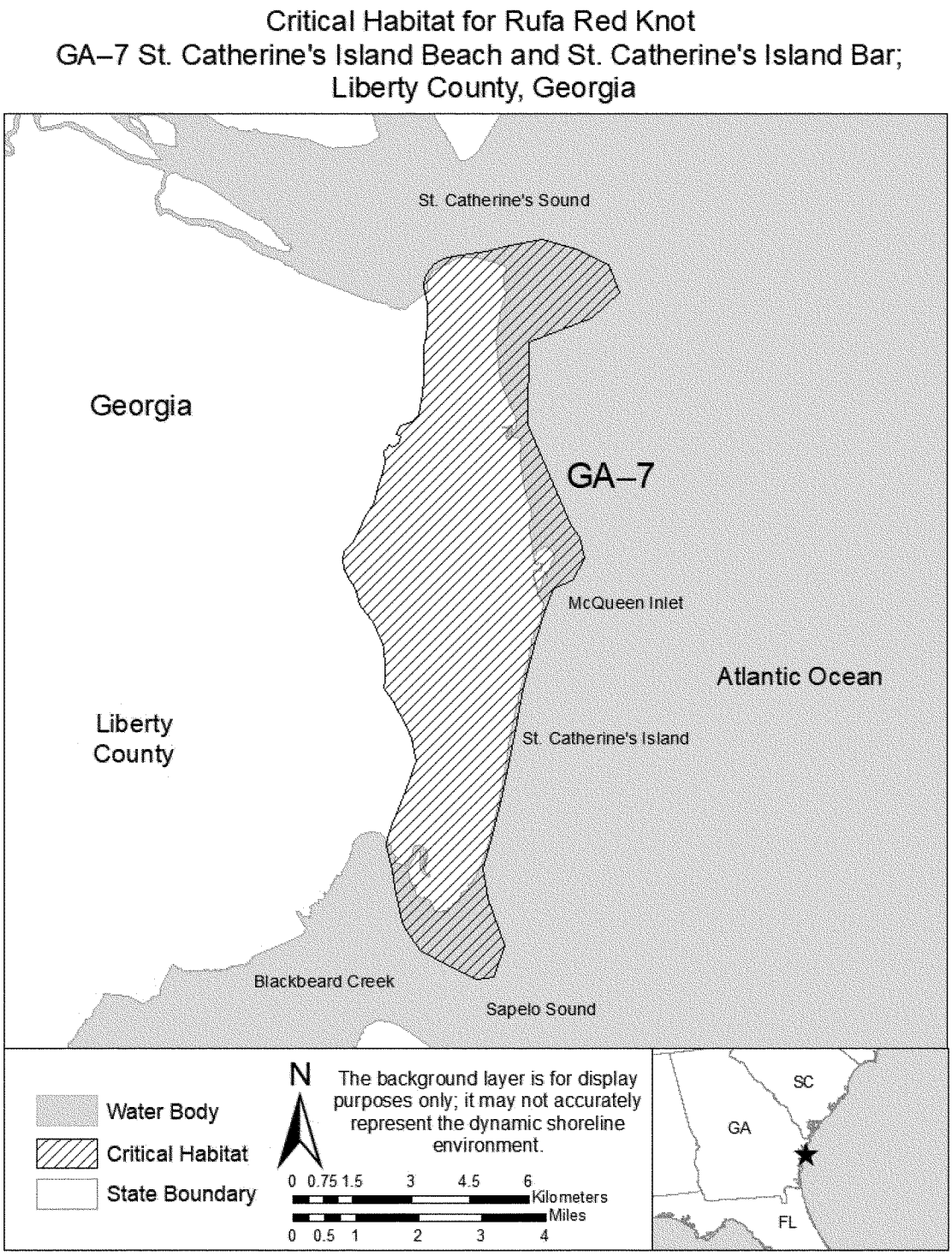


(82) Unit GA–7: St. Catherine's Island Beach and St. Catherine's Island Bar, Georgia.

(i) Unit GA–7 consists of approximately 15,962 ac (6,460 ha) of occupied habitat on St. Catherine's Island, a barrier island off the coast in Liberty County. The unit boundary begins at the St. Catherine's Sound shoreline of St. Catherine's Island and extends southwest to the Sapelo Sound shoreline. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with St. Catherine's Sound entrance off the northern tip of the island, McQueen Inlet, and Sapelo Sound entrance off the southern tip of the island. Lands within this unit include approximately 2,106 ac (853 ha) in State ownership, 11,810 ac (4,779 ha) in private/other ownership, and 2,046 ac (828 ha) that are uncategorized.

(ii) Map of Unit GA–7 follows:

Figure 66 to Rufa Red Knot paragraph (82)(ii)

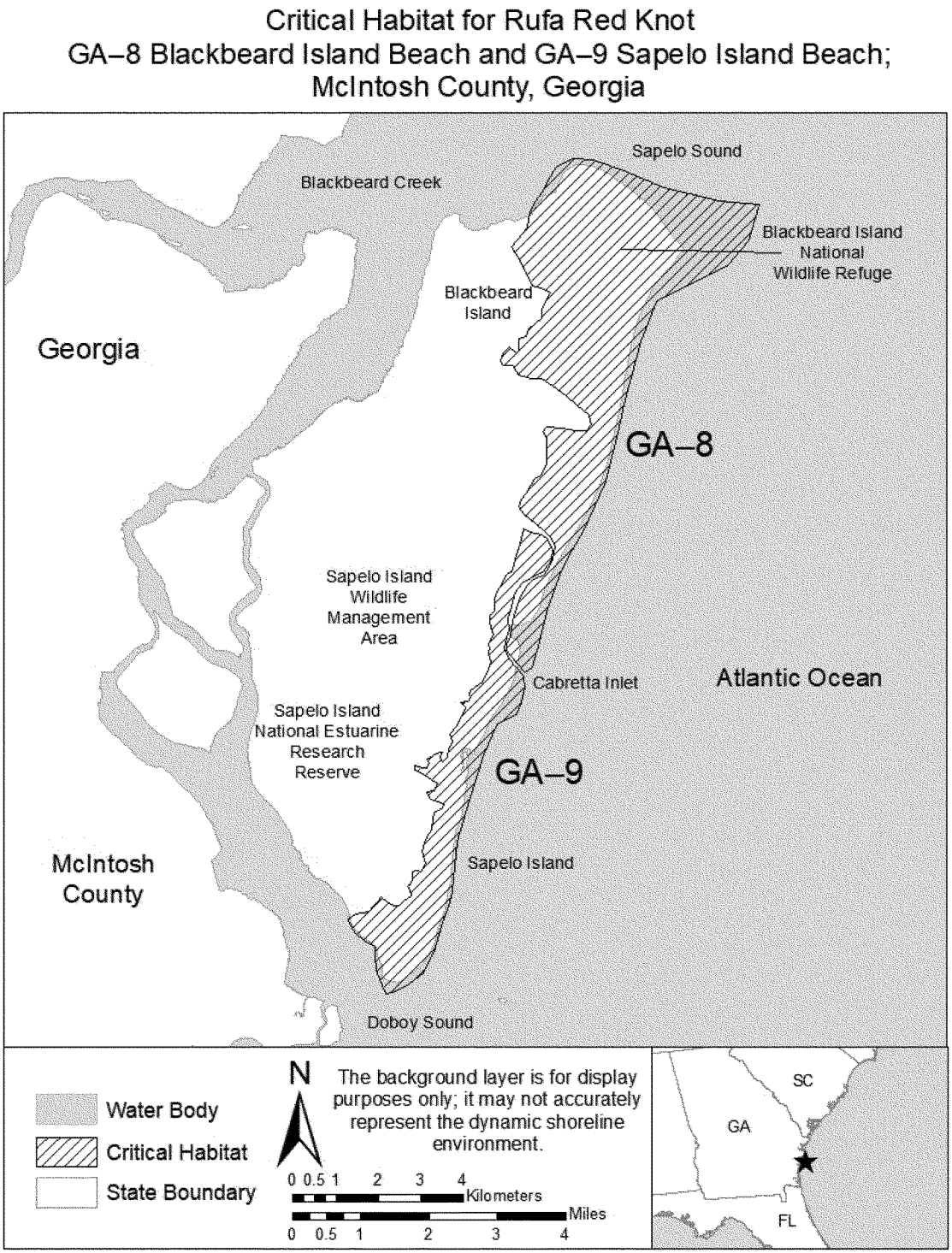


(83) Unit GA–8: Blackbeard Island Beach, Georgia.

(i) Unit GA–8 consists of approximately 6,321 ac (2,557 ha) of occupied habitat on Blackbeard Island, a barrier island off the coast in McIntosh County. The unit boundary begins at the Sapelo Sound shoreline of Blackbeard Island and extends southwest to the Cabretta Inlet shoreline. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the Sapelo Sound entrance off the northern tip of the island and the northeastern side of Cabretta Inlet's navigable channel. Lands within this unit include approximately 4,954 ac (2,006 ha) in Federal ownership (Blackbeard Island NWR), 80 ac (32 ha) in State ownership, and 1,287 ac (519 ha) that are uncategorized.

(ii) Map of Unit GA–8 follows:

Figure 67 to Rufa Red Knot paragraph (83)(ii)



(84) Unit GA–9: Sapelo Island Beach, Georgia.

(i) Unit GA–9 consists of approximately 2,481 ac (1,004 ha) of occupied habitat on Sapelo Island, a barrier island off the coast in McIntosh County. The unit boundary begins at the Cabretta Inlet shoreline of Sapelo Island and extends southwest to the Doboy Sound shoreline. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the southwestern side of Cabretta Inlet's navigable channel. The lands within this unit are State-owned and comprise the Sapelo Island Wildlife Management Area and Sapelo Island National Estuarine Research Reserve (NERR).

(ii) Map of Unit GA–9 is presented at paragraph (83)(ii) of this entry.

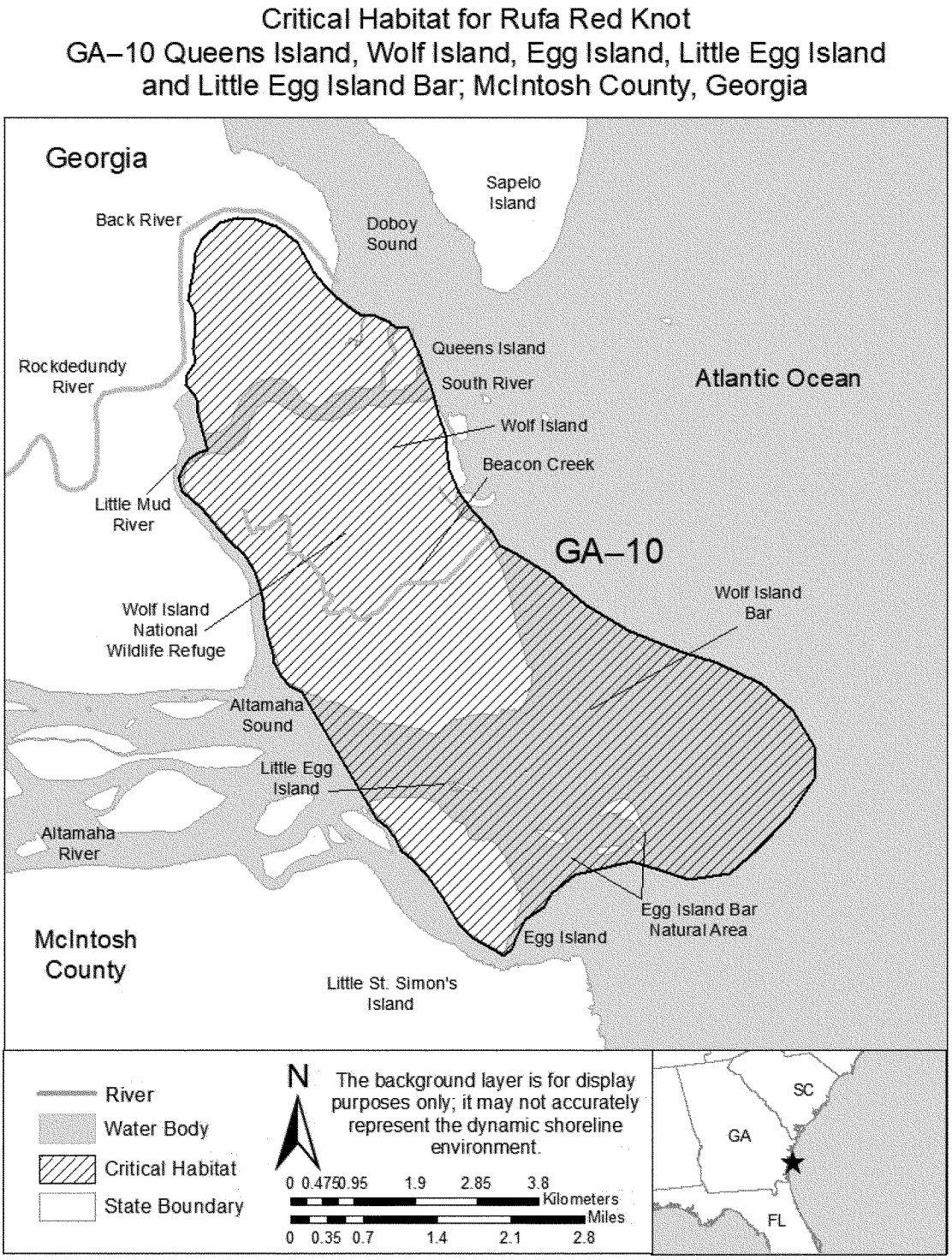
(85) Unit GA–10: Queens Island, Wolf Island, Egg Island, Little Egg Island, and Little Egg Island Bar, Georgia.

(i) Unit GA–10 consists of approximately 11,901 ac (4,816 ha) of

occupied habitat on Queens Island, Wolf Island, Egg Island, Little Egg Island, and Little Egg Island Bar at the Altamaha Sound in McIntosh County. The unit boundary begins at the Black River shoreline of Queens Island and extends south along the Wolf Island shoreline, which includes Wolf Island Bar, to the eastern and southern shorelines of Little Egg Island Bar Natural Area southwest to Egg Island in the Altamaha Sound. The boundary continues northwest along the Altamaha River shoreline of Egg Island and north along the Little Mud River shoreline of Wolf Island and Rockdedundy River shoreline of Queens Island. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the entrance to Altamaha Sound and Beacon Creek. Lands within this unit include approximately 5,527 ac (2,237 ha) in Federal ownership (Wolf Island NWR, which is also a designated wilderness area), 261 ac (106 ha) in State ownership, 1,865 ac (755 ha) in private/other ownership, and 4,248 ac (1,719 ha) that are uncategorized.

(ii) Map of Unit GA–10 follows:

Figure 68 to Rufa Red Knot paragraph (85)(ii)

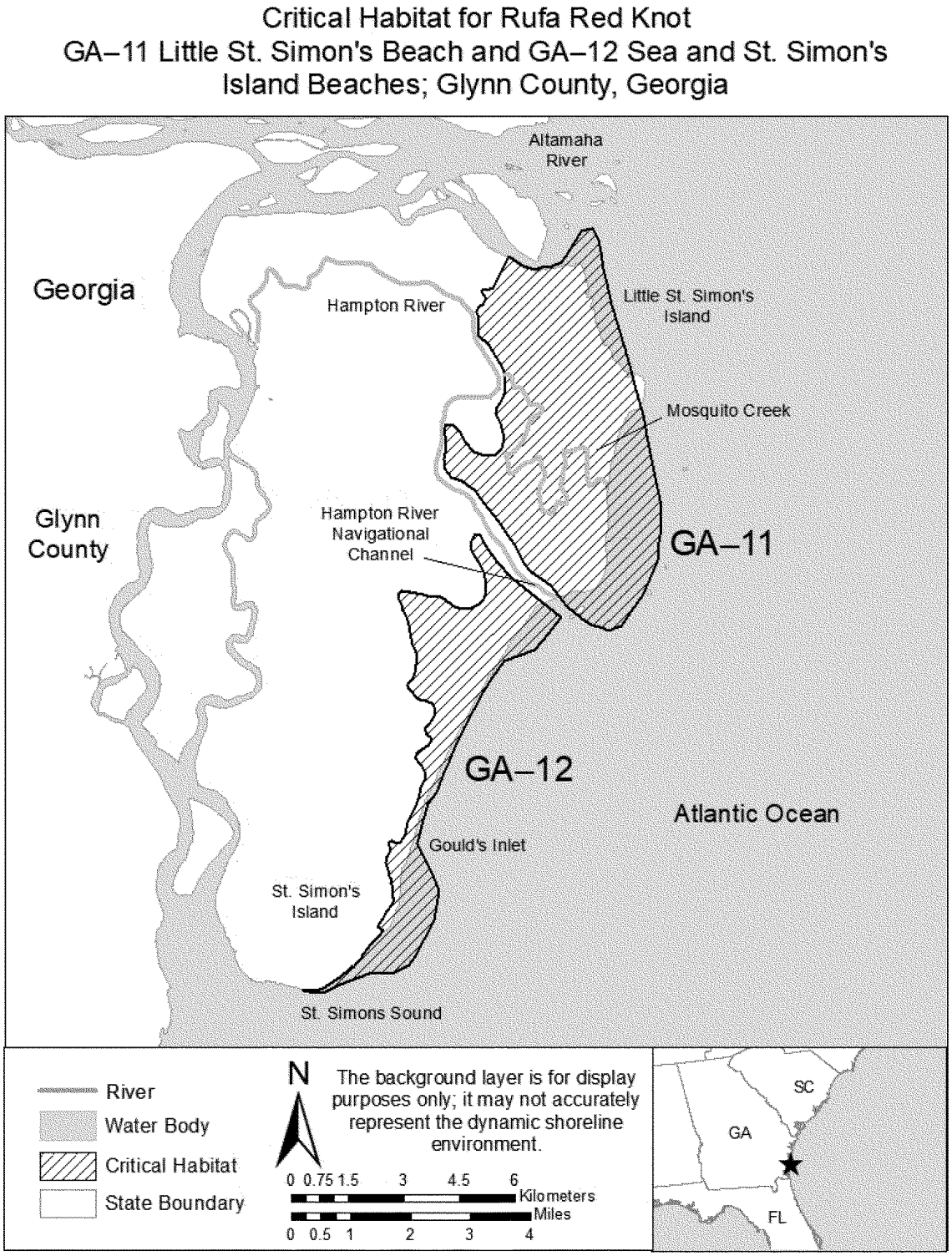


(86) Unit GA–11: Little St. Simon's Island Beach, Georgia.

(i) Unit GA–11 consists of approximately 9,053 ac (3,664 ha) of occupied habitat on Little St. Simon's Island off the coast of Glynn County. The unit boundary begins at the Altamaha Sound shoreline of Little St. Simon's Island and extends south to the Hampton River shoreline. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the Altamaha Sound off the northeastern tip of the island, Mosquito Creek, and the northern side of Hampton River Inlet's navigable channel. Lands within this unit include approximately 113 ac (46 ha) in State ownership, 7,462 ac (3,022 ha) in private/other ownership (TNC-owned preserve lands), and 1,479 ac (596 ha) that are uncategorized.

(ii) Map of Unit GA–11 follows:

Figure 69 to Rufa Red Knot paragraph (86)(ii)



(87) Unit GA–12: Sea and St. Simon's Island Beaches, Georgia.

(i) Unit GA–12 consists of approximately 4,033 ac (1,631 ha) of occupied habitat across the entirety of Sea Island and a portion of St. Simon's Island, both of which are barrier islands off the coast of Glynn County. The unit boundary begins at the Hampton River shoreline of Sea Island and extends southwest to the St. Simon's Sound shoreline of St. Simon's Island. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and

uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with Gould's Inlet. Lands within this unit include approximately 4 ac (2 ha) in State ownership, 3,448 ac (1,395 ha) in private/other ownership, and 581 ac (235 ha) that are uncategorized.

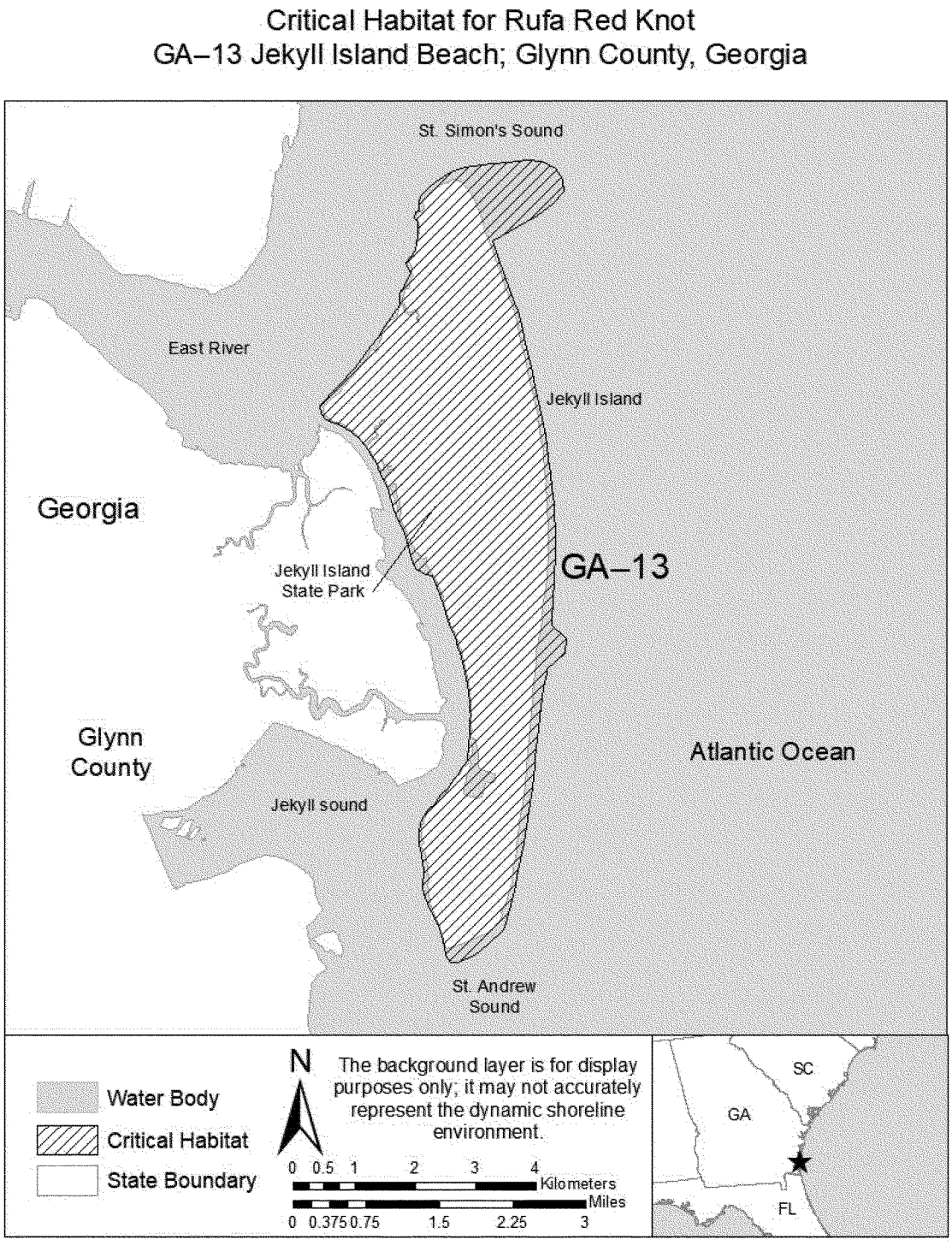
(ii) Map of Unit GA–12 is presented at paragraph (86)(ii) of this entry.

(88) Unit GA–13: Jekyll Island Beach, Georgia.

(i) Unit GA–13 consists of approximately 6,287 ac (2,545 ha) of occupied habitat on Jekyll Island, a barrier island off the coast of Glynn County. The unit boundary begins at the St. Simon's Sound shoreline of Jekyll Island and extends south to St. Andrew Sound shoreline. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with the southern side of St. Simon's Sound off the northern tip of the island. Lands within this unit include approximately 5,944 ac (2,406 ha) in State ownership (including Jekyll Island State Park) and 343 ac (139 ha) that are uncategorized.

(ii) Map of Unit GA–13 follows:

Figure 70 to Rufa Red Knot paragraph (88)(ii)



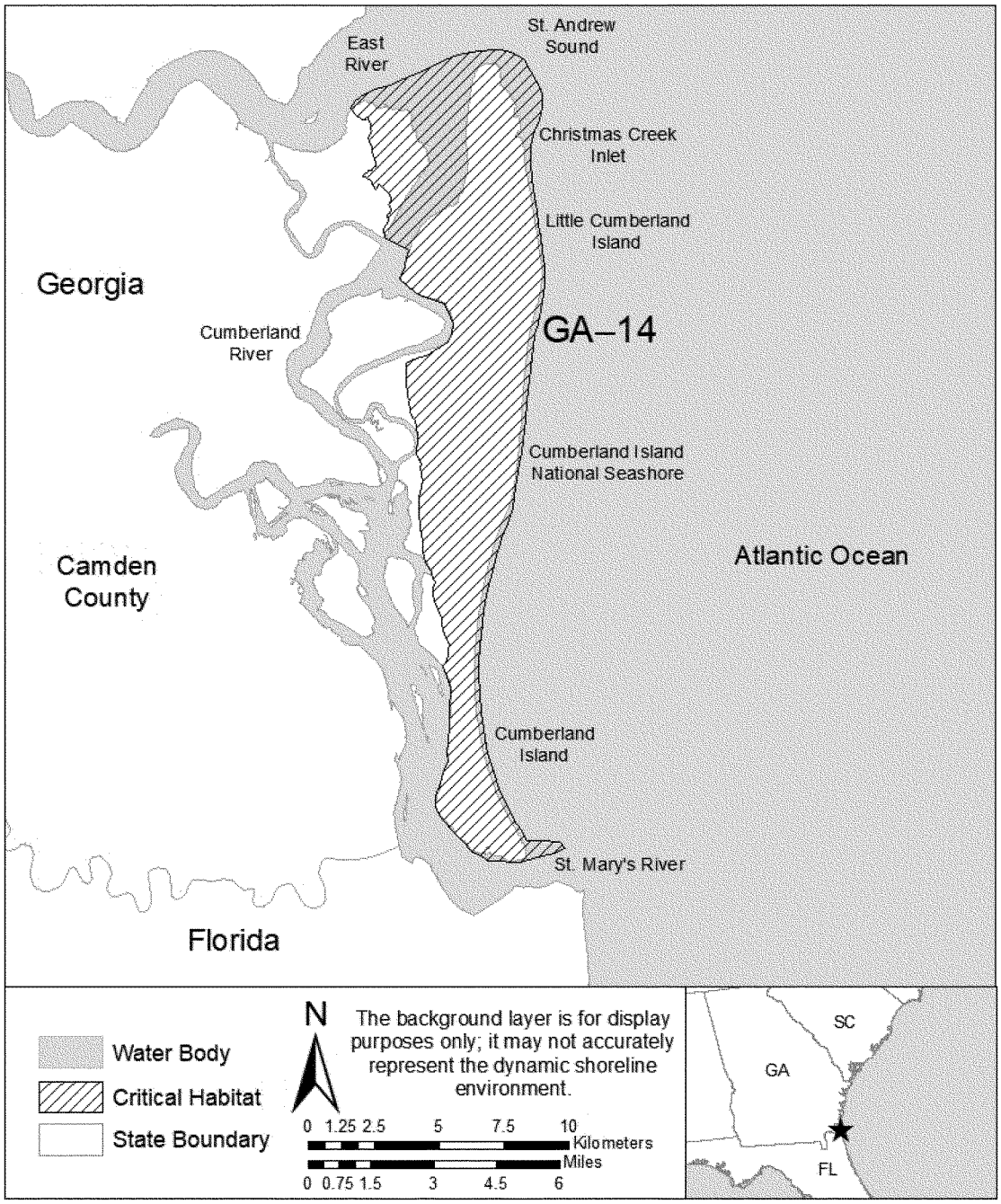
(89) Unit GA–14: Little Cumberland and Cumberland Island Beaches, Georgia.

(i) Unit GA–14 consists of approximately 28,137 ac (11,387 ha) of occupied habitat on Little Cumberland Island and Cumberland Island, a barrier island complex off the coast in Camden County. The unit boundary begins at the St. Andrew Sound shoreline of Little Cumberland Island and extends west across the Cumberland River and marsh to the East River and continues south to the St. Mary's River shoreline of Cumberland Island. The unit includes all emergent land from MLLW to the toe of the dunes or where densely vegetated habitat (not used by the rufa red knot) begins (*i.e.,* the highly dynamic shoreline and the sandy intertidal zone that are covered at high tide and uncovered at low tide). This dynamic habitat also includes the ephemeral emergent shoals (sand bars) within the flood-tidal and ebb-tidal deltas associated with St. Andrew Sound off the northern tip of Little Cumberland Island and Christmas Creek Inlet between Little Cumberland and Cumberland Islands. Lands within this unit include approximately 23,367 ac (9,456 ha) in Federal ownership (Cumberland Island National Seashore, which is also a designated wilderness area), 1,685 ac (682 ha) in State

ownership, and 3,085 ac (1,248 ha) that are uncategorized.

(ii) Map of Unit GA–14 follows:

Figure 71 to Rufa Red Knot paragraph (89)(ii)



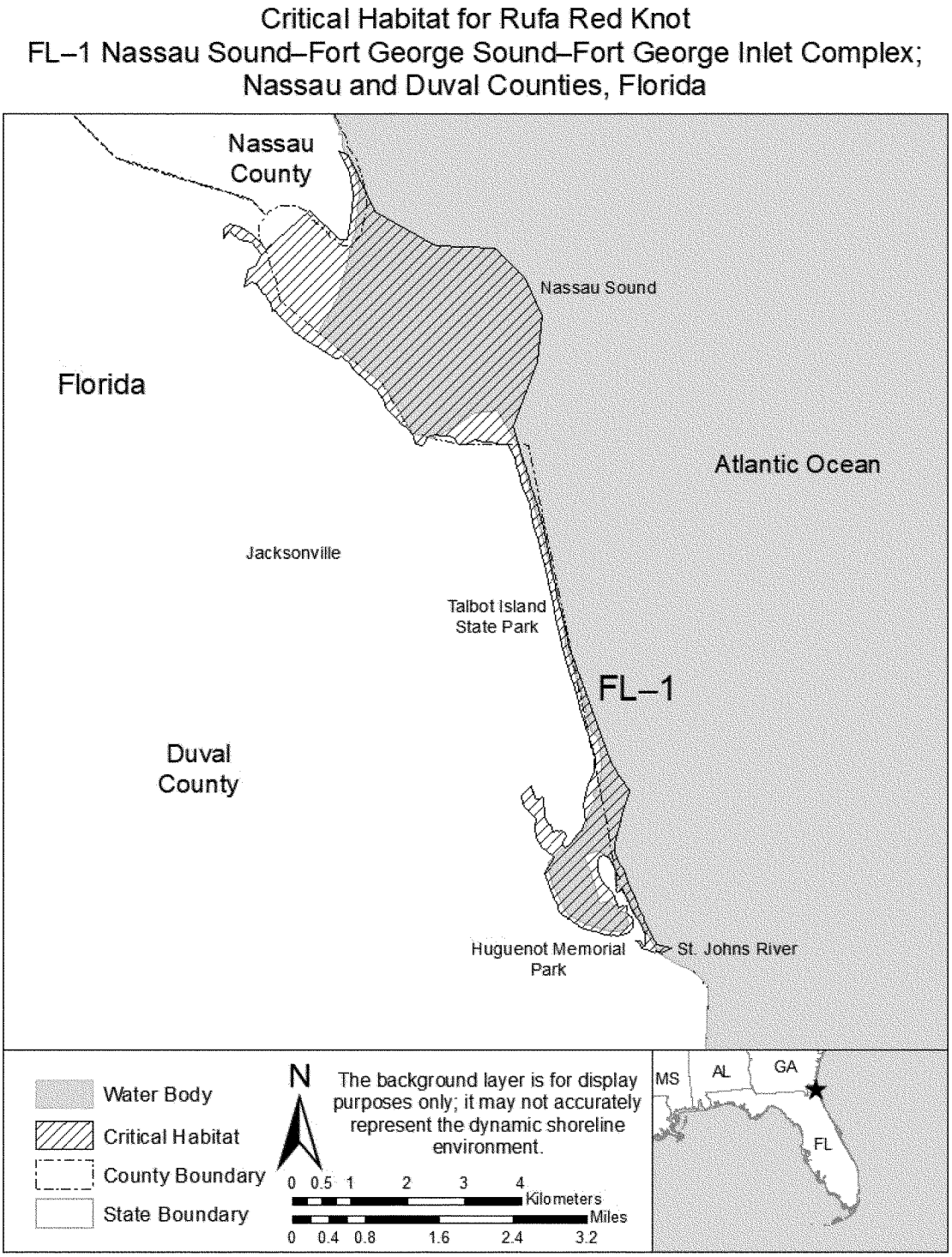
(90) Unit FL–1: Nassau Sound–Fort George Sound–Fort George Inlet Complex, Florida.

(i) Unit FL–1 consists of approximately 4,324 ac (1,750 ha) of occupied habitat consisting of beach, inlet, and intertidal sandflats in Nassau and Duval Counties. The unit extends from the north shore of Nassau Sound in Nassau County south to the north shore of the St. Johns River at Huguenot Memorial Park in Duval County. The landward boundary is the line indicating the beginning of dense vegetation or hardened structures,

including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. The majority of this unit is within the Talbot Islands State Parks Complex and Huguenot Memorial Park, which is a Federal and State-owned parcel leased to the City of Jacksonville. Lands within this unit include approximately 996 ac (404 ha) in Federal ownership, 522 ac (211 ha) in State ownership, 27 ac (11 ha) in private/other ownership, and 2,779 ac (1,125 ha) that are uncategorized.

(ii) Map of Unit FL–1 follows:

Figure 72 to Rufa Red Knot paragraph (90)(ii)



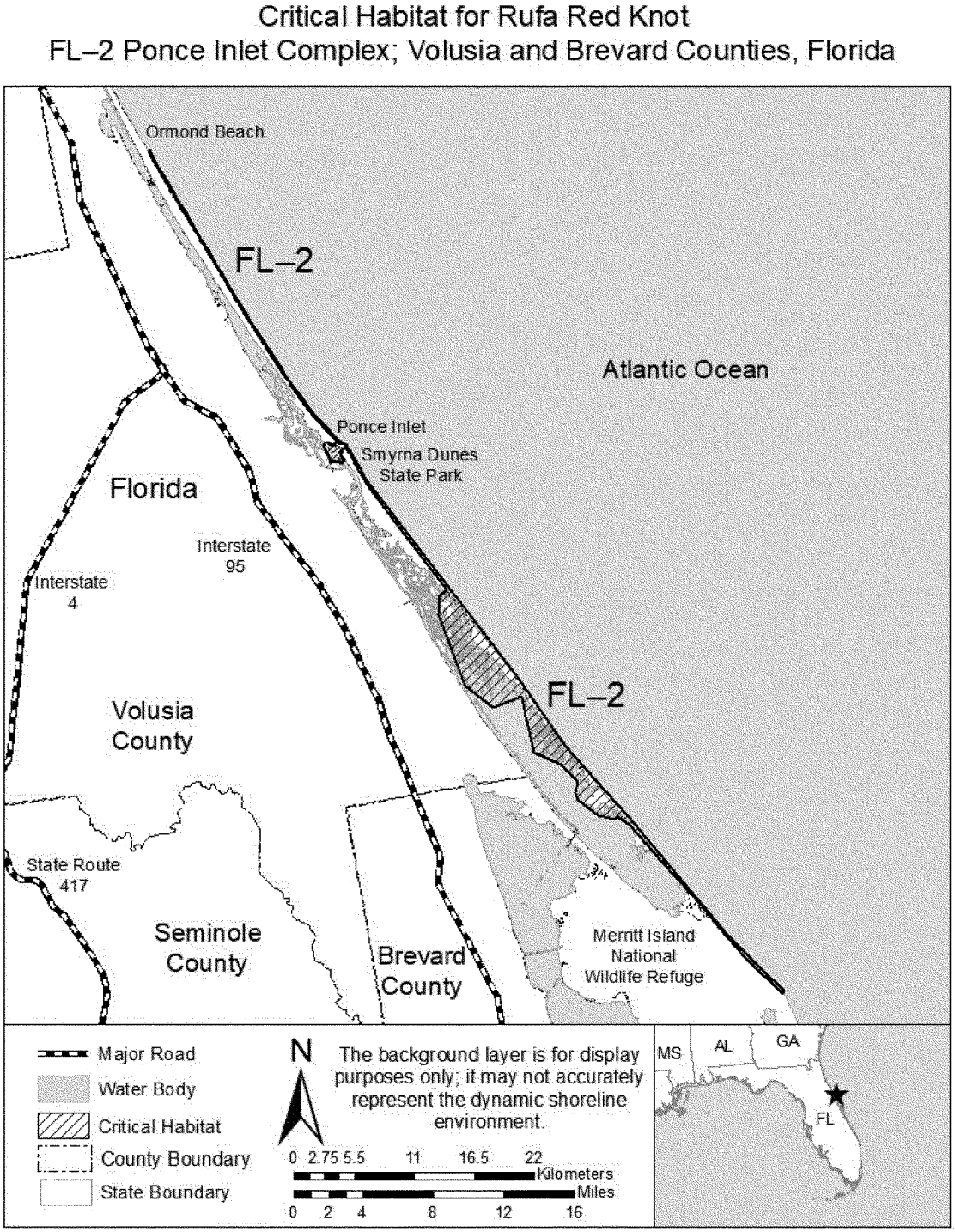
(91) Unit FL–2: Ponce Inlet Complex, Florida.

(i) Unit FL–2 consists of approximately 19,683 ac (7,965 ha) of occupied habitat consisting of beach, inlet, and intertidal sandflats in Volusia and Brevard Counties. The unit extends from approximately Ocean Edge Drive

in Ormond Beach south to the south end of Merritt Island NWR along the Atlantic Ocean. The landward boundary is the line indicating the beginning of dense vegetation or hardened structures, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this unit include approximately 16,660 ac (6,742 ha) in Federal ownership (Merritt Island NWR), 3,005 ac (1,216 ha) in State ownership (Smyrna Dunes State Park), and 18 ac (7 ha) that are uncategorized.

(ii) Map of Unit FL–2 follows:

Figure 73 to Rufa Red Knot paragraph (91)(ii)



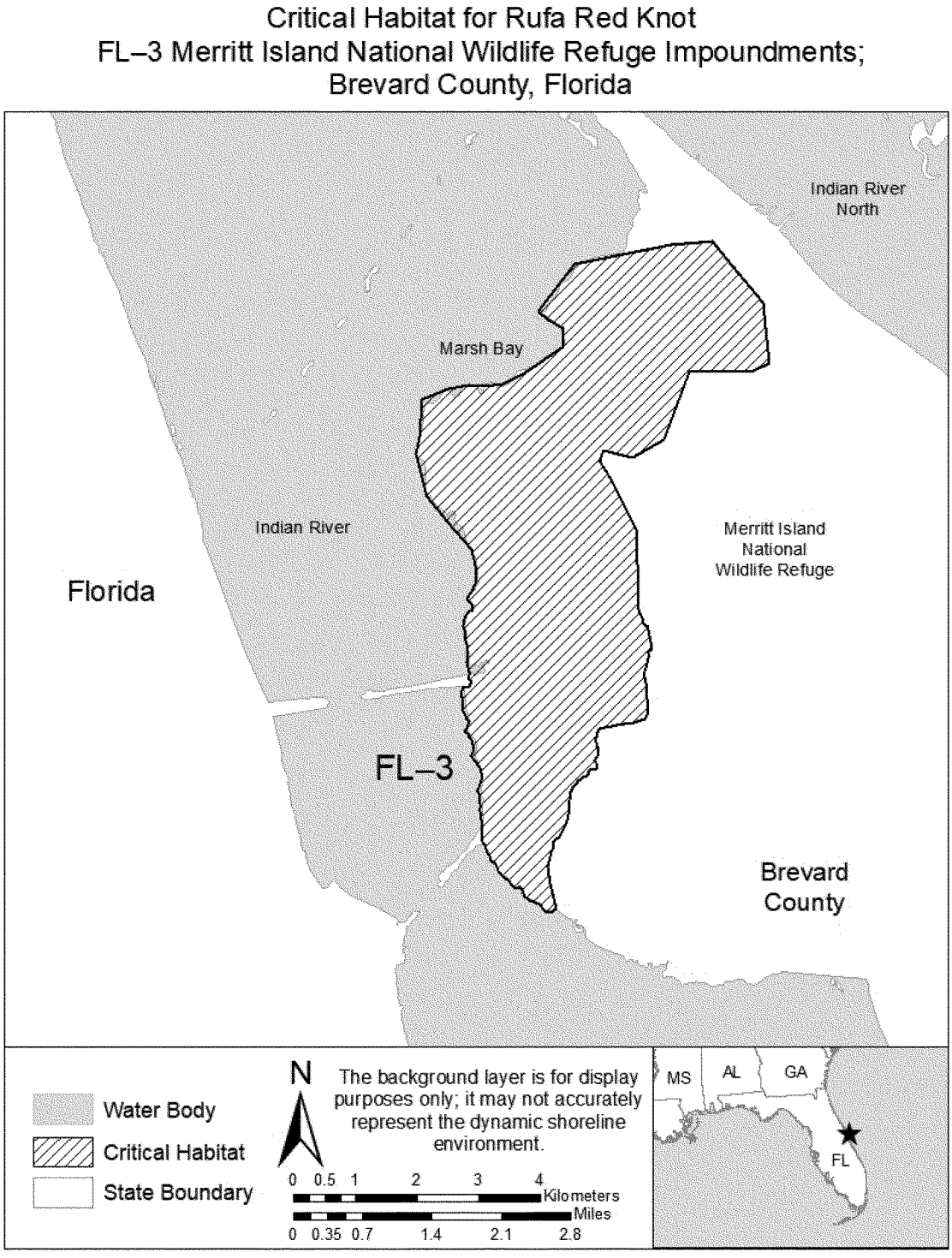
(92) Unit FL–3: Merritt Island National Wildlife Refuge Impoundments, Florida.

(i) Unit FL–3 consists of approximately 6,947 ac (2,811 ha) of occupied and managed impoundment and intertidal mudflats in Brevard County. The landward boundary is the line indicating the beginning of dense vegetation or hardened structures, including emergent, dynamic shoreline

to MLLW that is covered at high tide and uncovered at low tide. This unit consists of Federal lands (Merritt Island NWR).

(ii) Map of Unit FL–3 follows:

Figure 74 to Rufa Red Knot paragraph (92)(ii)

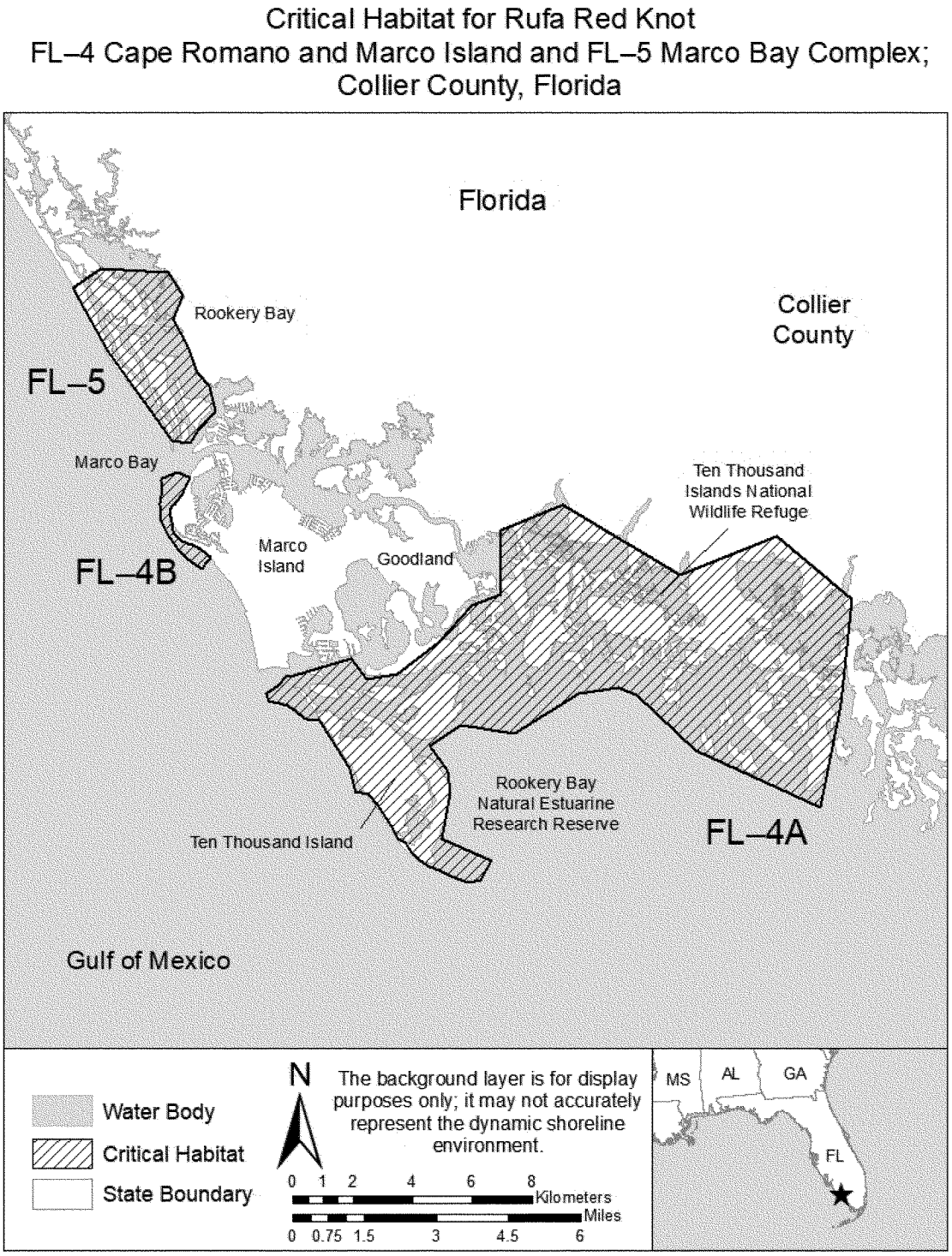


(93) Unit FL–4: Cape Romano and Marco Island, Florida.

(i) Unit FL–4 consists of two subunits comprising 26,629 ac (10,776 ha) of occupied habitat in Collier County. This unit consists of Federal (Ten Thousand Islands NWR), State, and private landowners.

(ii) Map of Unit FL–4 follows:

Figure 75 to Rufa Red Knot paragraph (93)(ii)



(iii) Subunit FL–4A (Cape Romano Complex) consists of approximately 26,213 ac (10,608 ha) of occupied beach and intertidal sandflats habitat in Collier County, in the wetland complex south of Marco Island and the community of Goodland. The landward boundary is the line indicating the beginning of dense vegetation, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this subunit include approximately 13,138 ac (5,317 ha) in Federal ownership (Ten Thousand Islands NWR), 12,605 ac (5,101 ha) in State ownership (Rookery Bay NERR), and 470 ac (190 ha) that are uncategorized.

(iv) Map of Subunit FL–4A is presented at paragraph (93)(ii) of this entry.

(v) Subunit FL–4B (Marco Island) consists of approximately 416 ac (168 ha) of occupied habitat beach, inlet, and intertidal sandflats in Collier County. The subunit extends from the south side of the inlet north of Marco Island south along the Gulf of Mexico approximately 4 mi (6.5 km). The landward boundary is the line indicating the beginning of dense vegetation or hardened structures, including emergent, dynamic shoreline

to MLLW that is covered at high tide and uncovered at low tide. Lands within this subunit include approximately 408 ac (165 ha) in State ownership (Rookery Bay NERR) and 8 ac (3 ha) in private/other ownership.

(vi) Map of Subunit FL–4B is presented at paragraph (93)(ii) of this entry.

(94) Unit FL–5: Marco Bay Complex, Florida.

(i) Unit FL–5 consists of approximately 3,589 ac (1,453 ha) of occupied beach, inlet, and intertidal sandflats habitat in Collier County, from the north side of the inlet north of Marco Island north along the Gulf of Mexico approximately 3.7 mi (6 km) and inclusive of the wetland complex inland to the east side of Rookery Bay. The landward boundary is the line indicating the beginning of dense vegetation, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this unit include approximately 3,531 ac (1,429 ha) in State ownership (Rookery Bay NERR) and 58 ac (24 ha) in private/other ownership.

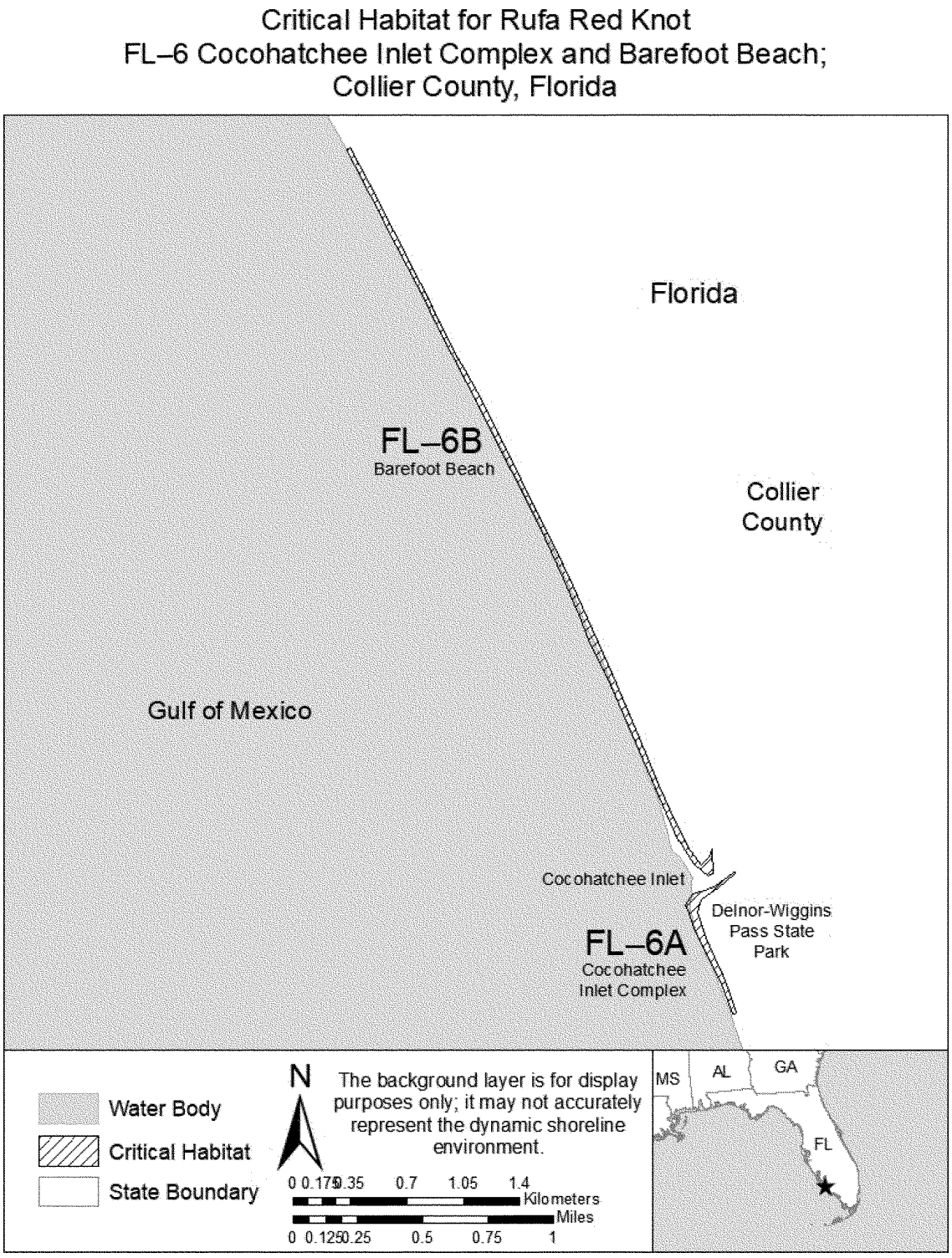
(ii) Map of Unit FL–5 is presented at paragraph (93)(ii) of this entry.

(95) Unit FL–6: Cocohatchee Inlet Complex and Barefoot Beach, Florida.

(i) Unit FL–6 consists of two subunits comprising 48 ac (20 ha) of occupied habitat in Collier County. This unit consists of Delnor-Wiggins Pass State Park and private landowners.

(ii) Map of Unit FL–6 follows:

Figure 76 to Rufa Red Knot paragraph (95)(ii)



(iii) Subunit FL–6A (Cocohatchee Inlet Complex) consists of approximately 9 ac (4 ha) of occupied beach, inlet, and intertidal sandflats habitat in Collier County, from the south side of the Cocohatchee Inlet south along the Gulf of Mexico approximately 3,281 ft (1 km). The landward boundary is the line indicating the beginning of dense vegetation, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this subunit are entirely under State ownership (Delnor-Wiggins Pass State Park).

(iv) Map of Subunit FL–6A is presented at paragraph (95)(ii) of this entry.

(v) Subunit FL–6B (Barefoot Beach) consists of approximately 39 ac (16 ha) of occupied beach, inlet, and intertidal sandflats habitat in Collier County, from the north side of the Cocohatchee Inlet north along the Gulf of Mexico approximately 3.1 mi (5 km). The landward boundary is the line indicating the beginning of dense vegetation or hardened structures, including emergent, dynamic shoreline to MLLW that is covered at high tide

and uncovered at low tide. Lands within this subunit include approximately 18 ac (7 ha) in State ownership and 21 ac (9 ha) in private/other ownership.

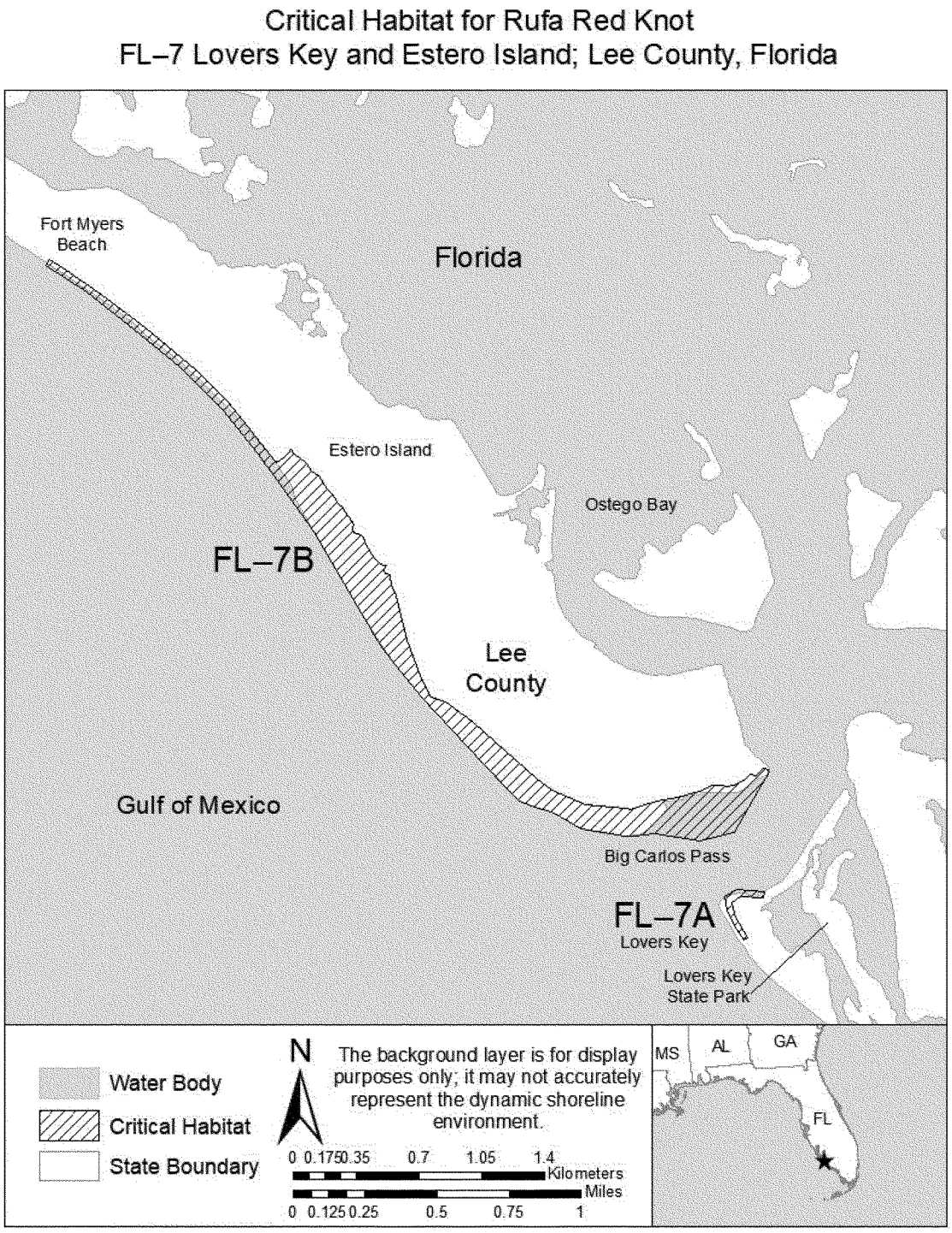
(vi) Map of Subunit FL–6B is presented at paragraph (95)(ii) of this entry.

(96) Unit FL–7: Lovers Key and Estero Island, Florida.

(i) Unit FL–7 consists of two subunits comprising 175 ac (70 ha) of occupied habitat in Lee County. This unit consists of portions of Lovers Key State Park and Estero Island.

(ii) Map of Unit FL–7 follows:

Figure 77 to Rufa Red Knot paragraph (96)(ii)



(iii) Subunit FL–7A (Lovers Key) consists of approximately 4 ac (1 ha) of occupied beach, inlet, and intertidal sandflats habitat in Lee County, at the north point of Lovers Key. The landward boundary is the line indicating the beginning of dense vegetation or hardened structures, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within

this subunit are entirely State owned (Lovers Key State Park).

(iv) Map of Subunit FL–7A is presented at paragraph (96)(ii) of this entry.

(v) Subunit FL–7B (Estero Island) consists of approximately 171 ac (69 ha) of occupied beach, inlet, and intertidal sandflats habitat in Lee County, from Key West Court on Fort Myers Beach south along the Gulf of Mexico to the southern point of the island. The landward boundary is the line indicating the beginning of dense vegetation or hardened structures, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this subunit are entirely in State ownership.

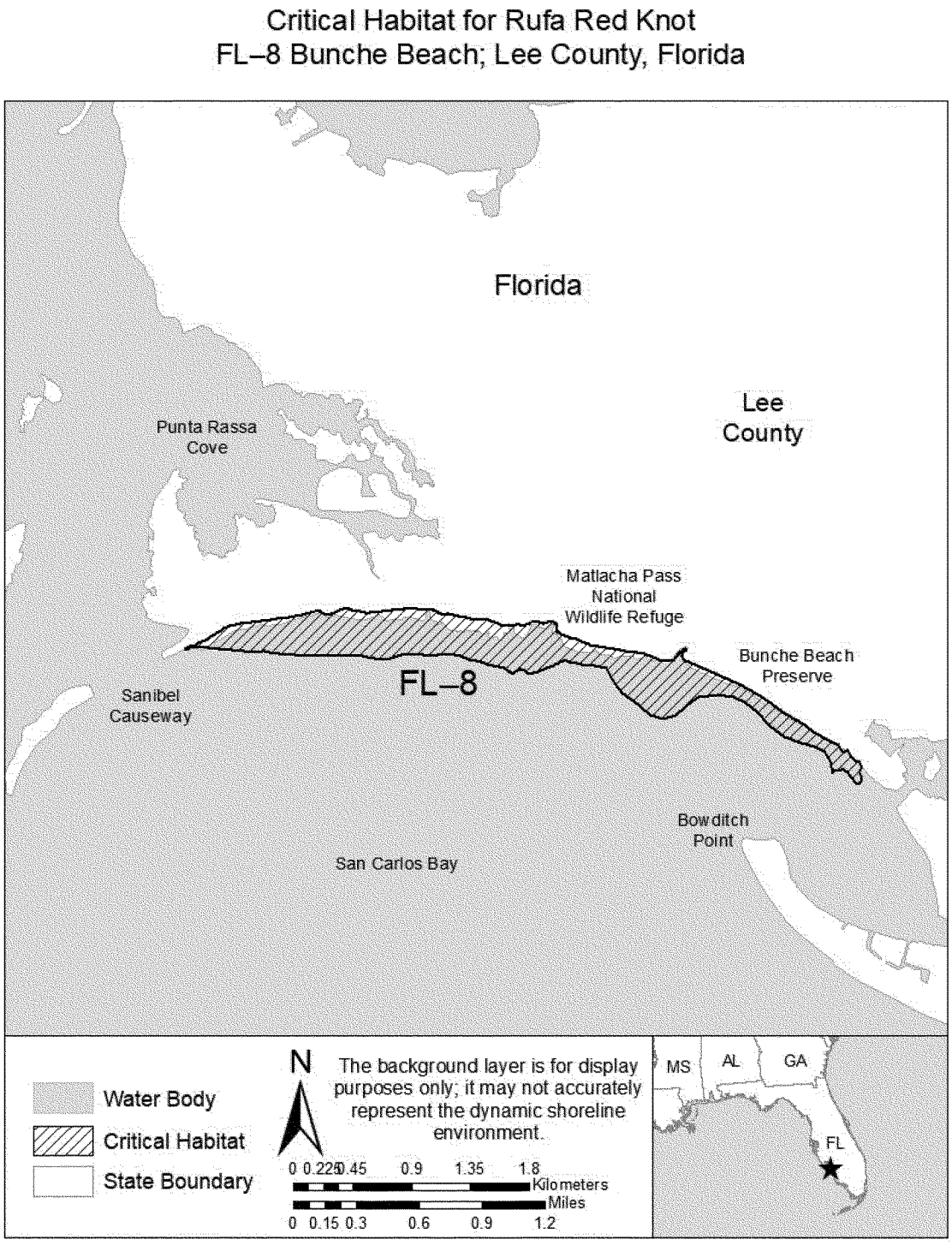
(vi) Map of Subunit FL–7B is presented at paragraph (96)(ii) of this entry.

(97) Unit FL–8: Bunche Beach, Florida.

(i) Unit FL–8 consists of approximately 334 ac (135 ha) of occupied beach, inlet, and intertidal sandflats habitat in Lee County, in San Carlos Bay south of the Sanibel Causeway in Fort Myers. The landward boundary is the line indicating the beginning of dense vegetation or hardened structures, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this unit include approximately 23 ac (9 ha) in Federal ownership (Matlacha Pass NWR), 264 ac (107 ha) in State ownership (Bunche Beach Preserve), and 47 ac (19 ha) in private/other ownership.

(ii) Map of Unit FL–8 follows:

Figure 78 to Rufa Red Knot paragraph (97)(ii)

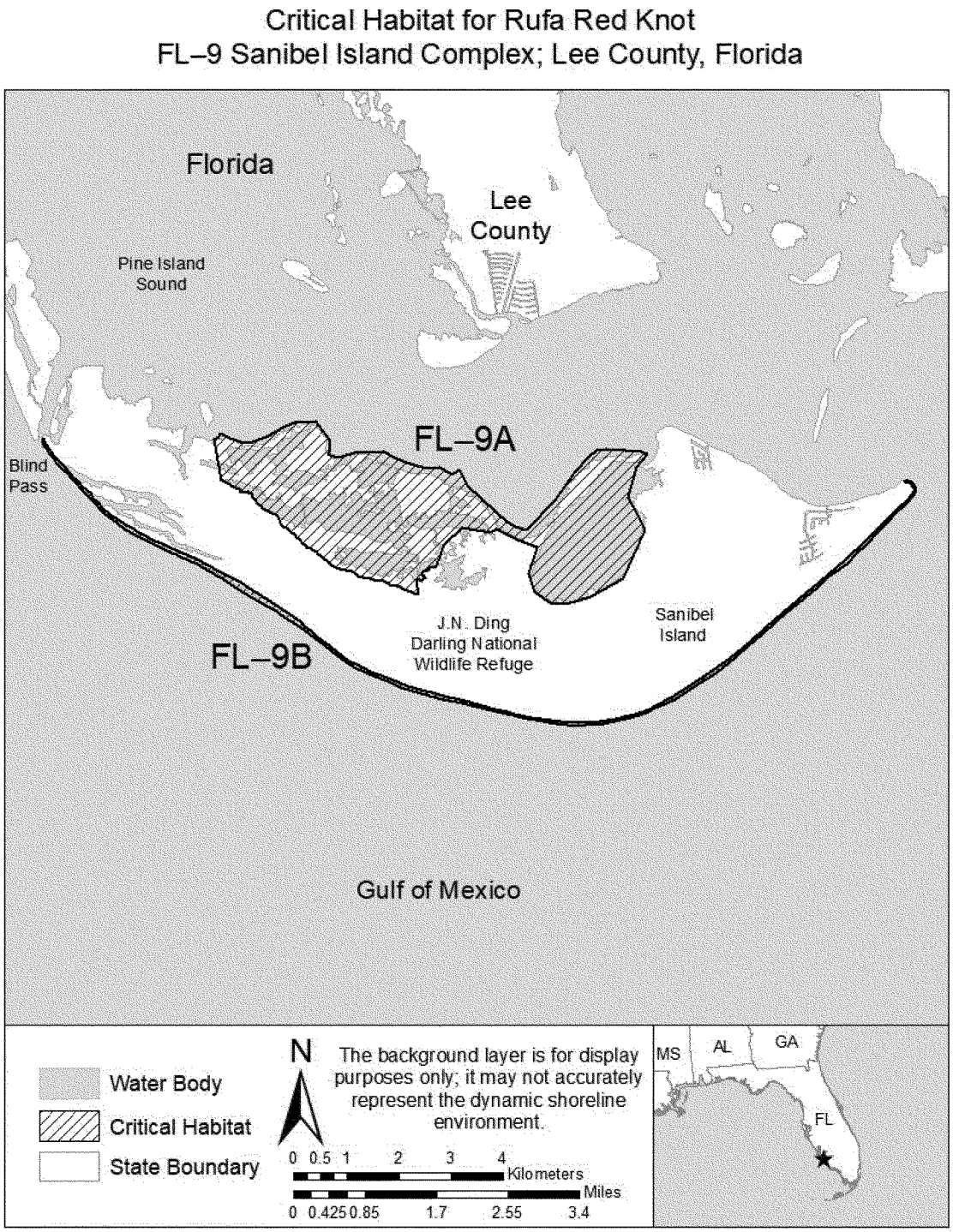


(98) Unit FL–9: Sanibel Island Complex, Florida.

(i) Unit FL–9 consists of two subunits comprising 3,759 ac (1,521 ha) of occupied habitat in Lee County. This unit consists of Federal lands that are part of the J.N. ''Ding'' Darling NWR and Sanibel Island.

(ii) Map of Unit FL–9 follows:

Figure 79 to Rufa Red Knot paragraph (98)(ii)



(iii) Subunit FL–9A (J.N. ''Ding'' Darling National Wildlife Refuge) consists of approximately 3,451 ac (1,397 ha) of occupied beach, inlet, and intertidal sandflats habitat, as well as managed impoundments in Lee County on Sanibel Island. The landward boundary is the line indicating the beginning of dense vegetation or hardened structures, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this subunit are entirely in Federal ownership (J.N. ''Ding'' Darling NWR).

(iv) Map of Subunit FL–9A is presented at paragraph (98)(ii) of this entry.

(v) Subunit FL–9B (Sanibel Island) consists of approximately 307 ac (124 ha) of occupied beach, inlet, and intertidal sandflats habitat in Lee County on Sanibel Island. The landward boundary is the line indicating the beginning of dense vegetation or hardened structures, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this subunit are entirely in State ownership.

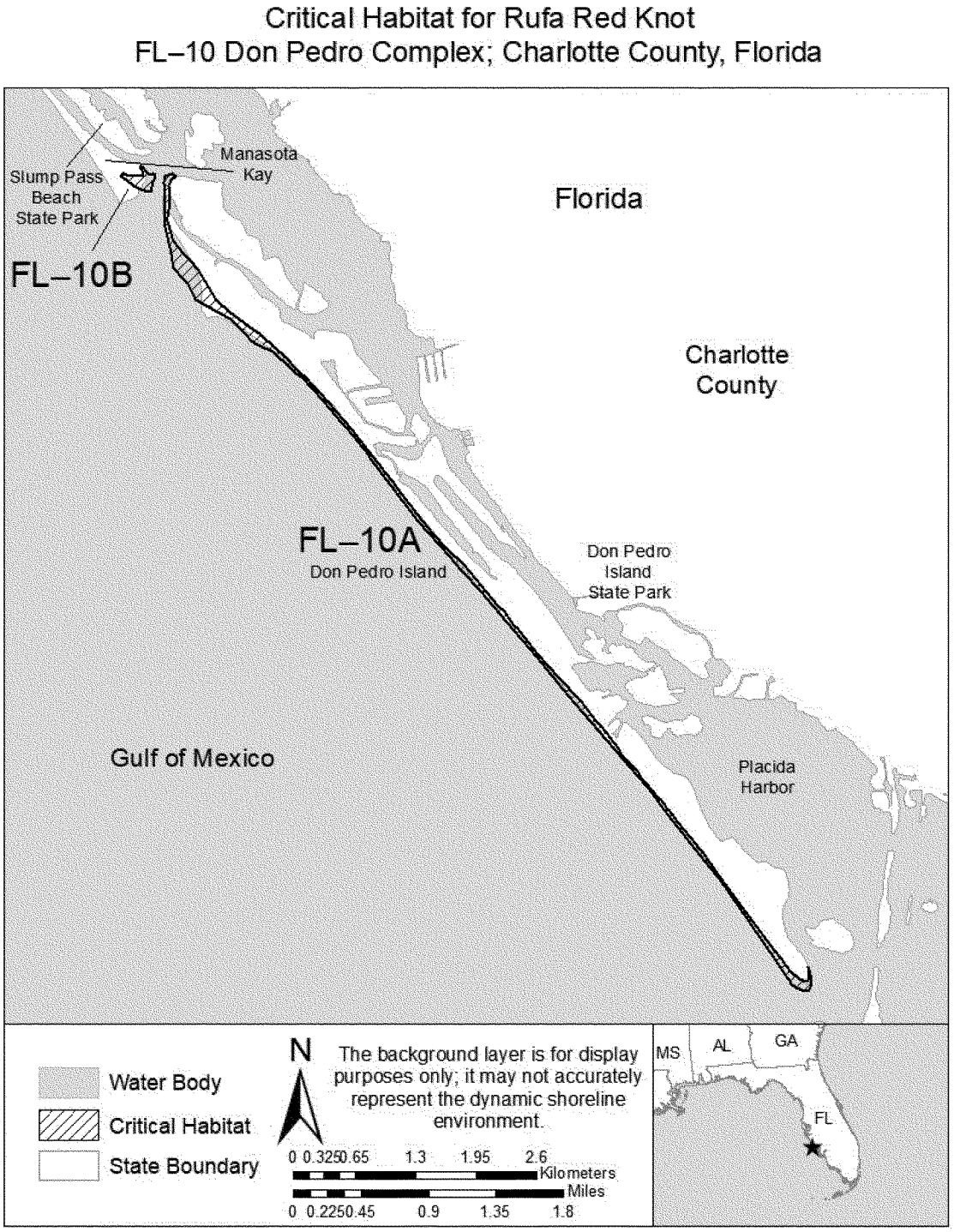
(vi) Map of Subunit FL–9B is presented at paragraph (98)(ii) of this entry.

(99) Unit FL–10: Don Pedro Complex, Florida.

(i) Unit FL–10 consists of two subunits comprising 158 ac (64 ha) of occupied habitat in Charlotte County. This unit consists of State lands, a portion of which are part of the Don Pedro Island State Park and Stump Pass Beach State Park.

(ii) Map of Unit FL–10 follows:

Figure 80 to Rufa Red Knot paragraph (99)(ii)



(iii) Subunit FL–10A (Don Pedro) consists of approximately 147 ac (60 ha) of occupied beach, inlet, and intertidal sandflats habitat in Charlotte County on Don Pedro Island. The landward boundary is the line indicating the beginning of dense vegetation or hardened structures, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this subunit are entirely in State ownership, a portion of which includes Don Pedro Island State Park.

(iv) Map of Subunit FL–10A is presented at paragraph (99)(ii) of this entry.

(v) Subunit FL–10B (Stump Pass Beach State Park) consists of approximately 11 ac (4 ha) of occupied beach, inlet, and intertidal sandflats habitat in Charlotte County at the southern point of Manasota Key. The landward boundary is the line indicating the beginning of dense vegetation, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this subunit are entirely in State ownership (Stump Pass Beach State Park).

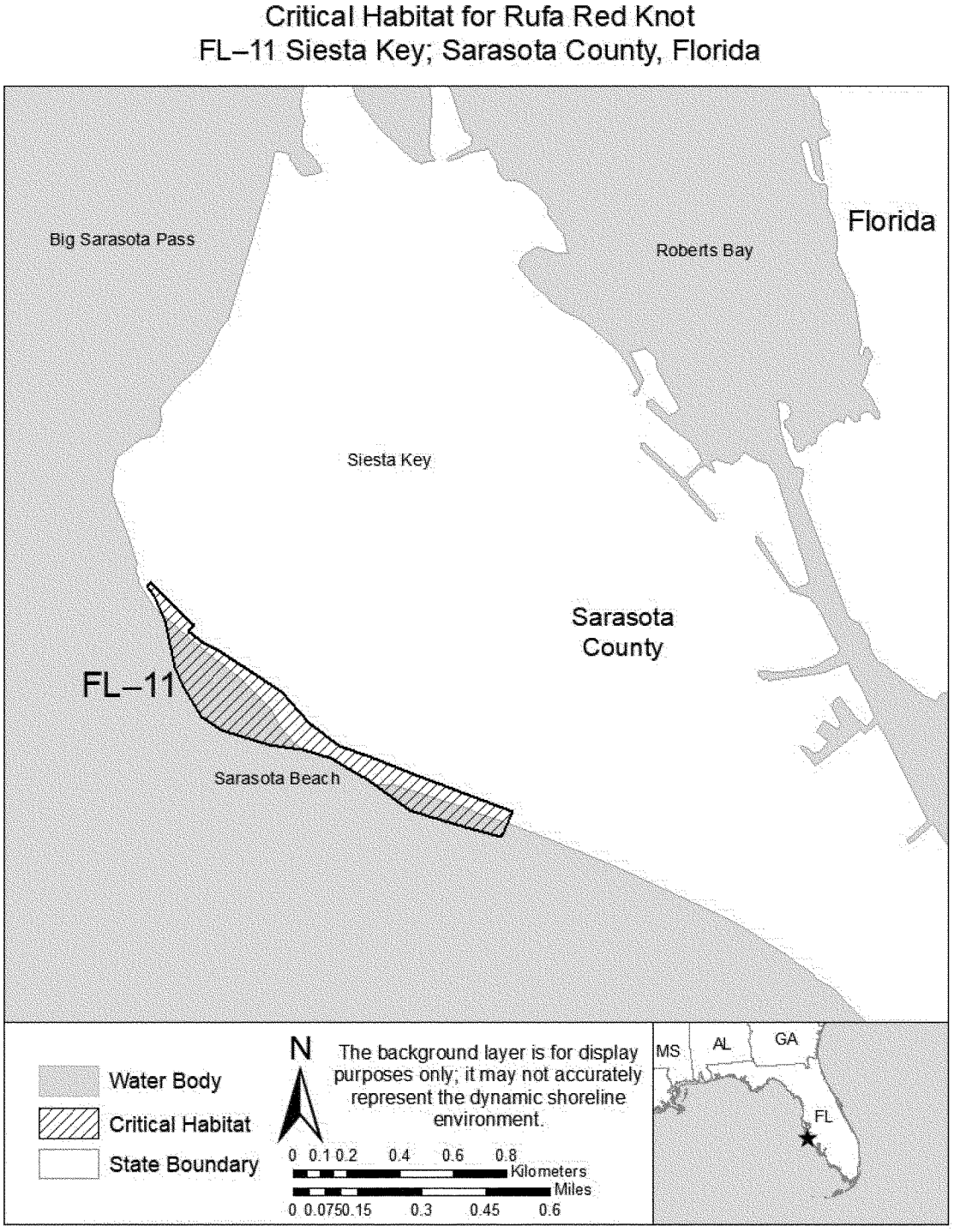
(vi) Map of Subunit FL–10B is presented at paragraph (99)(ii) of this entry.

(100) Unit FL–11: Siesta Key, Florida.

(i) Unit FL–11 consists of approximately 53 ac (21 ha) of occupied beach, inlet, and intertidal sandflats habitat in Sarasota County on Siesta Key, from Avenida Messina (road) south to Avenida del Mare. The landward boundary is the line indicating the beginning of dense vegetation, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this unit are entirely in State ownership.

(ii) Map of Unit FL–11 follows:

Figure 81 to Rufa Red Knot paragraph (100)(ii)

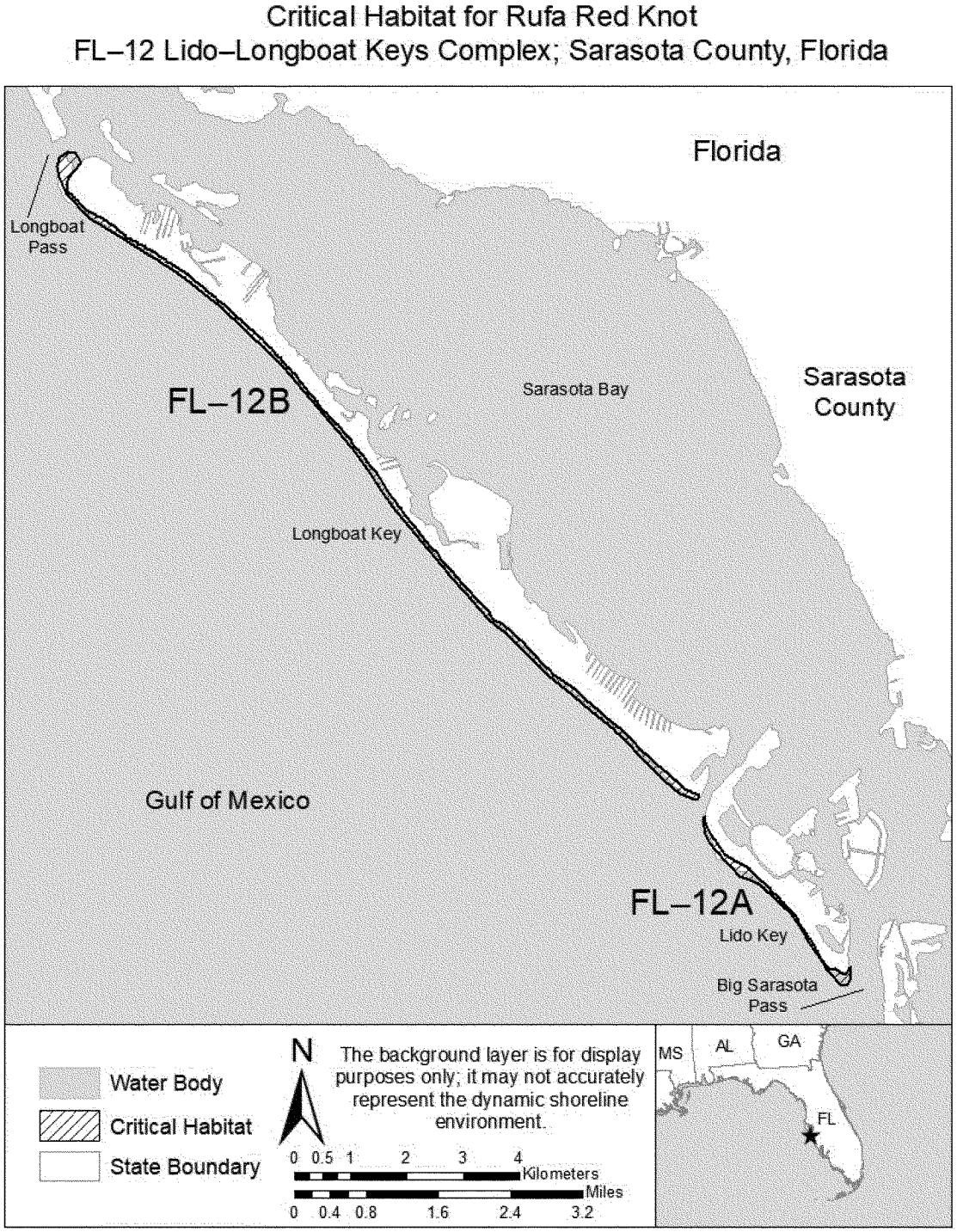


(101) Unit FL–12: Lido–Longboat Keys Complex, Florida.

(i) Unit FL–12 consists of two subunits comprising 450 ac (182 ha) of occupied habitat in Sarasota County. This unit consists of State lands.

(ii) Map of Unit FL–12 follows:

Figure 82 to Rufa Red Knot paragraph (101)(ii)



(iii) Subunit FL–12A (Lido Key) consists of approximately 81 ac (33 ha) of occupied beach, inlet, and intertidal sandflats habitat in Sarasota County on Lido Key. The landward boundary is the line indicating the beginning of dense vegetation, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this subunit are entirely in State ownership.

(iv) Map of Subunit FL–12A is presented at paragraph (101)(ii) of this entry.

(v) Subunit FL–12B (Longboat Key) consists of approximately 369 ac (149 ha) of occupied beach, inlet, and

intertidal sandflats habitat in Sarasota County on Longboat Key. The landward boundary is the line indicating the beginning of dense vegetation or hardened structures, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this subunit are entirely in State ownership.

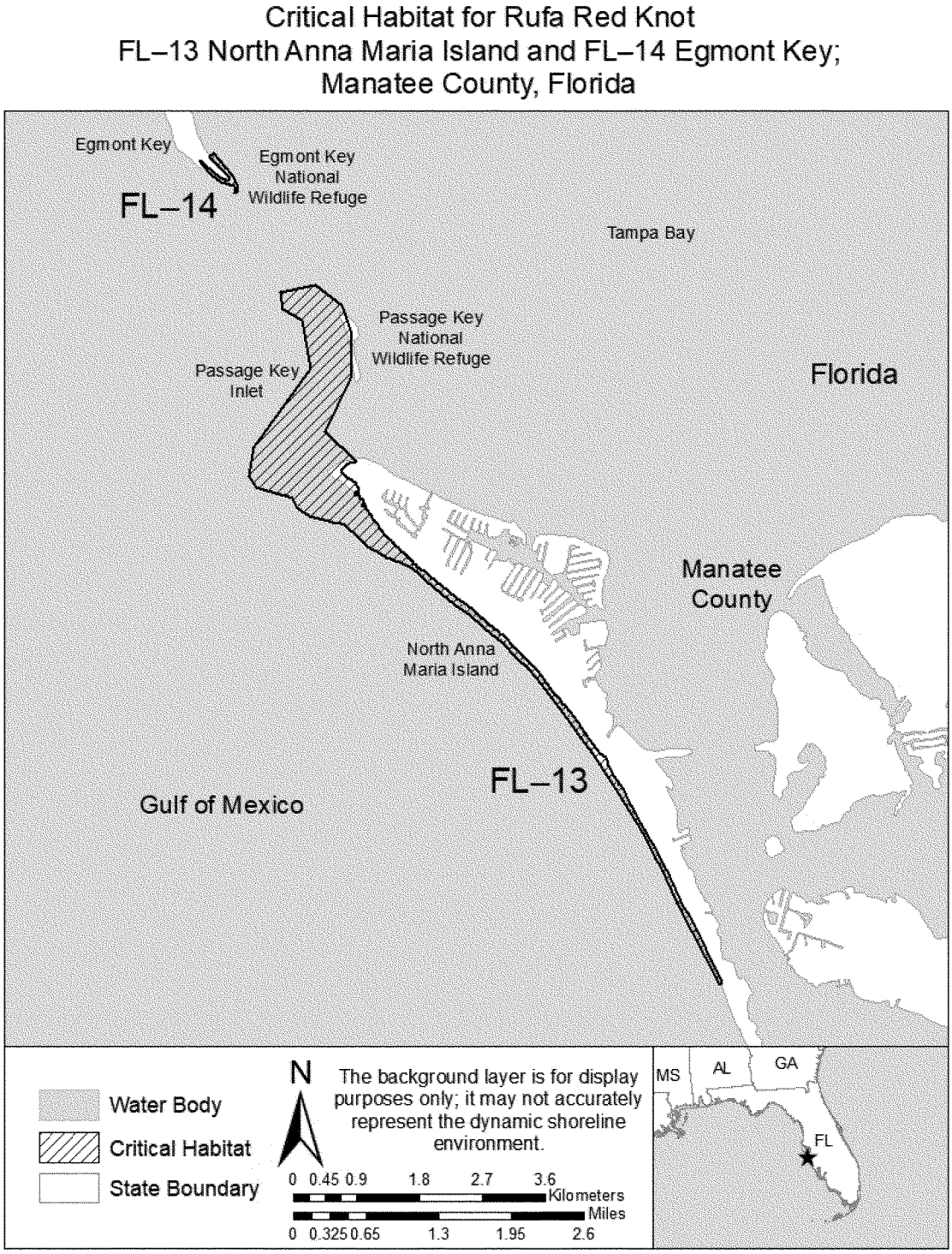
(vi) Map of Subunit FL–12B is presented at paragraph (101)(ii) of this entry.

(102) Unit FL–13: North Anna Maria Island, Florida.

(i) Unit FL–13 consists of approximately 945 ac (383 ha) of occupied beach, inlet, and intertidal sandflats habitat in Manatee County, from the north point of Anna Maria Island south to Cortez Road West. The landward boundary is the line indicating the beginning of dense vegetation, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this unit include approximately 56 ac (23 ha) in Federal ownership (Passage Key NWR) and 889 ac (360 ha) in State ownership.

(ii) Map of Unit FL–13 follows:

Figure 83 to Rufa Red Knot paragraph (102)(ii)



(103) Unit FL–14: Egmont Key, Florida.

(i) Unit FL–14 consists of approximately 15 ac (6 ha) of occupied beach and intertidal sandflats habitat in Manatee County, on the south end of Egmont Key at the mouth of Tampa Bay. The landward boundary is the line indicating the beginning of dense vegetation, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this unit are entirely under Federal ownership (Egmont Key NWR).

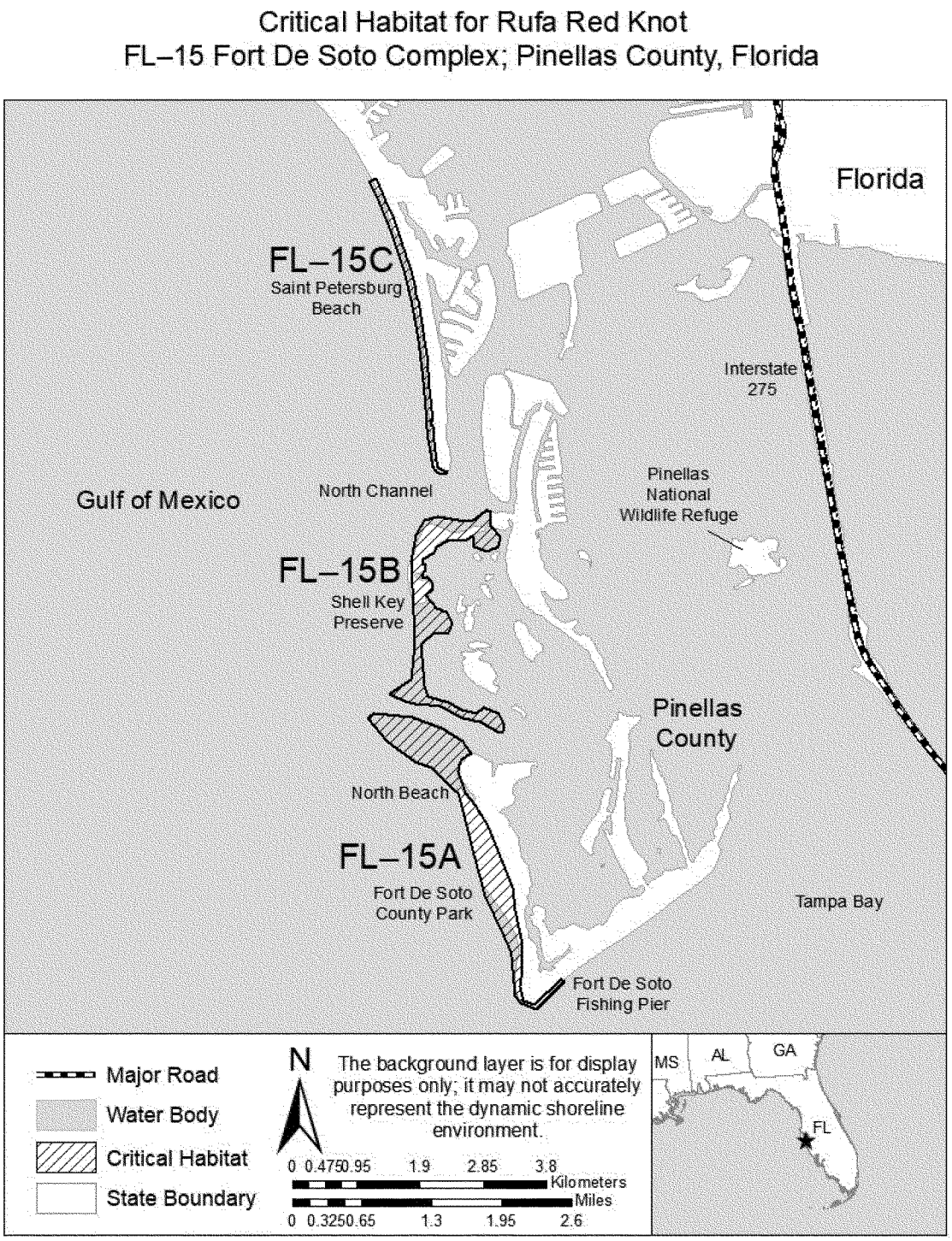
(ii) Map of Unit FL–14 is presented at paragraph (102)(ii) of this entry.

(104) Unit FL–15: Fort De Soto Complex, Florida.

(i) Unit FL–15 consists of three subunits comprising 856 ac (346 ha) of occupied habitat in Pinellas County. This unit consists of State lands and private/other ownership.

(ii) Map of Unit FL–15 follows:

Figure 84 to Rufa Red Knot paragraph (104)(ii)



(iii) Subunit FL–15A (Fort De Soto County Park) consists of approximately 427 ac (173 ha) of occupied beach, inlet, and intertidal sandflats habitat in Pinellas County, from North Beach south along the Gulf of Mexico to the Fort De Soto Fishing Pier at the mouth of Tampa Bay. The landward boundary is the line indicating the beginning of dense vegetation or hardened structures, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this subunit are entirely in county ownership (which is captured under the private/other category) within Fort De Soto County Park.

(iv) Map of Subunit FL–15A is presented at paragraph (104)(ii) of this entry.

(v) Subunit FL–15B (Shell Key Preserve) consists of approximately 322 ac (130 ha) of occupied beach, inlet, and intertidal sandflats habitat in Pinellas County on Shell Key. The landward boundary is the line indicating the beginning of dense vegetation, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this subunit are entirely in State/county ownership (Shell Key Preserve).

(vi) Map of Subunit FL–15B is presented at paragraph (104)(ii) of this entry.

(vii) Subunit FL–15C (Saint Petersburg Beach) consists of approximately 107 ac (43 ha) of occupied beach, inlet, and intertidal sandflats habitat in Pinellas County on Saint Petersburg Beach from 46th Avenue south to 1st Avenue inclusive of the inlet. The landward boundary is the line indicating the beginning of dense vegetation, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this subunit are entirely in State ownership.

(viii) Map of Subunit FL–15C is presented at paragraph (104)(ii) of this entry.

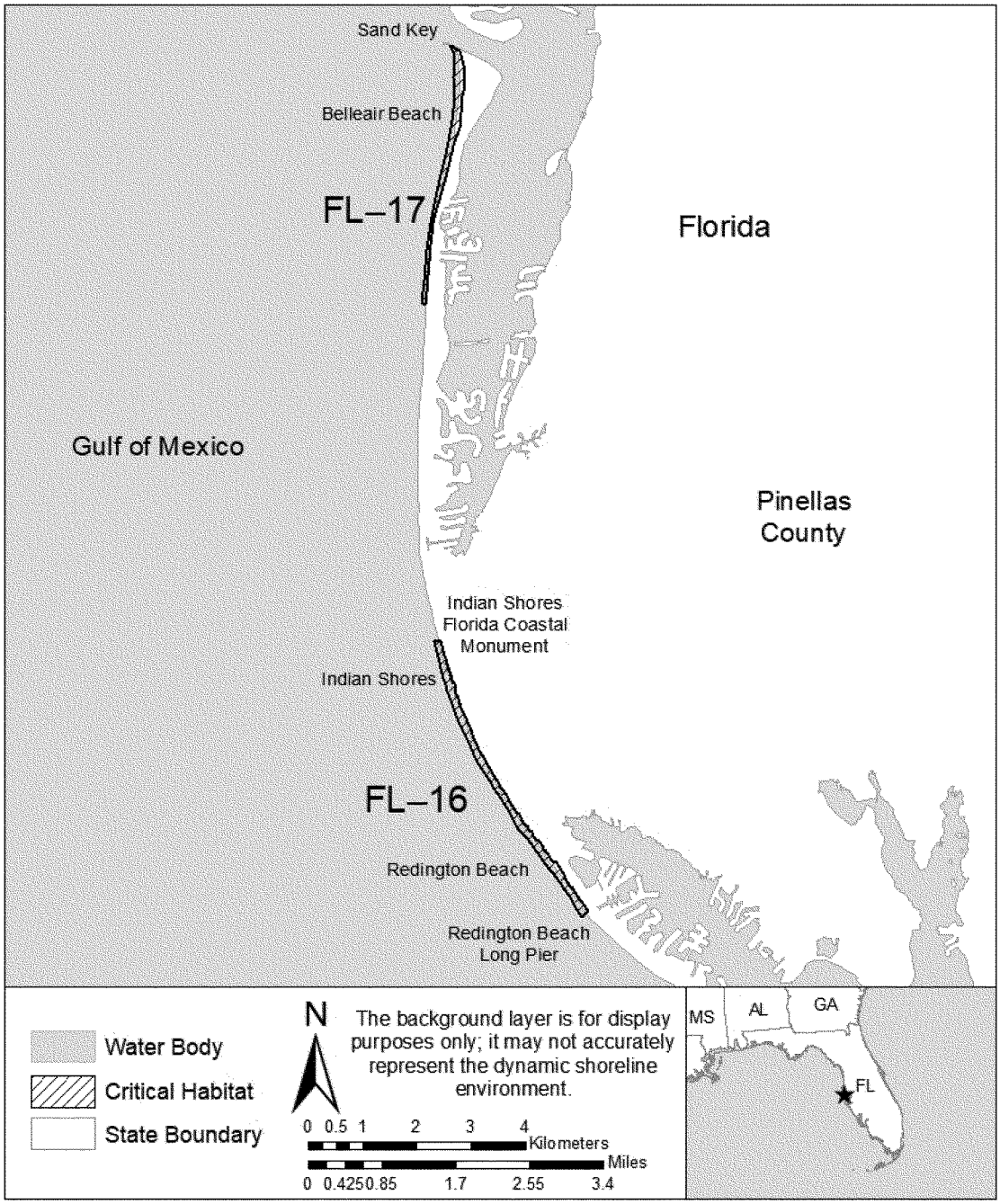
(105) Unit FL–16: Indian Shores–Redington Beach, Florida.

(i) Unit FL–16 consists of approximately 196 ac (79 ha) of occupied beach, inlet, and intertidal sandflats habitat in Pinellas County, from the Indian Shores Florida Coastal Range Monument R–086 at the north end of the unit to the Redington Beach Long Pier at the south end of the unit. The landward boundary is the line indicating the beginning of dense vegetation, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this unit are entirely in State ownership.

(ii) Map of Unit FL–16 follows:

Figure 85 to Rufa Red Knot paragraph (105)(ii)

Critical Habitat for Rufa Red Knot
FL–16 Indian Shores–Redington Beach and FL–17 Belleair Beach;
Pinellas County, Florida



(106) Unit FL–17: Belleair Beach, Florida.

(i) Unit FL–17 consists of approximately 123 ac (50 ha) of occupied beach, inlet, and intertidal sandflats habitat in Pinellas County, on Belleair Beach from the north point (Sand Key) south to 19th Street. The landward boundary is the line indicating the beginning of dense vegetation, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this unit are entirely in State ownership.

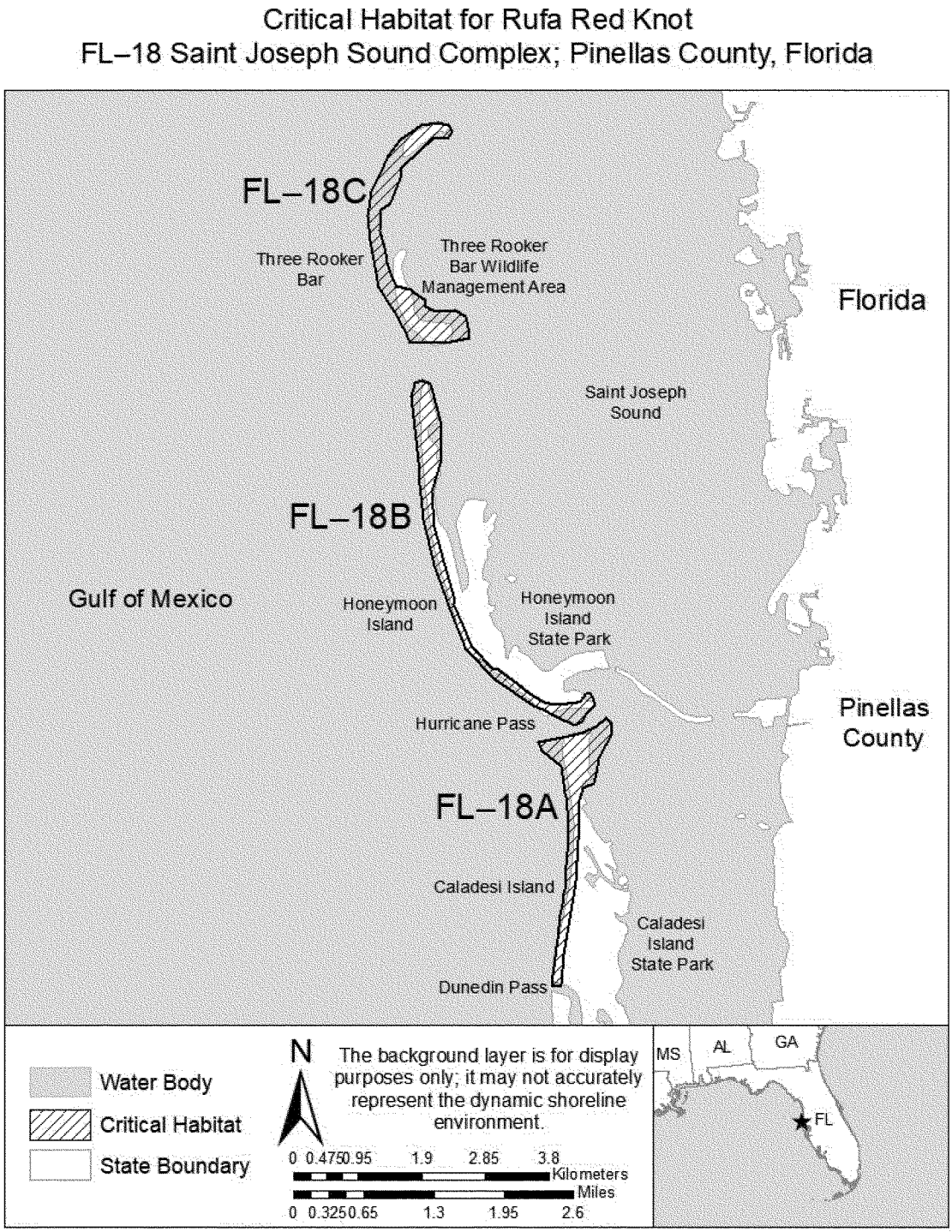
(ii) Map of Unit FL–17 is presented at paragraph (105)(ii) of this entry.

(107) Unit FL–18: Saint Joseph Sound Complex, Florida.

(i) Unit FL–18 consists of three subunits comprising 888 ac (360 ha) of occupied habitat in Pinellas County. This unit consists of State-owned lands.

(ii) Map of Unit FL–18 follows:

Figure 86 to Rufa Red Knot paragraph (107)(ii)



(iii) Subunit FL–18A (Caladesi Island) consists of approximately 259 ac (105 ha) of occupied beach and intertidal sandflats habitat in Pinellas County. This subunit includes shoreline from the southern boundary of Caladesi Island State Park to Dunedin Pass. The landward boundary is the line indicating the beginning of dense vegetation, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands in this subunit are entirely in State ownership (Caladesi Island State Park).

(iv) Map of Subunit FL–18A is presented at paragraph (107)(ii) of this entry.

(v) Subunit FL–18B (Honeymoon Island) consists of approximately 294 ac (119 ha) of occupied beach and intertidal sandflats habitat in Pinellas County. This subunit includes the Gulf of Mexico shoreline in Honeymoon Island State Park from Dunedin Pass to Hurricane Pass. The landward boundary is the line indicating the beginning of dense vegetation, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands in this subunit are entirely in State ownership (Honeymoon Island State Park).

(vi) Map of Subunit FL–18B is presented at paragraph (107)(ii) of this entry.

(vii) Subunit FL–18C (Three Rooker Bar) consists of approximately 335 ac (136 ha) of occupied beach and intertidal sandflats habitat on Three Rooker Island in Pinellas County. Three Rooker Island includes shoreline from Hurricane Pass to the northern tip of Three Rooker Island. The landward boundary is the line indicating the beginning of dense vegetation, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands in this subunit are entirely in State ownership (Three Rooker Bar Wildlife Management Area).

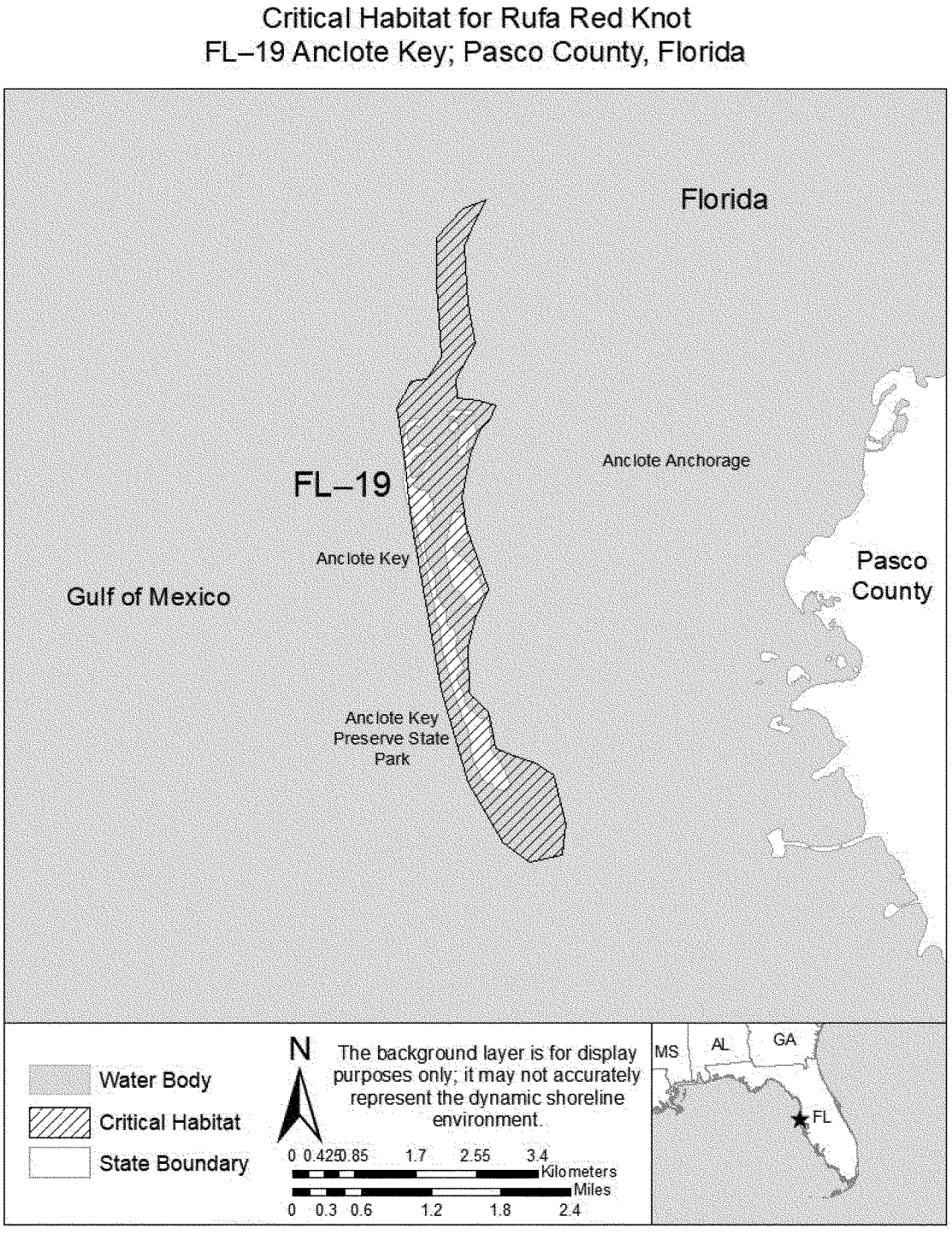
(viii) Map of Subunit FL–18C is presented at paragraph (107)(ii) of this entry.

(108) Unit FL–19: Anclote Key, Florida.

(i) Unit FL–19 consists of approximately 1,547 ac (626 ha) of occupied beach and intertidal sandflats habitat in Pasco County on Anclote Key. The landward boundary is the line indicating the beginning of dense vegetation, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this unit are entirely in State ownership (Anclote Key Preserve State Park).

(ii) Map of Unit FL–19 follows:

Figure 87 to Rufa Red Knot paragraph (108)(ii)

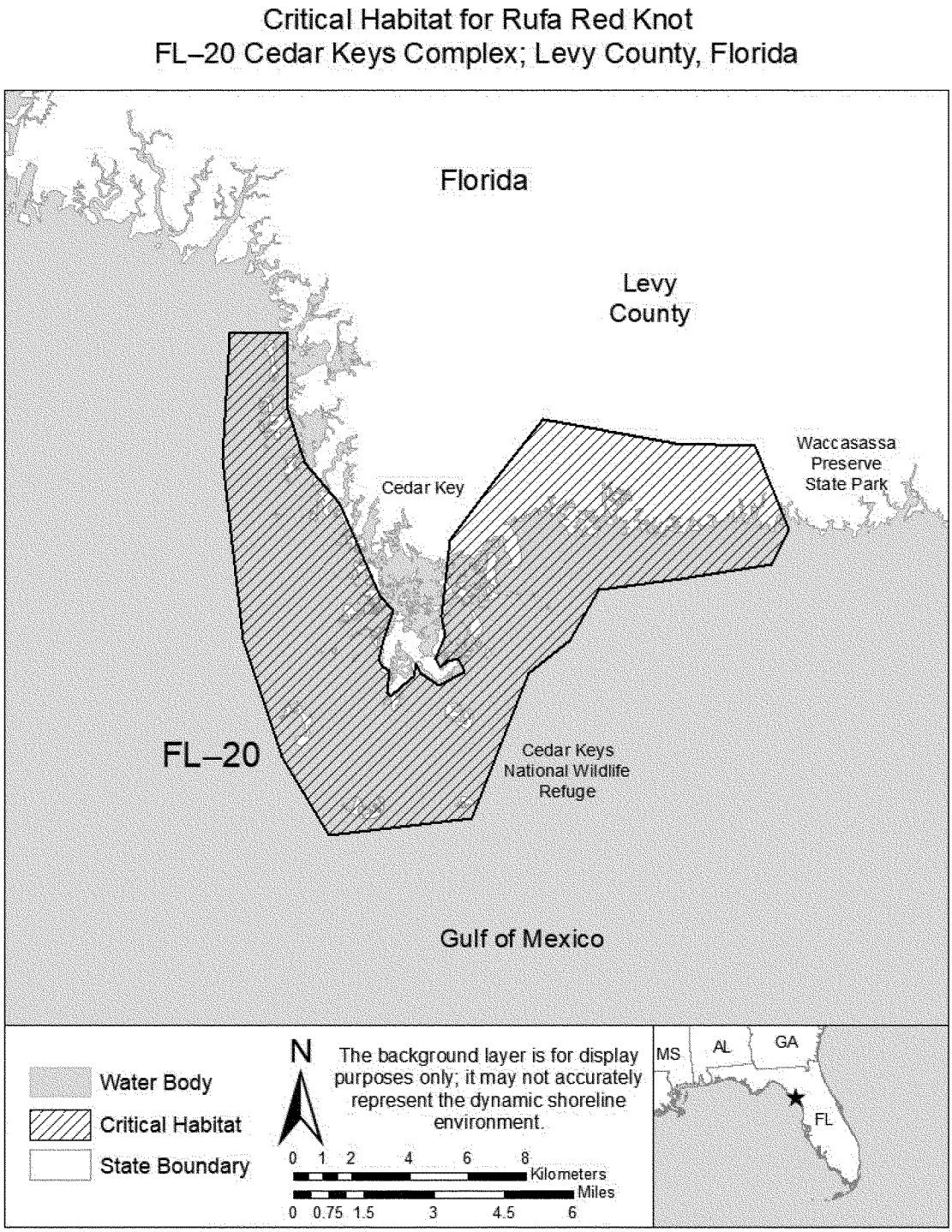


(109) Unit FL–20: Cedar Keys Complex, Florida.

(i) Unit FL–20 consists of approximately 35,626 ac (14,417 ha) of occupied beach and intertidal sandflats habitat in Levy County on Cedar Key, including the complex of sandbars and flats seaward. The landward boundary is the line indicating the beginning of dense vegetation or hardened structures, including emergent, dynamic shoreline to MLLW that is covered at high tide and uncovered at low tide. Lands within this unit include approximately 2,498 ac (1,011 ha) in Federal ownership (Cedar Keys NWR), 7,792 ac (3,153 ha) in State ownership (Waccasassa Preserve State Park), 5,928 ac (2,399 ha) in private/other ownership, and 19,407 ac (7,854 ha) that are uncategorized.

(ii) Map of Unit FL–20 follows:

Figure 88 to Rufa Red Knot paragraph (109)(ii)



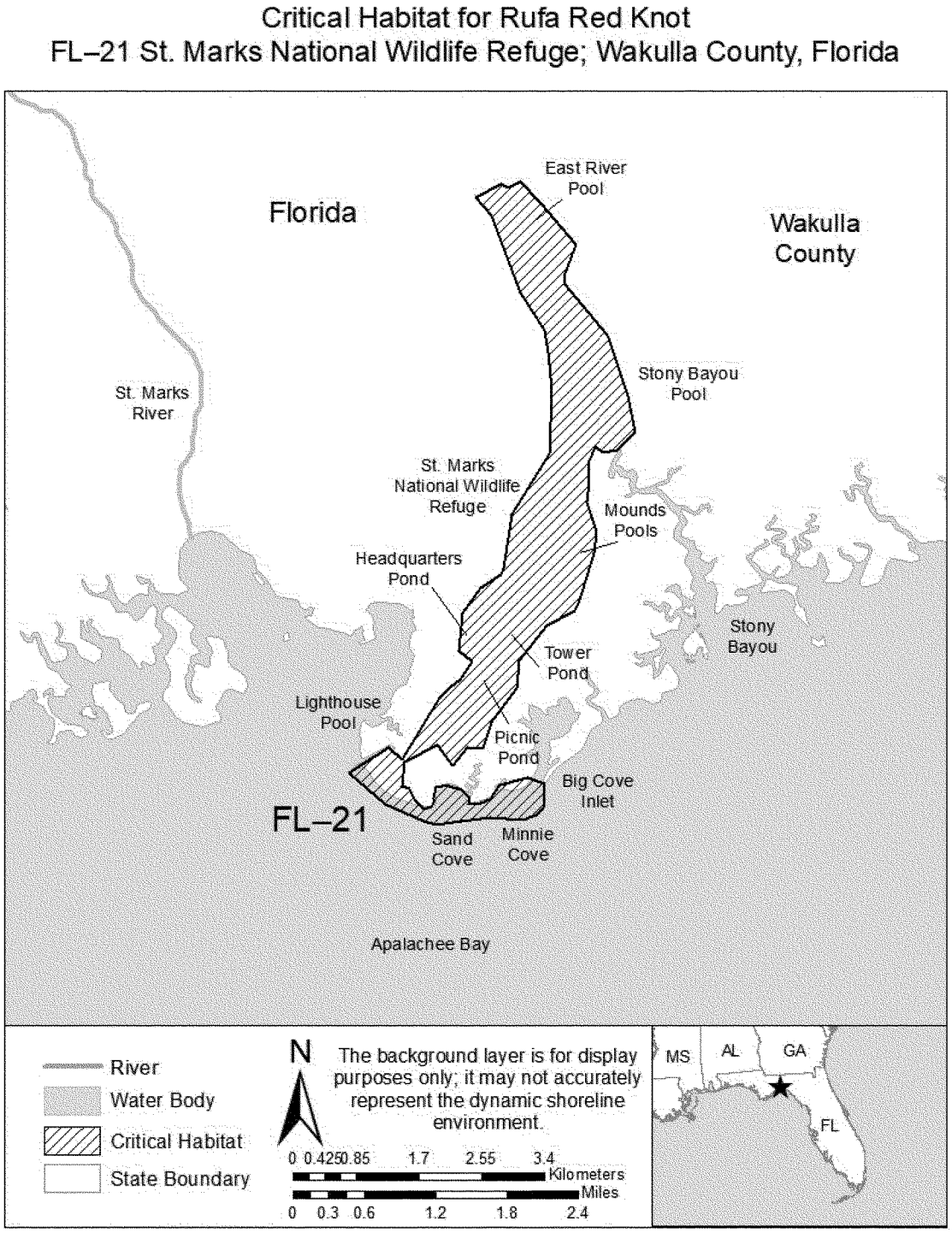
(110) Unit FL–21: St. Marks National Wildlife Refuge, Florida.

(i) Unit FL–21 consists of approximately 2,074 ac (839 ha) of occupied beach, inlets, shoals, intertidal mud, mud flats, and impoundments habitat in Wakulla County. The unit extends from the eastern boundary of Big Cove inlet west to the inlet west of Lighthouse Pool and includes areas to the north up to 1.25 mi (2 km) into East River Pool. This unit includes from the base of the berm road to the lowest water level and areas up to 4 in (10 cm) of water depth within Lighthouse Pool, Picnic Pond, Tower Pond, Headquarters Pond, Mounds Pools 1 and 2, Stoney Bayou Pool 1, and within the open water and emergent marsh portion of East River Pool and all shoals and shoreline habitats within Sand Cove and Minnie Cove. Areas to the east of Lighthouse Road between Lighthouse Pool and Picnic Pond, and areas to the east of Picnic and Tower Ponds that have the physical or biological features, are also included. This unit includes lands from MLLW to the landward limit of the physical or biological features and any ephemeral pools or natural brackish ponds and any emergent sand shoals in Apalachee Bay appearing near shore within 3 mi (4.8 km) of the critical habitat boundary found along the southernmost portion of Lighthouse Road and Lighthouse Levee Trail that

parallels Apalachee Bay. Lands within this unit are entirely in Federal ownership (St. Marks NWR).

(ii) Map of Unit FL–21 follows:

Figure 89 to Rufa Red Knot paragraph (110)(ii)

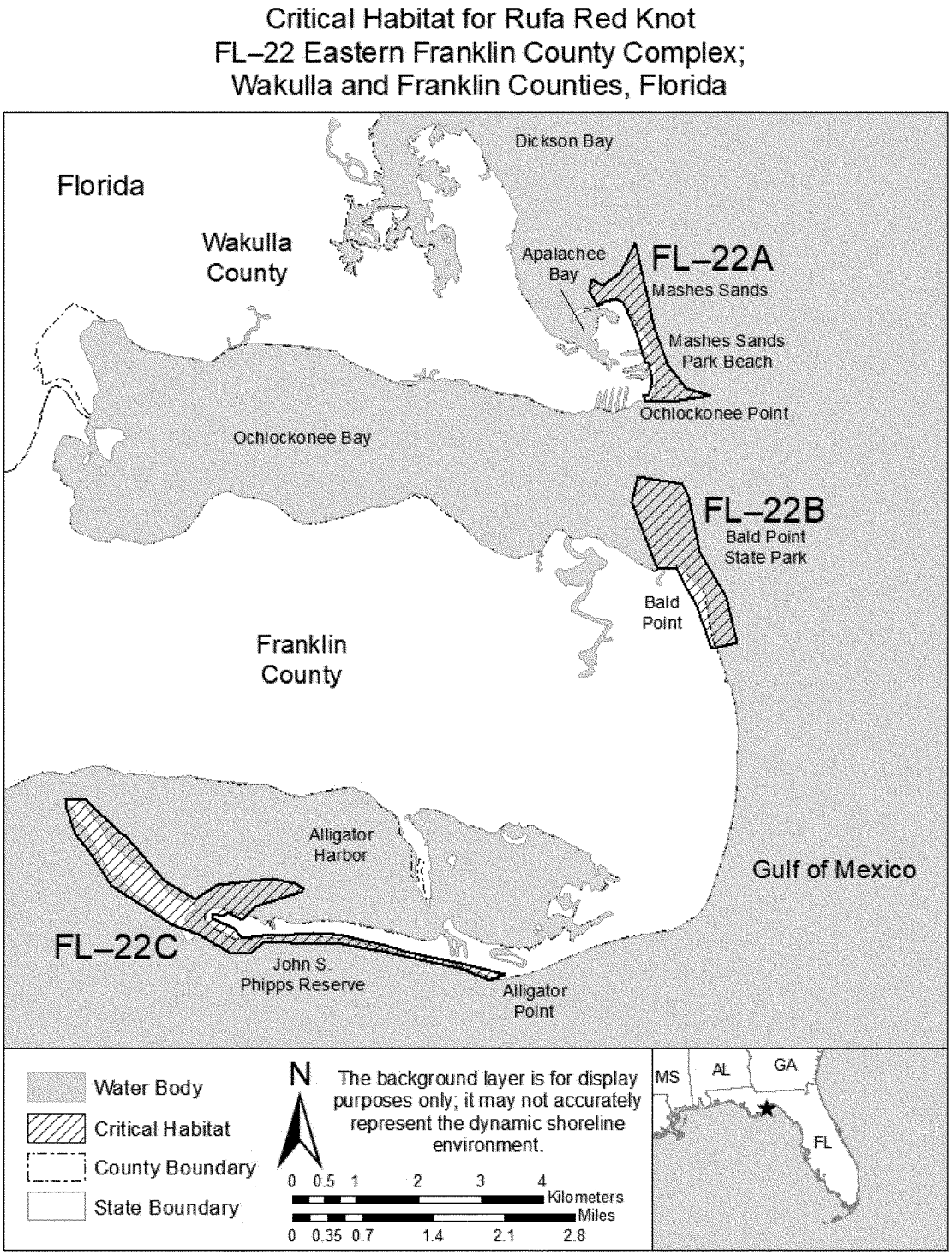


(111) Unit FL–22: Eastern Franklin County Complex, Florida.

(i) Unit FL–22 consists of three subunits comprising 1,429 ac (578 ha) of occupied habitat in Wakulla and Franklin Counties. This unit consists of beaches within the areas of Apalachee Bay, Dickson Bay, Ochlockonee Bay, and Alligator Point.

(ii) Map of Unit FL–22 follows:

Figure 90 to Rufa Red Knot paragraph (111)(ii)



(iii) Subunit FL–22A (Mashes Sands) consists of approximately 262 ac (106 ha) of occupied beach, inlet, shoals, and intertidal sandflats at Mashes Sands Park beach, and the inlet and shoals of Apalachee Bay, Dickson Bay, and Ochlockonee Bay in Wakulla County, from near Ochlockonee Point in Ochlockonee Bay north towards Dickson Bay. This subunit includes lands from MLLW (*i.e.,* highly dynamic beach and intertidal seashore that is covered at high tide and uncovered at low tide) to the landward boundary indicated by the beginning of dense vegetation or hardened structures. This area includes any ephemeral pools, lagoons, or natural brackish ponds and any adjacent or near-shore emergent sand shoals. Lands within this subunit are all in State ownership but leased and managed by Wakulla County.

(iv) Map of Subunit FL–22A is presented at paragraph (111)(ii) of this entry.

(v) Subunit FL–22B (Bald Point State Park) consists of approximately 445 ac (180 ha) of occupied beaches and shoals habitat in Franklin County, from a dirt road 0.35 mi (0.56 km) north of Marlin Street to the north near Bald Point, and including shoals within Ochlockonee Bay approximately 0.9 mi (1.4 km) north

of Bald Point. This subunit includes lands from MLLW (*i.e.,* highly dynamic beach and intertidal seashore that is covered at high tide and uncovered at low tide) to the landward boundary indicated by the beginning of dense vegetation or hardened structures. It includes any ephemeral pools, lagoons, or natural brackish ponds and any adjacent or near-shore emergent sand shoals. Lands within this subunit include approximately 439 ac (178 ha) in State ownership (Bald Point State Park) and 6 ac (2 ha) in private/other ownership.

(vi) Map of Subunit FL–22B is presented at paragraph (111)(ii) of this entry.

(vii) Subunit FL–22C (Alligator Point) consists of approximately 722 ac (292 ha) of occupied beaches at Alligator Point and John S. Phipps Preserve, and shoals in Franklin County, from 0.07 mi (0.11 km) east of Florida Coastal Range Monument 210 west to the shoals associated with the northwestern end of the point. This subunit includes lands from MLLW (*i.e.,* highly dynamic beach and intertidal seashore that is covered at high tide and uncovered at low tide) to the landward boundary indicated by the beginning of dense vegetation or hardened structures. It includes any ephemeral pools, lagoons, or natural brackish ponds and any adjacent or near-shore emergent sand shoals. Lands within this subunit are entirely in private/other ownership (John S. Phipps Preserve, managed by the TNC).

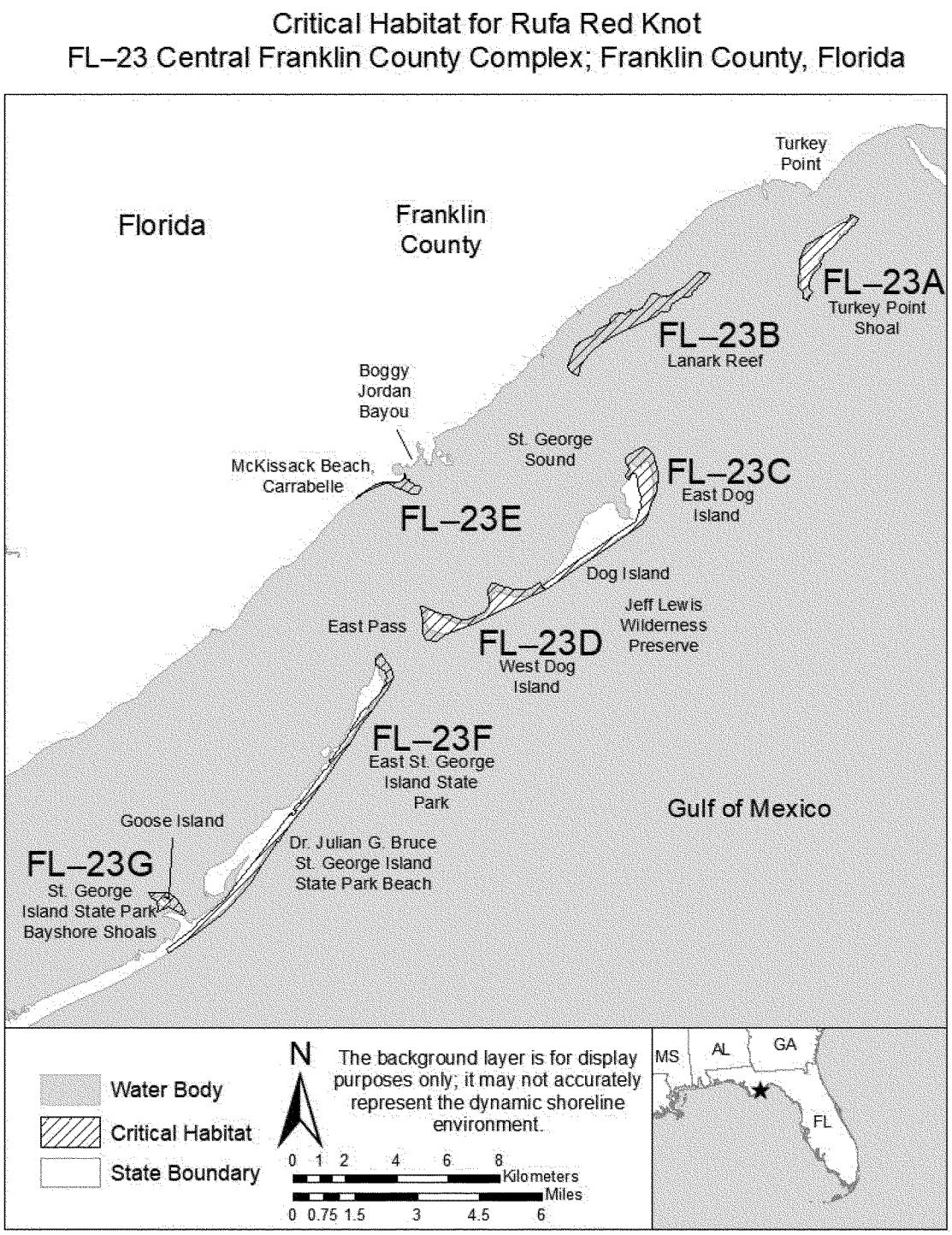
(viii) Map of Subunit FL–22C is presented at paragraph (111)(ii) of this entry.

(112) Unit FL–23: Central Franklin County Complex, Florida.

(i) Unit FL–23 consists of seven subunits comprising 4,175 ac (1,689 ha) of occupied habitat in Franklin County. This unit consists of beaches and barrier island areas of St. George Sound shoreline, the Carrabelle River outlet, Boggy Jordan Bayou outlet, Dog Island, and St. George Island.

(ii) Map of Unit FL–23 follows:

Figure 91 to Rufa Red Knot paragraph (112)(ii)



(iii) Subunit FL–23A (Turkey Point Shoal) consists of approximately 531 ac (215 ha) of occupied habitat, including emergent, isolated shoal habitat within the Gulf of Mexico and St. George Sound, Franklin County. This subunit includes emergent shoals approximately 1 mi (1.5 km) south of Turkey Point. This subunit includes lands from MLLW (*i.e.,* highly dynamic beach and intertidal seashore that is covered at high tide and uncovered at low tide) to the landward limit of the physical or biological features, including any ephemeral pools, lagoons, and emergent sand shoals adjacent to the island or reef. All lands within this subunit are in State ownership.

(iv) Map of Subunit FL–23A is presented at paragraph (112)(ii) of this entry.

(v) Subunit FL–23B (Lanark Reef) consists of approximately 865 ac (350 ha) of occupied beach and intertidal shoreline habitat of Lanark Reef in St. George Sound off the coast of Franklin County. This subunit includes lands from MLLW (*i.e.,* highly dynamic beach and intertidal seashore that is covered at high tide and uncovered at low tide) to the landward limit of the physical or biological features, including any ephemeral pools, lagoons, and emergent sand shoals within 3 mi (4.8 km) of the island or reef. Lands within this subunit include 805 ac (326 ha) in State

ownership and 61 ac (25 ha) in private/other ownership.

(vi) Map of Subunit FL–23B is presented at paragraph (112)(ii) of this entry.

(vii) Subunit FL–23C (East Dog Island) consists of approximately 771 ac (312 ha) of occupied beach shoreline and shoals on East Dog Island off the coast of Franklin County. The subunit is from midway between Florida Coastal Range Monuments 168 and 169 east to the tip of the island and extending around the tip to include St. George Sound shoreline and shoals approximately horizontal to Florida Coastal Range Monument 190. This subunit includes lands from MLLW (*i.e.,* highly dynamic beach and intertidal seashore that is covered at high tide and uncovered at low tide) to the landward boundary indicated by the beginning of dense vegetation or hardened structures, and also includes ephemeral pools, lagoons, natural brackish ponds, and any adjacent or near-shore emergent sand shoals. Lands within this subunit are entirely private/other ownership (including the Jeff Lewis Wilderness Preserve, which is owned/managed by the TNC).

(viii) Map of Subunit FL–23C is presented at paragraph (112)(ii) of this entry.

(ix) Subunit FL–23D (West Dog Island) consists of approximately 751 ac (304 ha) of occupied habitat on West Dog Island in Franklin County. This subunit includes the entirety of this island from the eastern boundary at the Gulf of Mexico shoreline midway between Florida Coastal Range Monuments 168 and 169 and west 3.1 mi (5 km) to East Pass. This subunit includes lands from MLLW (*i.e.,* highly dynamic beach and intertidal seashore that is covered at high tide and uncovered at low tide) to the landward boundary indicated by the beginning of dense vegetation or hardened structures, as well as ephemeral and emergent sand shoals appearing in the near shore. Lands within this subunit are entirely in private/other ownership, including the Jeff Lewis Wilderness Preserve that is owned/managed by the TNC.

(x) Map of Subunit FL–23D is presented at paragraph (112)(ii) of this entry.

(xi) Subunit FL–23E (McKissack Beach, Carrabelle) consists of approximately 117 ac (47 ha) of occupied habitat along McKissack Beach and Marsh in Carrabelle and associated shoals in Franklin County, from 0.18 mi (0.30 km) east of the intersection of U.S. Highway 98 and Cape Street east to the cove that forms the outlet of Boggy Jordan Bayou. This subunit includes lands from MLLW (*i.e.,* highly dynamic beach and intertidal seashore that is covered at high tide and uncovered at low tide) to the landward boundary indicated by the beginning of dense vegetation or hardened structures, as well as any ephemeral and emergent sand shoals appearing in the near shore. Lands within this subunit include 114 ac (46 ha) in State ownership (the Florida Trustees of the Internal Improvement Fund, although the City of Carrabelle retains a lease on McKissack Beach and Marsh), and 3 ac (1 ha) in private/other ownership.

(xii) Map of Subunit FL–23E is presented at paragraph (112)(ii) of this entry.

(xiii) Subunit FL–23F (East St. George Island State Park) consists of approximately 978 ac (396 ha) of occupied habitat within Dr. Julian G. Bruce St. George Island State Park Beach in Franklin County, from Florida Coastal Range Monument 105 to the eastern tip of the island at East Pass. This subunit includes lands from MLLW (*i.e.,* highly dynamic beach and intertidal seashore that is covered at high tide and uncovered at low tide) to the landward boundary indicated by the beginning of dense vegetation or hardened structures. All lands within this subunit are in State ownership (East St. George Island State Park).

(xiv) Map of Subunit FL–23F is presented at paragraph (112)(ii) of this entry.

(xv) Subunit FL–23G (St. George Island State Park and Bayshore Shoals) consists of approximately 162 ac (65 ha) of occupied habitat on Goose Island and associated shoals in Franklin County. This subunit includes lands from MLLW (*i.e.,* highly dynamic beach and intertidal seashore that is covered at high tide and uncovered at low tide) to the landward limit of the physical and biological features, including ephemeral pools, lagoons, and any emergent sand shoals adjacent to the island. All lands within this subunit are in State ownership (St. George Island State Park).

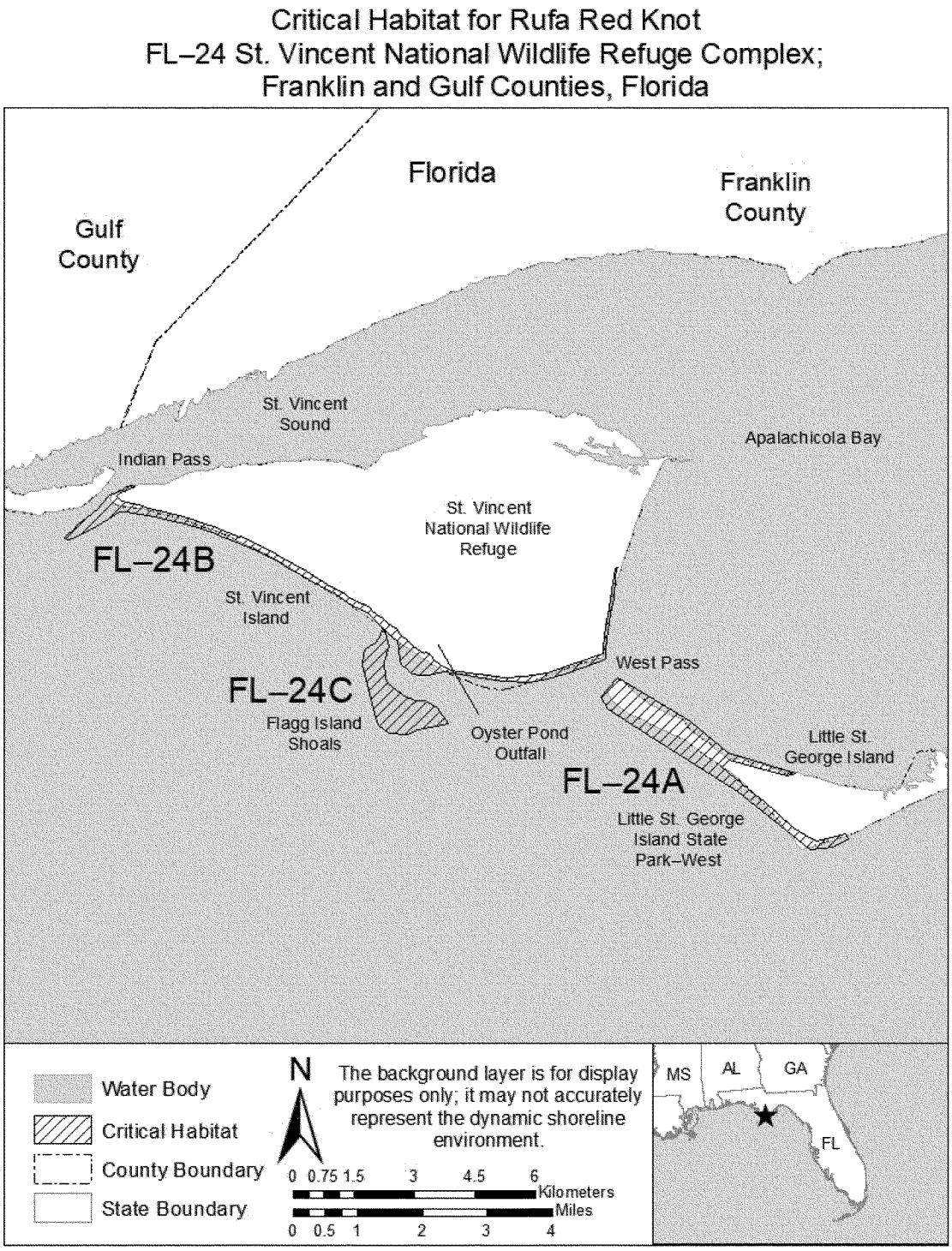
(xvi) Map of Subunit FL–23G is presented at paragraph (112)(ii) of this entry.

(113) Unit FL–24: St. Vincent National Wildlife Refuge Complex, Florida.

(i) Unit FL–24 consists of three subunits comprising 2,212 ac (895 ha) of occupied habitat in Franklin and Gulf Counties. This unit consists of beaches of Apalachicola Bay, St. Vincent Sound, Indian Pass, St. Vincent Island, and Flagg Island.

(ii) Map of Unit FL–24 follows:

Figure 92 to Rufa Red Knot paragraph (113)(ii)



(iii) Subunit FL–24A (Little St. George Island State Park–West) consists of approximately 953 ac (386 ha) of occupied habitat on Little St. George Island beach and shoals in Franklin County, from West Pass east to Florida Coastal Range Monument 25 and including bayside beach from West Pass east to the point at the Marshall Dock. This subunit includes lands from MLLW (*i.e.,* highly dynamic beach and intertidal seashore that is covered at high tide and uncovered at low tide) to the landward boundary indicated by the beginning of dense vegetation or hardened structures, and includes ephemeral pools, natural brackish ponds, and emergent sand shoals appearing in the near shore of the Gulf or Apalachicola Bay. All lands within this subunit are in State ownership (Little St. George Island State Park).

(iv) Map of Subunit FL–24A is presented at paragraph (113)(ii) of this entry.

(v) Subunit FL–24B (St. Vincent National Wildlife Refuge) consists of approximately 742 ac (300 ha) of occupied beach and shoals habitat on the St. Vincent NWR in Franklin and Gulf Counties, from the Refuge boat house at the confluence of St. Vincent Sound and Indian Pass east to 0.60 mi

(0.96 km) north of Shell Road. This subunit includes lands from MLLW (*i.e.,* highly dynamic beach and intertidal seashore that is covered at high tide and uncovered at low tide) to the landward boundary indicated by the beginning of dense vegetation or hardened structures, including ephemeral pools, natural brackish ponds, and emergent sand shoals appearing in the near shore of the Gulf. Lands within this subunit are all in Federal ownership (St. Vincent NWR).

(vi) Map of Subunit FL–24B is presented at paragraph (113)(ii) of this entry.

(vii) Subunit FL–24C (Flagg Island Shoals) consists of approximately 517 ac (209 ha) of occupied habitat that encompasses the entire ebb-tidal delta referred to as Flagg Island off the southernmost tip of St. Vincent Island (near Oyster Pond outfall) in Franklin County. This subunit includes lands from MLLW (*i.e.,* highly dynamic beach and intertidal seashore that is covered at high tide and uncovered at low tide) to the landward limit of the physical or biological features, including ephemeral pools, natural brackish ponds, and emergent sand shoals. All lands within this subunit (which constantly change in size and shape due to the dynamic nature of the area) are in State ownership.

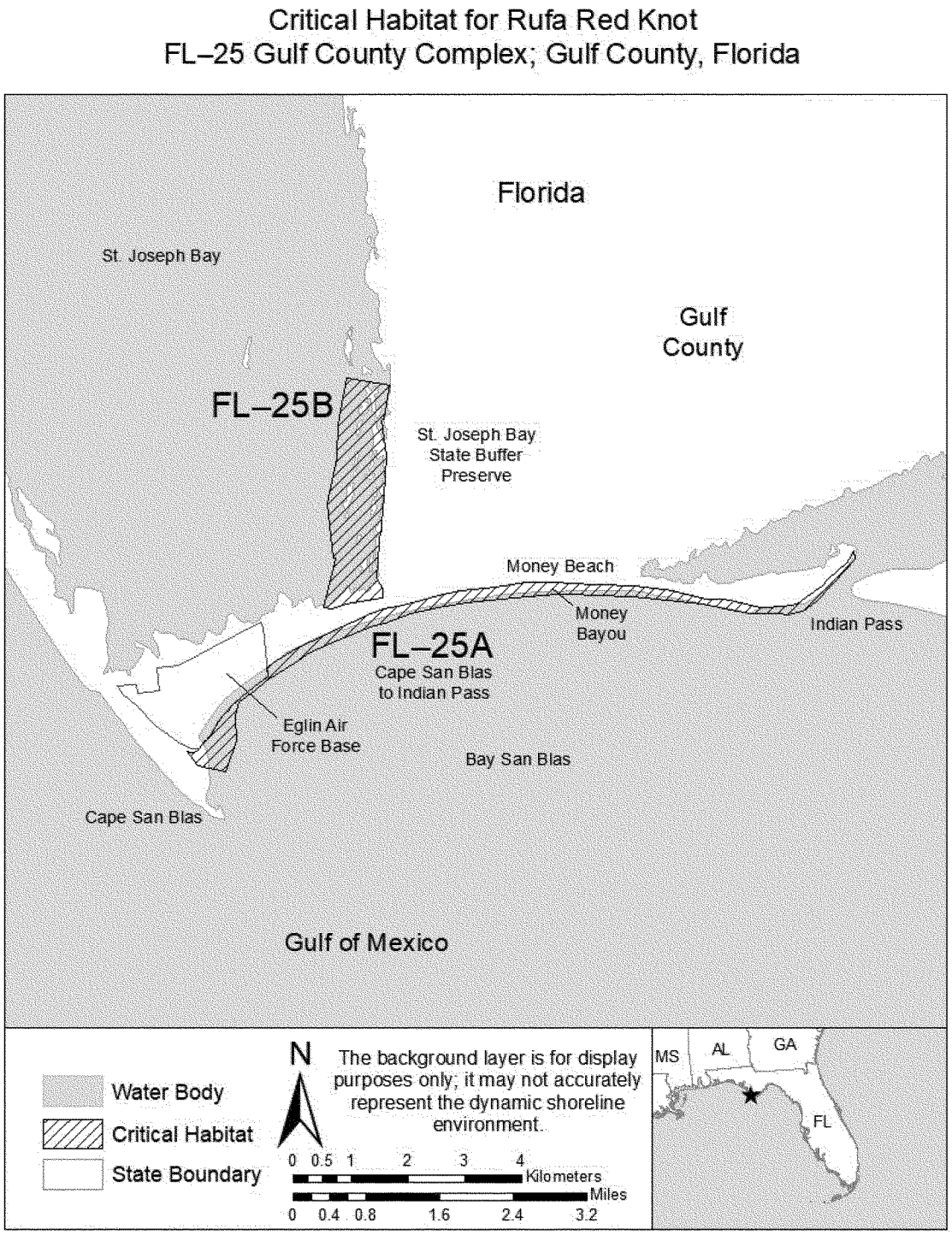
(viii) Map of Subunit FL–24C is presented at paragraph (113)(ii) of this entry.

(114) Unit FL–25: Gulf County Complex, Florida.

(i) Unit FL–25 consists of two subunits comprising 1,520 ac (616 ha) of occupied habitat in Gulf County. This unit consists of beaches of Cape San Blas, Money, and Indian Pass, and the southeastern portion of St. Joseph Bay.

(ii) Map of Unit FL–25 follows:

Figure 93 to Rufa Red Knot paragraph (114)(ii)



(iii) Subunit FL–25A (Cape San Blas to Indian Pass) consists of approximately 620 ac (251 ha) of occupied beach habitat at Cape San Blas, Money Bayou, and Indian Pass beaches in Gulf County, from the southwestern point of Cape San Blas to 0.11 mi (0.18 km) northeast of the Indian Pass Beach Boat Ramp. This subunit includes lands from MLLW (*i.e.,* highly dynamic beach and intertidal seashore that is covered at high tide and uncovered at low tide) to the landward limit of the physical or biological features, including ephemeral pools, natural brackish ponds, and emergent sand shoals in the near shore. Lands within this subunit include 133 ac (54 ha) in State ownership and 486 ac (197 ha) in private/other ownership. Adjacent Federal lands under Eglin Air Force Base jurisdiction are exempt under section 4(a)(3) of the Act, but the shoal and any emergent shoal formations that appear along the shoreline are considered part of this unit, starting from the MLLW south and up 0.5 mi (0.81 km) from Eglin Air Force Base lands on the southernmost side of Cape San Blas.

(iv) Map of Subunit FL–25A is presented at paragraph (114)(ii) of this entry.

(v) Subunit FL–25B (St. Joseph Bay–Eastern Shore) consists of approximately 827 ac (335 ha) of

occupied beaches and shoals within the southeastern portion of St. Joseph Bay in Gulf County, from 0.09 mi (0.14 km) east of the intersection of County Road 30A and Cape San Blas Road to the west 0.66 mi (1.1 km) and to the north 2.4 mi (3.8 km). This subunit includes lands from MLLW (*i.e.,* highly dynamic beach and intertidal seashore that is covered at high tide and uncovered at low tide) to the landward limit of the physical or biological features, including ephemeral pools, natural brackish ponds, lagoons, and emergent sand shoals in the near shore. Lands within this subunit include 761 ac (308 ha) in State ownership (St. Joseph Bay State Buffer Preserve) and 66 ac (27 ha) in private/other ownership.

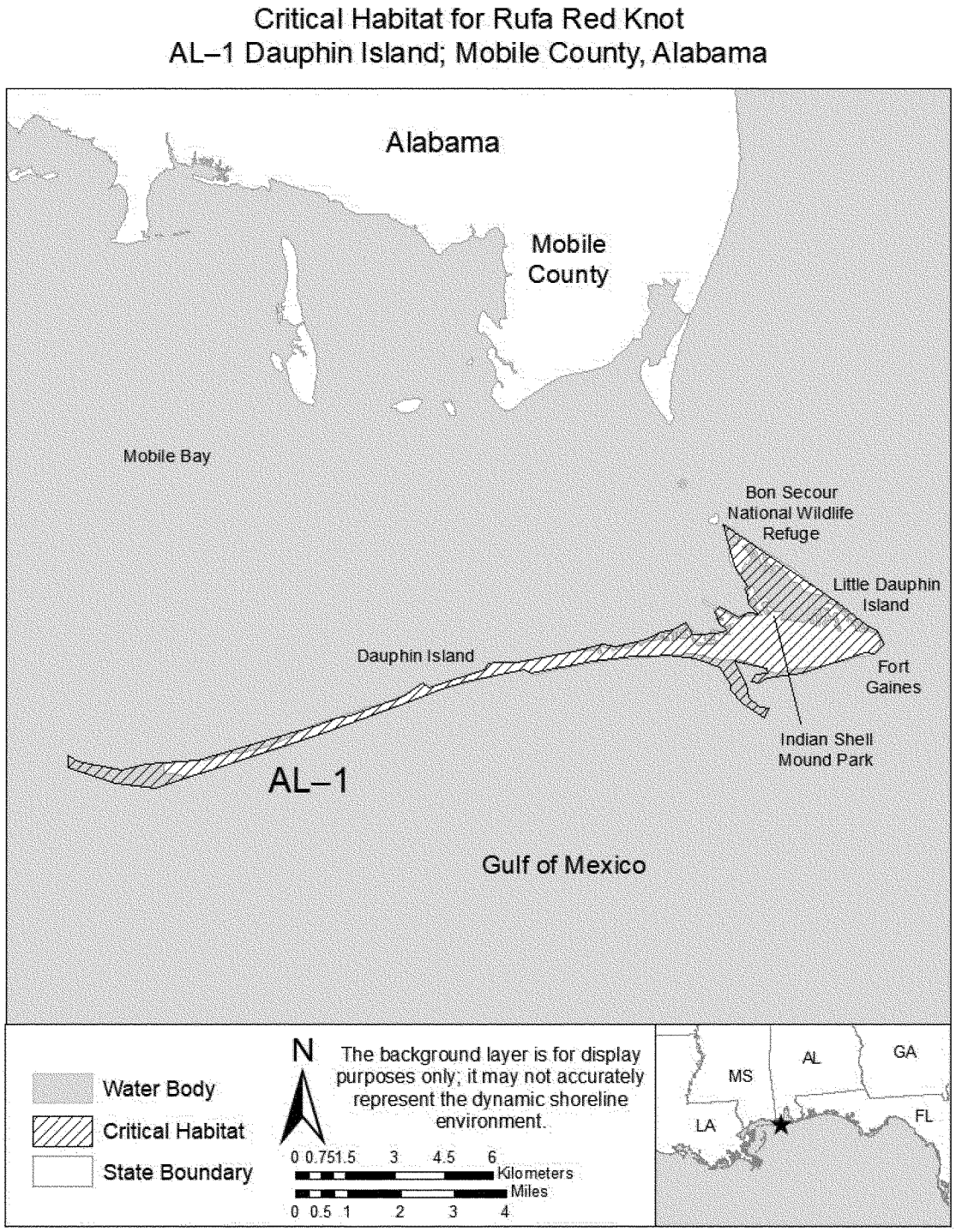
(vi) Map of Subunit FL–25B is presented at paragraph (114)(ii) of this entry.

(115) Unit AL–1: Dauphin Island, Alabama.

(i) Unit AL–1 consists of approximately 5,167 ac (2,091 ha) of occupied habitat on Dauphin Island, a barrier island south of Mobile Bay in Mobile County. The unit includes all of Dauphin Island from the historic 19th Century Fort Gaines site on the eastern side of the island, continuing approximately 16 mi (26 km) west to the MLLW on the westernmost tip, and all of Little Dauphin Island (which is uninhabited) to MLLW. Lands within this unit include approximately 484 ac (196 ha) in Federal ownership (Bon Secour NWR), 848 ac (343 ha) in State ownership (Shell Mound Park or Indian Mound Park, and a newly acquired habitat conservation area on the west end of the island), and 3,834 ac (1,552 ha) in private/other ownership.

(ii) Map of Unit AL–1 follows:

Figure 94 to Rufa Red Knot paragraph (115)(ii)

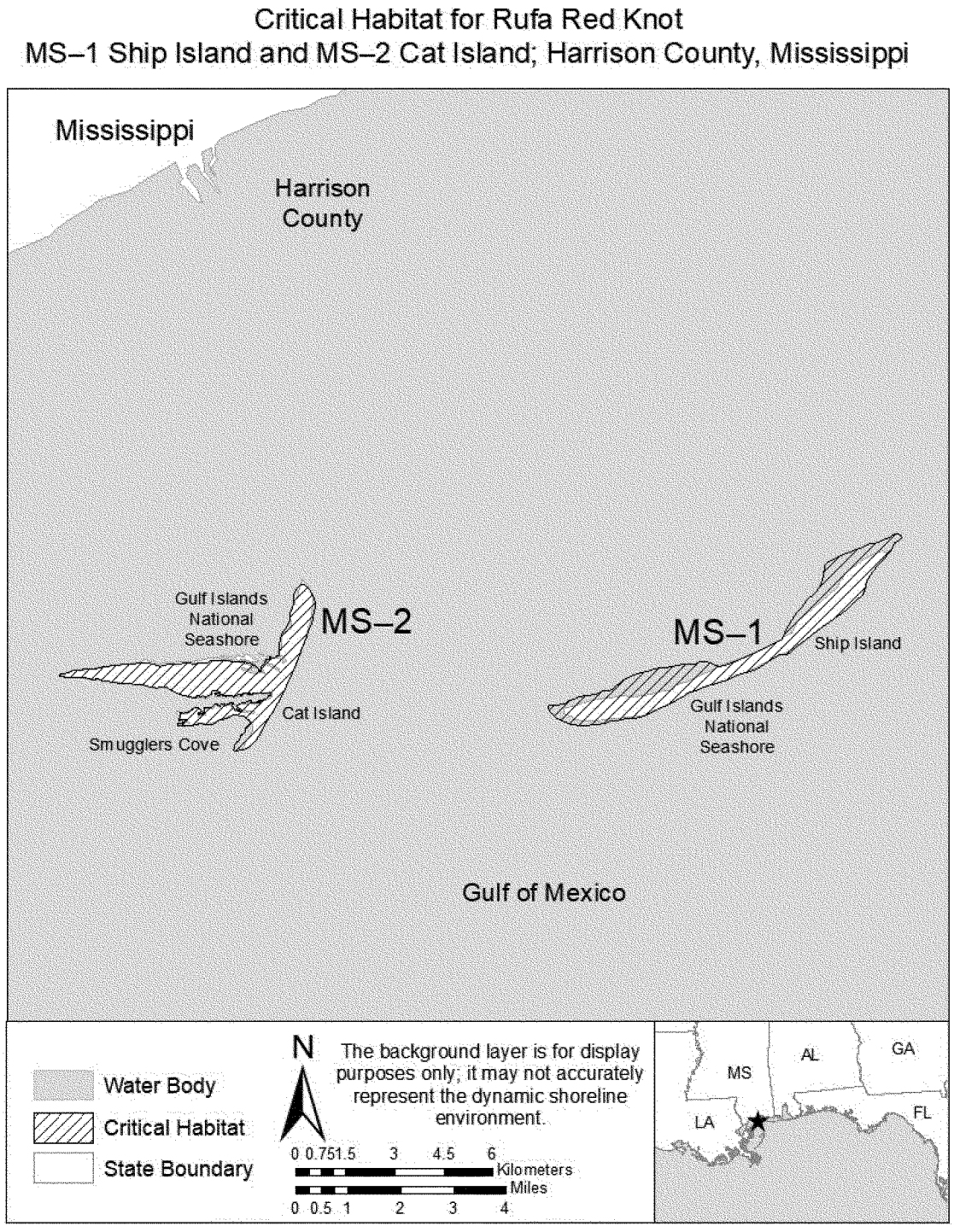


(116) Unit MS–1: Ship Island, Mississippi.

(i) Unit MS–1 consists of approximately 2,452 ac (993 ha) of occupied habitat on Ship Island in Harrison County. The unit consists of emergent lands and intertidal area to MLLW on the island and its adjacent sand shoals (*i.e.,* highly dynamic beaches and intertidal seashore that is covered at high tide and uncovered at low tide). This unit is all under Federal ownership (Gulf Islands National Seashore).

(ii) Map of Unit MS–1 follows:

Figure 95 to Rufa Red Knot paragraph (116)(ii)



(117) Unit MS–2: Cat Island, Mississippi.

(i) Unit MS–2 consists of approximately 2,121 ac (858 ha) of occupied habitat on Cat Island in Harrison County. This unit consists of emergent lands and intertidal area to MLLW on Cat Island and its adjacent sand shoals (*i.e.,* highly dynamic beaches and intertidal seashore that is covered at high tide and uncovered at low tide). Lands within this unit include approximately 686 ac (278 ha) in Federal ownership (Gulf Islands National Seashore), 1,305 ac (528 ha) in State ownership, and 129 ac (52 ha) in private/other ownership.

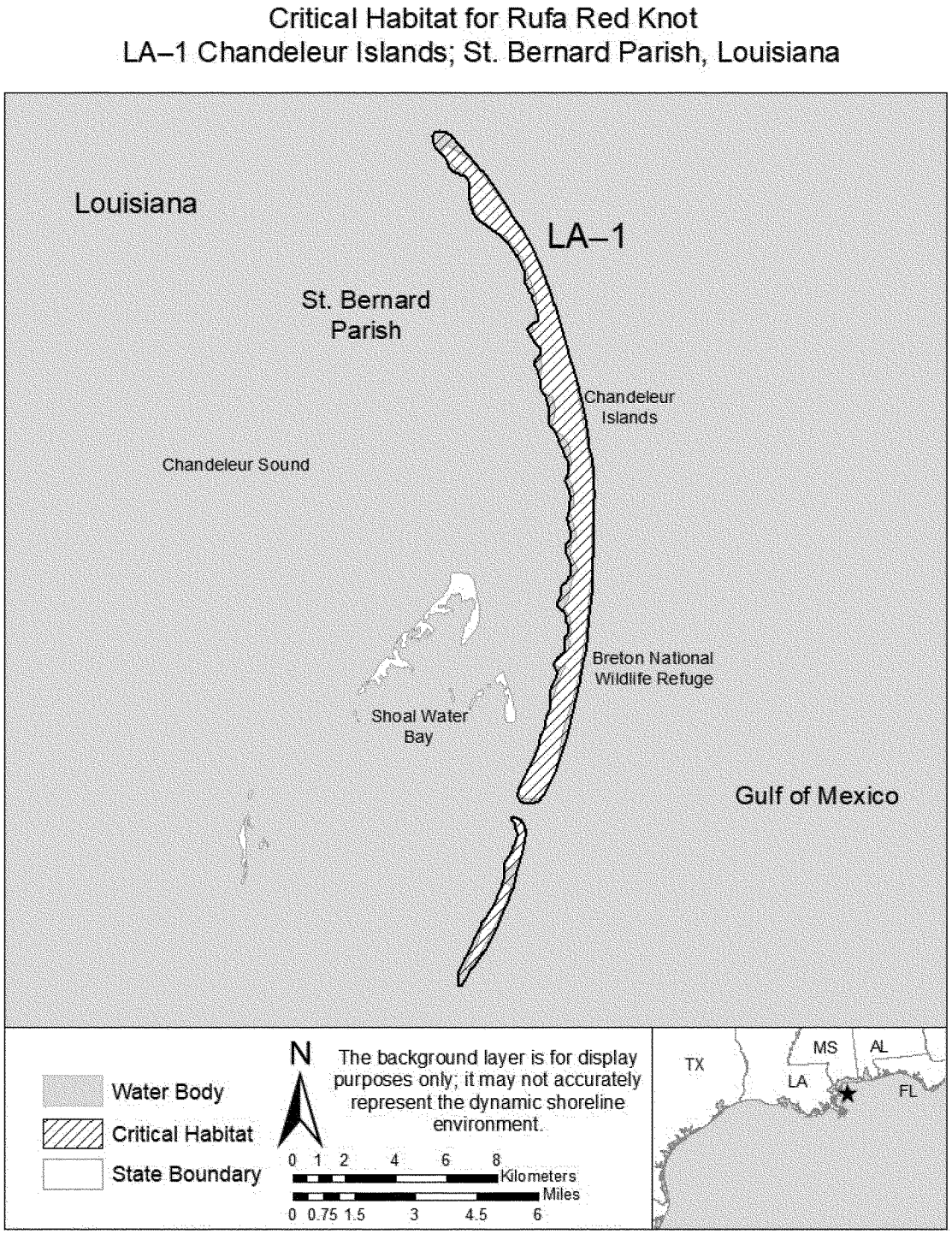
(ii) Map of Unit MS–2 is presented at paragraph (116)(ii) of this entry.

(118) Unit LA–1: Chandeleur Islands, Louisiana.

(i) Unit LA–1 consists of approximately 7,632 ac (3,088 ha) of occupied habitat in St. Bernard Parish. The unit includes all emergent lands to MLLW on the Chandeleur Islands and their adjacent sand shoals (*i.e.,* highly dynamic beaches and intertidal seashore that is covered at high tide and uncovered at low tide). All lands in this unit are federally owned (Breton NWR, and designated wilderness area created as a refuge and breeding ground for resident and migratory birds).

(ii) Map of Unit LA–1 follows:

Figure 96 to Rufa Red Knot paragraph (118)(ii)



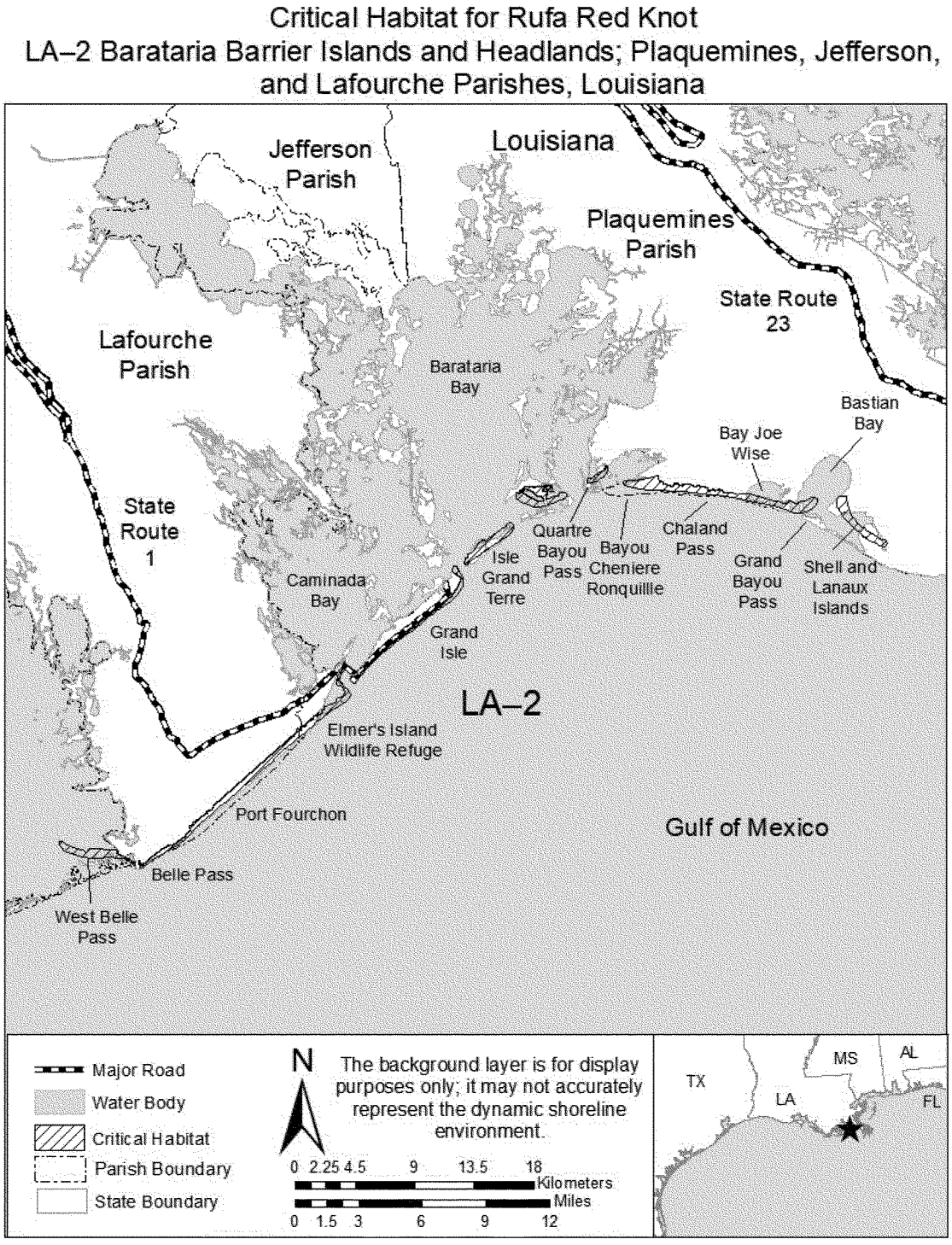
(119) Unit LA–2: Barataria Barrier Islands and Headlands, Louisiana.

(i) Unit LA–2 consists of approximately 7,795 ac (3,155 ha) of occupied habitat within Plaquemines, Jefferson, and Lafourche Parishes, including emergent lands and/or sand shoals to MLLW (*i.e.,* highly dynamic beaches and intertidal seashore that is covered at high tide and uncovered at low tide). This unit includes: Emergent lands of Lanaux and Shell Islands to MLLW in Plaquemines Parish; emergent sand shoals of Grand Bayou Pass in Plaquemines Parish; the Gulf of Mexico shoreline to MLLW between Grand Bayou Pass and Quatre Bayou Pass (known as the Chaland Headland and Chenier Ronquille); emergent sand shoals of Bastian Bay, Bay Joe Wise, Chaland Pass, and Bayou Cheniere Ronquille in Plaquemines Parish; all emergent lands of the Grand Terre Islands and adjacent unnamed island to

MLLW between Quatre Bayou Pass and Barataria Pass in Plaquemines and Jefferson Parishes; the Gulf of Mexico shoreline of Grand Isle from the toe of the Gulf-side hurricane protection levee to MLLW in Jefferson Parish; the west side of the Caminada Pass shoreline and the Gulf of Mexico shoreline to MLLW beginning just north of Louisiana Highway 1 in Caminada Pass extending approximately 15 mi (24 km) westward to the east side of Belle Pass (known as the Caminada Headland, which includes the Louisiana Department of Wildlife and Fisheries' Elmer's Island Wildlife Refuge) in Jefferson and Lafourche Parishes; and all emergent lands of the West Belle Pass peninsula to the MLLW. Lands within this unit include approximately 126 ac (51 ha) in State ownership (Grand Isle State Park and Elmer's Island Wildlife Refuge) and 7,669 ac (3,104 ha) in private/other ownership.

(ii) Map of Unit LA–2 follows:

Figure 97 to Rufa Red Knot paragraph (119)(ii)

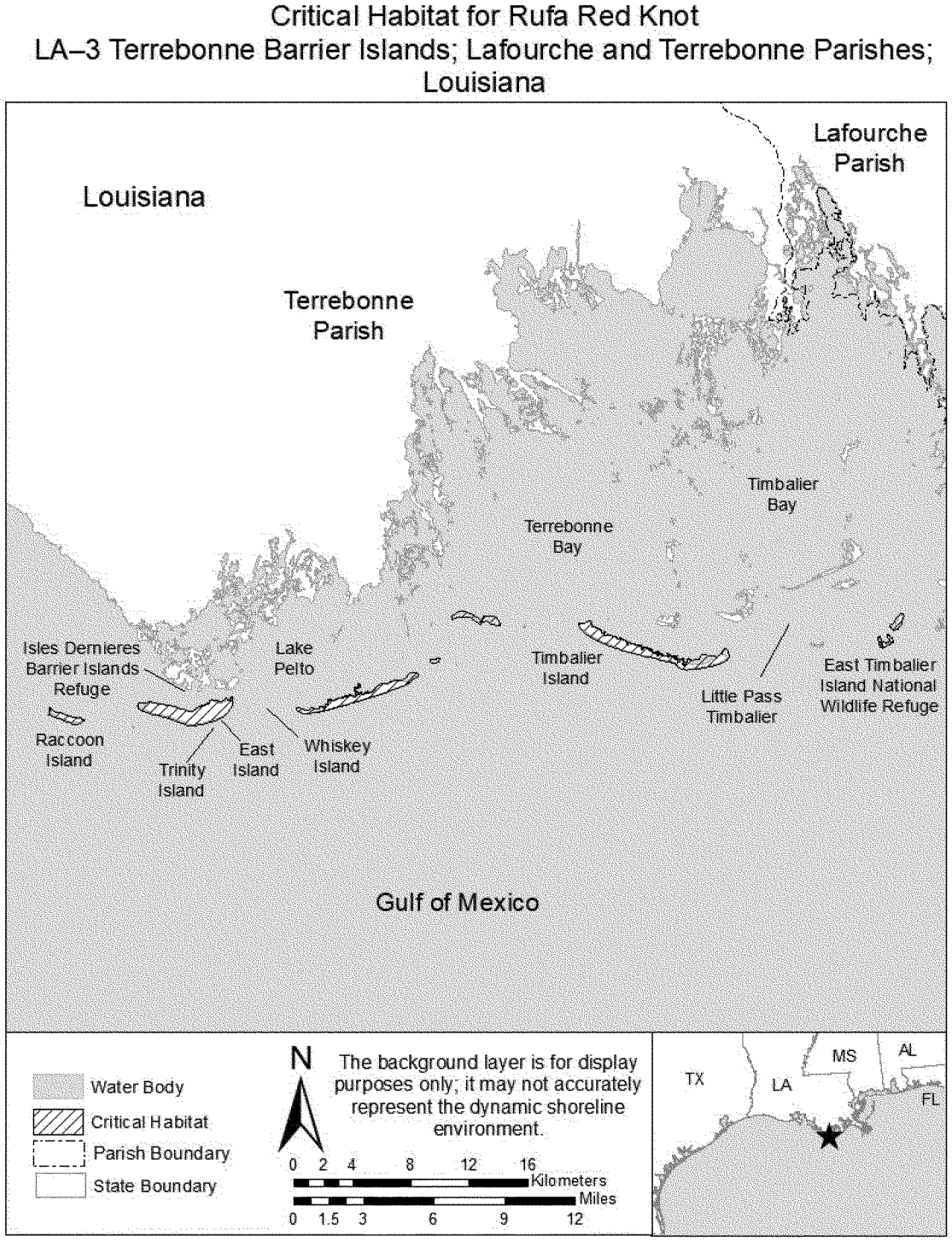


(120) Unit LA–3: Terrebonne Barrier Islands, Louisiana.

(i) Unit LA–3 consists of approximately 5,072 ac (2,052 ha) of occupied habitat within Lafourche and Terrebonne Parishes, including emergent lands and/or sand shoals to MLLW (*i.e.,* highly dynamic beaches and intertidal seashore that is covered at high tide and uncovered at low tide). This unit includes: Emergent lands on East Timbalier Island in Lafourche Parish; emergent sand shoals at Little Pass Timbalier in Jefferson Parish; emergent lands of Timbalier Island (also known as Big or West Timbalier Island) in Terrebonne Parish; and emergent lands and associated sand shoals on East, Trinity, Whiskey, and Raccoon Islands (known as the Louisiana Department of Wildlife and Fisheries Isles Dernieres Barrier Islands Refuge) in Terrebonne Parish. Lands within this unit include approximately 2,900 ac (1,173 ha) in State ownership (Isles Dernieres Barrier Islands Refuge) and 2,172 ac (879 ha) in private/other ownership.

(ii) Map of Unit LA–3 follows:

Figure 98 to Rufa Red Knot paragraph (120)(ii)

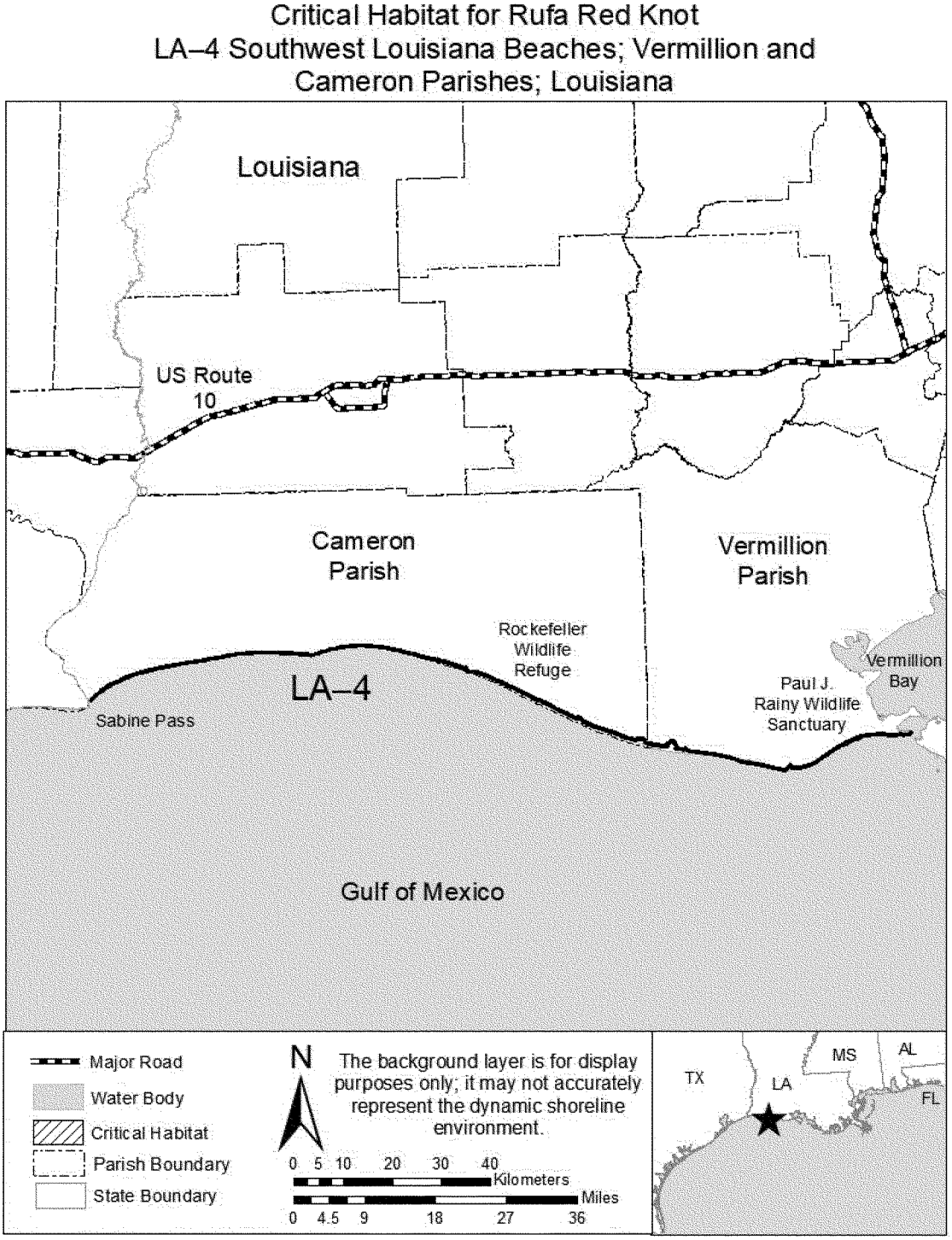


(121) Unit LA–4: Southwest Louisiana Beaches, Louisiana.

(i) Unit LA–4 consists of approximately 6,130 ac (2,481 ha) of occupied habitat within Cameron and Vermillion Parishes. The unit includes land along the Gulf of Mexico shoreline to the MLLW (*i.e.,* highly dynamic intertidal seashore that is covered at high tide and uncovered at low tide) from the eastern Vermilion Parish line starting at the eastern boundary of the Audubon Society's Paul J. Rainey Wildlife Sanctuary, extending approximately 128 mi (206 km) westward and terminating at Louisiana Point, and also including its associated sand/mud shoals on the east side of Sabine Pass in Cameron Parish. Along its entire length, the unit includes the shoreline beach from the MLLW line landward to the edge of where dense vegetation begins. Lands within this unit include approximately 1,497 ac (606 ha) in State ownership (Rockefeller Wildlife Refuge) and 4,633 ac (1,875 ha) in private/other ownership (including the Paul J. Rainey Wildlife Sanctuary, managed by the Audubon Society).

(ii) Map of Unit LA–4 follows:

Figure 99 to Rufa Red Knot paragraph (121)(ii)

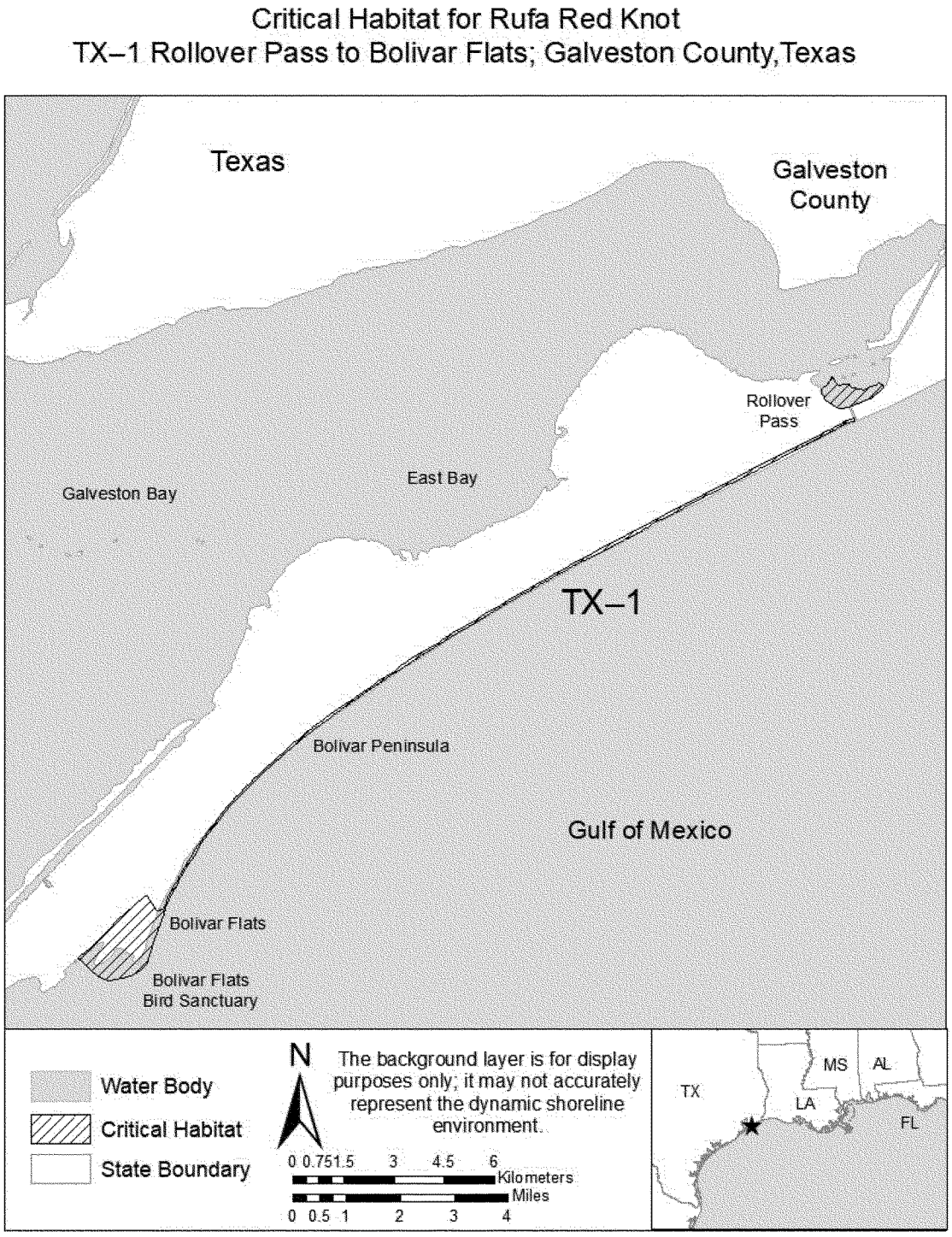


(122) Unit TX–1: Rollover Pass to Bolivar Flats, Texas.

(i) Unit TX–1 consists of approximately 1,478 ac (598 ha) of occupied habitat in Galveston County. This unit begins bayside of Rollover Pass and extends southwest along the beachfront ending at the north jetty on the Bolivar Peninsula. It includes 17 mi (27 km) of Gulf shoreline. The landward boundary is the line indicating the beginning of dense vegetation, and the gulfside boundary is the MLLW, including emergent lands and intertidal area characterized as highly dynamic beach/seashore that is covered at high tide and uncovered at low tide. The bayside of Rollover Pass and west end of the unit includes lands known as wind tidal flats that are infrequently inundated. Specific habitat types within this unit include: estuarine (bayside) seagrass mud or sand flats that are subtidal, seagrass flats that are nearly flat areas with rooted vascular plants (seagrass) growing below the water surface in subtidal mud or sand substrate; estuarine (bayside) sandy shore (beach/sandbar) rarely exposed due to tidal fluctuation; estuarine (bayside) sandy shore (beach/sandbar) that is irregularly or regularly, depending upon the location, inundated by tides; and marine sandy coastline (beach) irregularly or regularly inundated by tides, depending upon the location. Lands within this unit include approximately 482 ac (195 ha) in State ownership and 996 ac (403 ha) in private/other ownership (includes the Bolivar Flats Bird Sanctuary).

(ii) Map of Unit TX–1 follows:

Figure 100 to Rufa Red Knot paragraph (122)(ii)

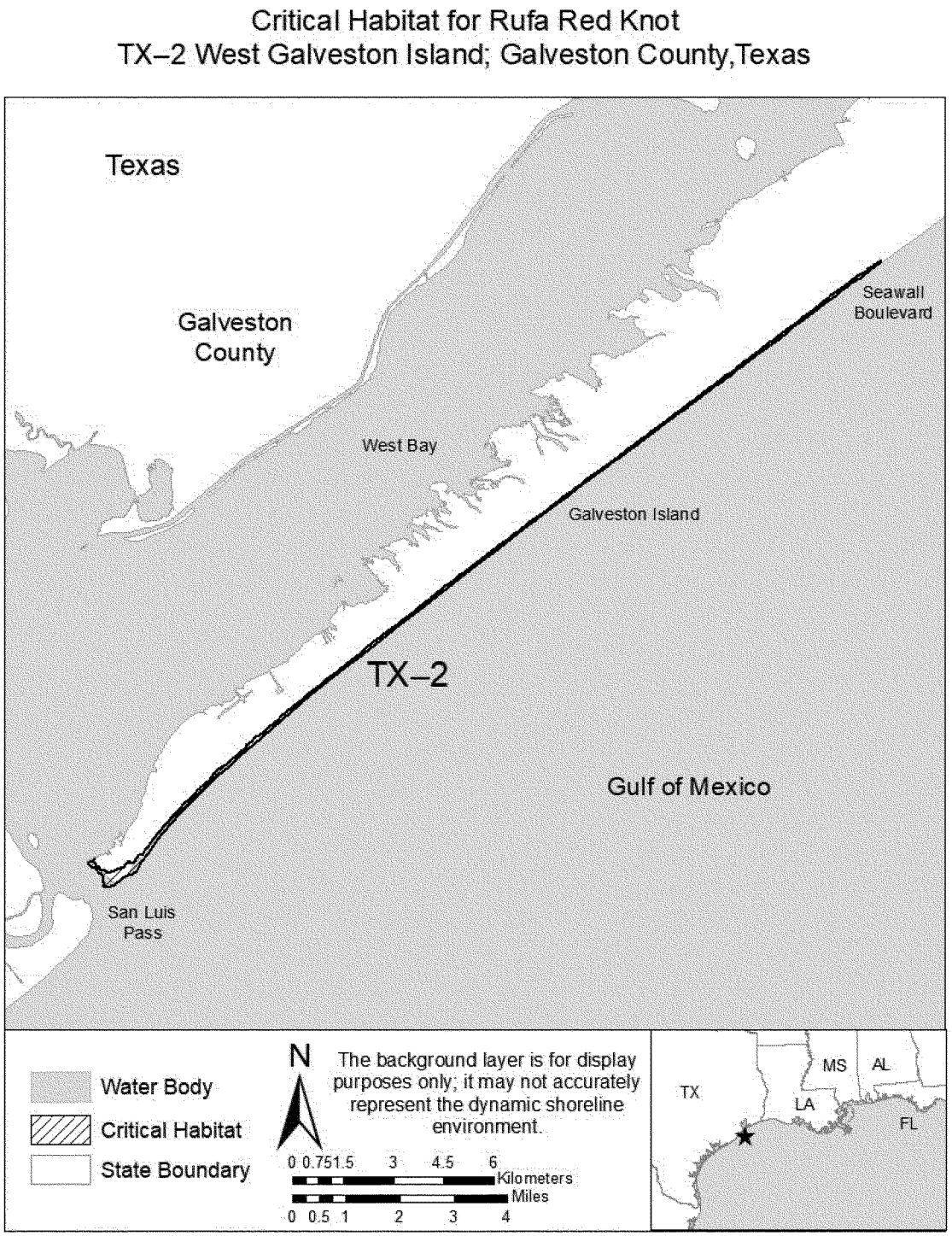


(123) Unit TX–2: West Galveston Island, Texas.

(i) Unit TX–2 consists of approximately 590 ac (239 ha) of occupied habitat in Galveston County. The unit is along the gulf with boundaries from the MLLW up to the vegetation line, including emergent lands and intertidal area characterized as highly dynamic beach/seashore that is covered at high tide and uncovered at low tide. The northeastern boundary is the end of the Seawall Boulevard (end of the seawall), and the southwestern boundary is San Luis Pass. Specific habitat types within this unit include marine sandy coastline beach that is irregularly or regularly inundated by tides, depending upon the location. Lands within this unit include approximately 307 ac (124 ha) in State ownership and 282 ac (114 ha) in private/other ownership.

(ii) Map of Unit TX–2 follows:

Figure 101 to Rufa Red Knot paragraph (123)(ii)

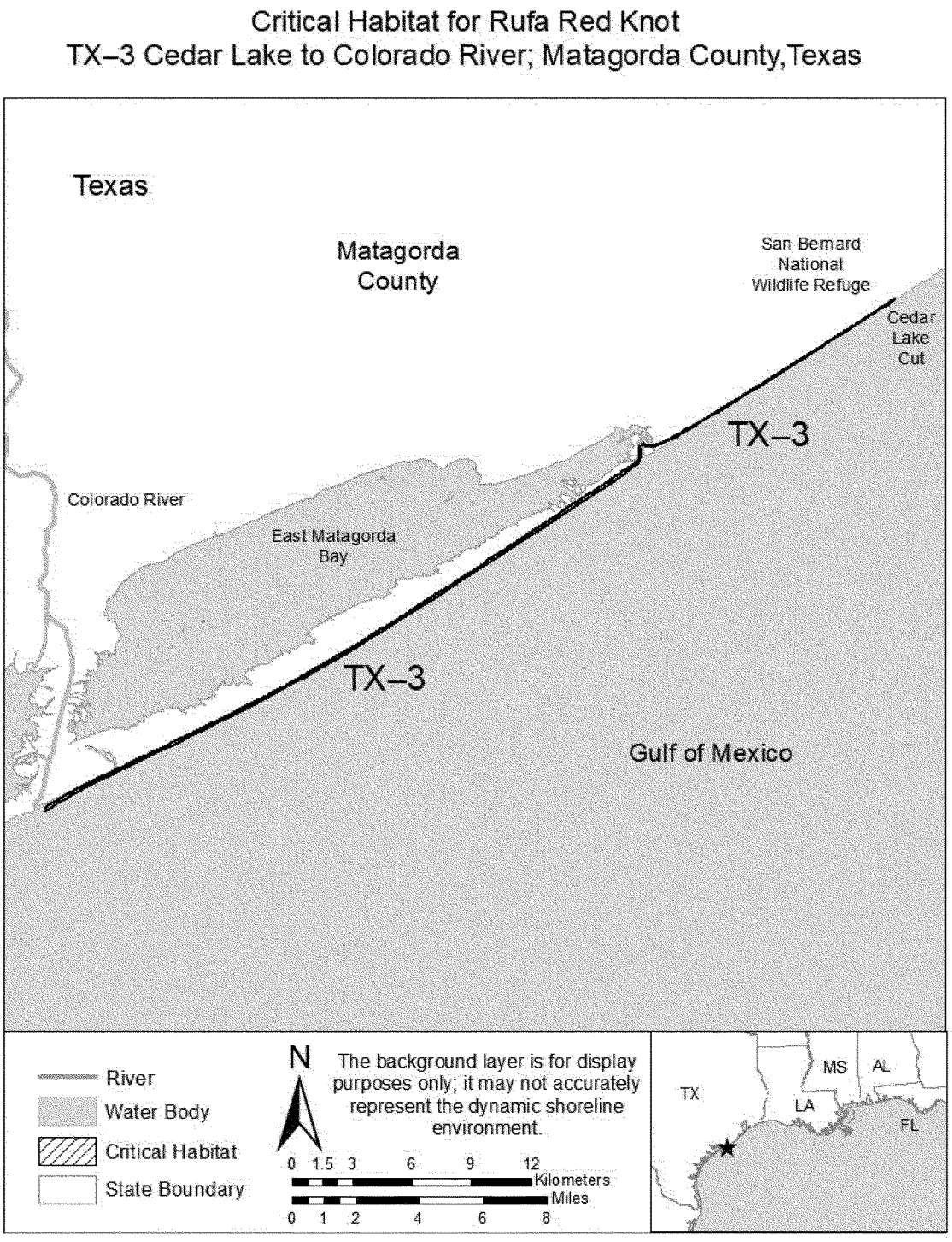


(124) Unit TX–3: Cedar Lake to Colorado River, Texas.

(i) Unit TX–3 consists of approximately 1,204 ac (487 ha) of occupied habitat in Matagorda County. The unit is along the gulf with boundaries from the MLLW up to the vegetation line, including emergent lands and intertidal area characterized as highly dynamic beach/seashore that is covered at high tide and uncovered at low tide. The northeastern boundary is the south side of Cedar Lake Cut, and the southwestern boundary is near the Colorado River. Specific habitat types within this unit include marine sandy coastline beach that is irregularly or regularly inundated by tides, depending upon the location. Lands within this unit include 1,075 ac (435 ha) in State ownership and 128 ac (52 ha) in private/other ownership.

(ii) Map of Unit TX–3 follows:

Figure 102 to Rufa Red Knot paragraph (124)(ii)

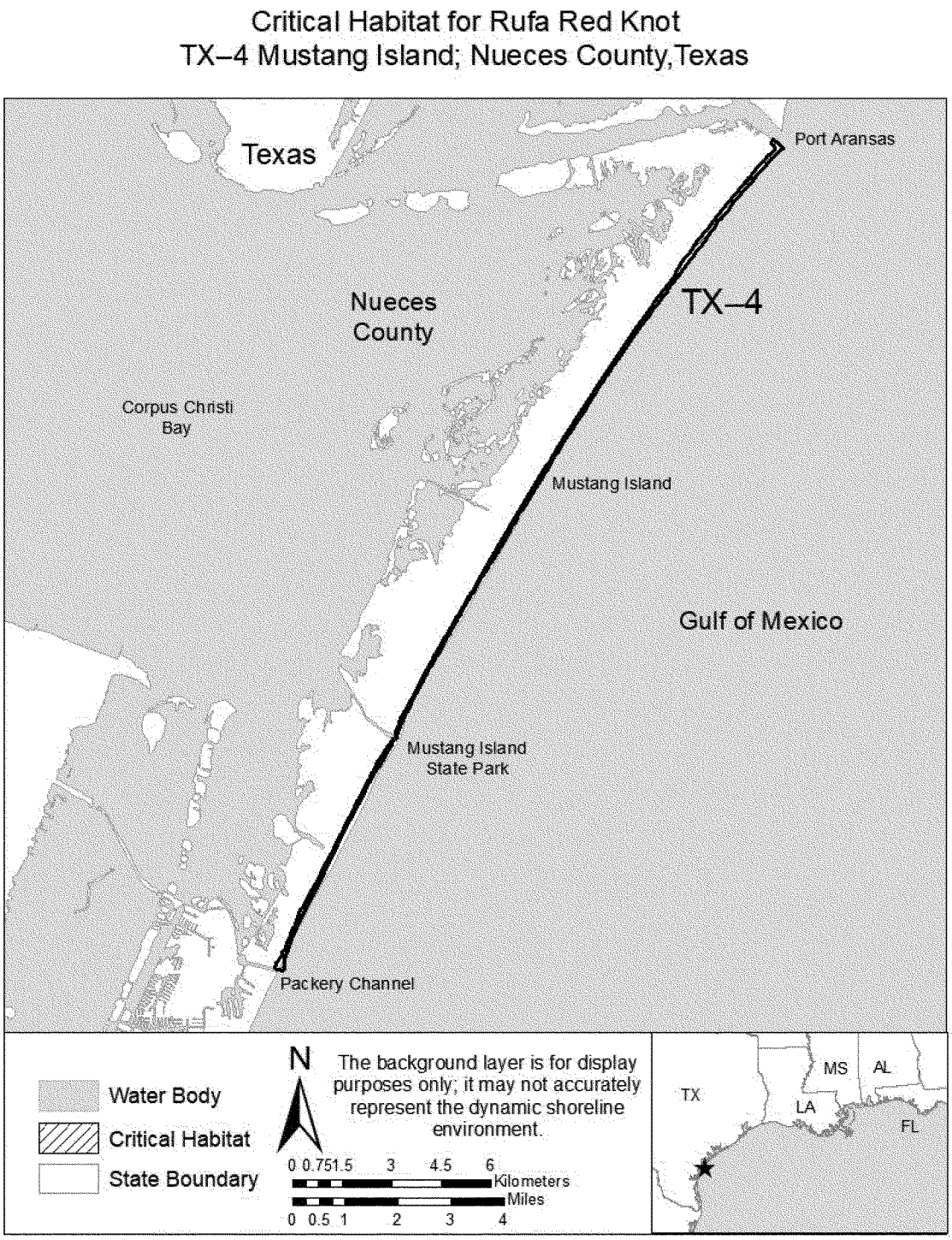


(125) Unit TX–4: Mustang Island, Texas.

(i) Unit TX–4 consists of approximately 648 ac (262 ha) of occupied habitat in Nueces County. The unit is along the gulf with boundaries from the MLLW up to the vegetation line, including emergent lands and intertidal area characterized as highly dynamic beach/seashore that is covered at high tide and uncovered at low tide. The northern boundary is the south jetty at Port Aransas, and the southern boundary is the north jetty of Packery Channel. Specific habitat types within this unit include marine sandy coastline beach that is irregularly or regularly inundated by tides, depending upon the location. Lands within this unit include approximately 395 ac (160 ha) in State ownership and 253 ac (102 ha) in private/other ownership.

(ii) Map of Unit TX–4 follows:

Figure 103 to Rufa Red Knot paragraph (125)(ii)



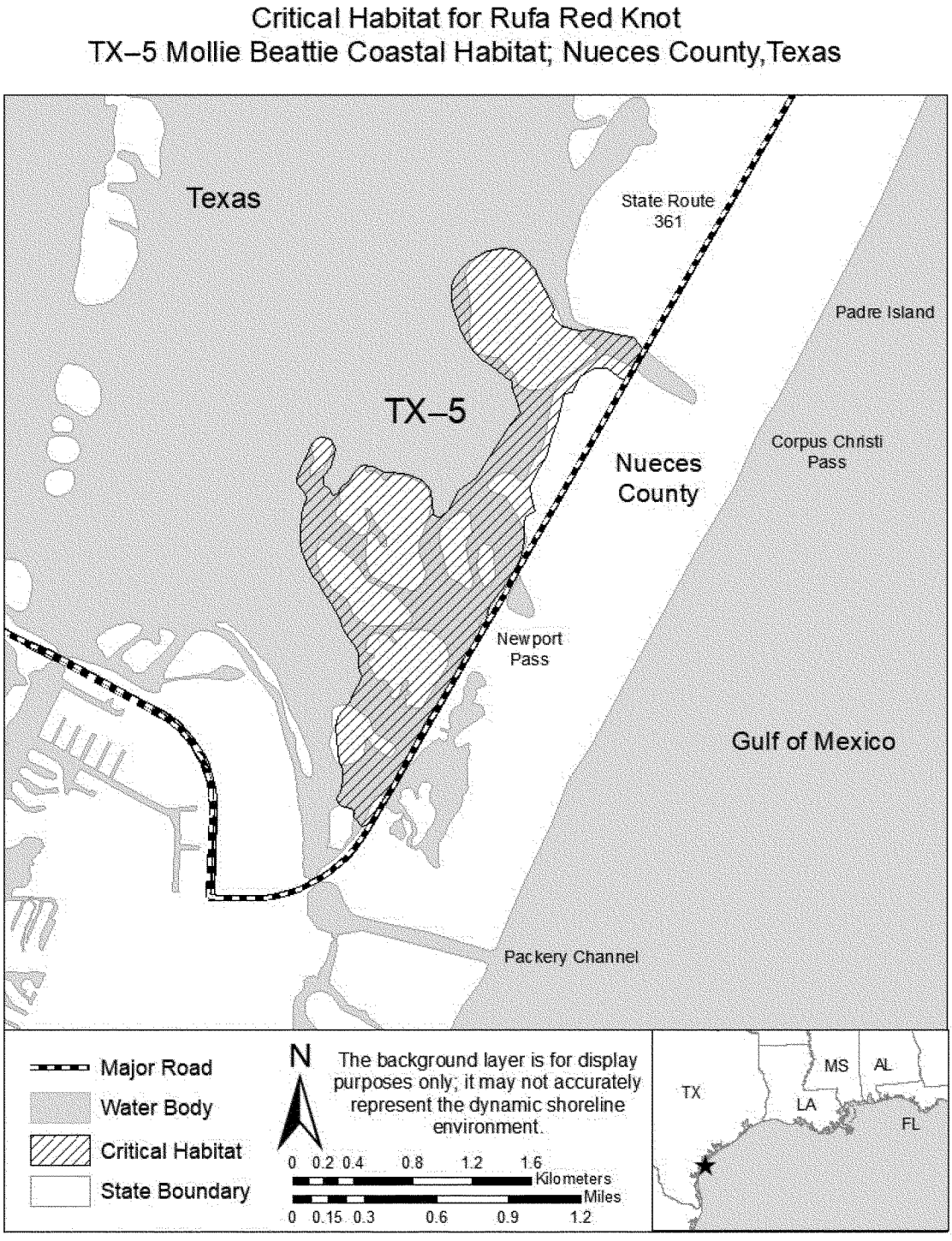
(126) Unit TX–5: Mollie Beattie Coastal Habitat, Texas.

(i) Unit TX–5 consists of approximately 723 ac (293 ha) of occupied habitat in Nueces County. This unit is located north of Packery Channel and extends along the bayside west of Sylvan Beach Park west of Texas State Highway 361. The northern boundary is the Corpus Christi Pass with the southern boundary approximately 2 mi (3.2 km) south of Corpus Christi Pass. The eastern boundary is where the dense vegetation begins, and the western boundary is the MLLW (*i.e.,* the highly dynamic beach and intertidal seashore that is covered at high tide and uncovered at low tide). This unit includes two hurricane washover passes known as Newport and Corpus Christi Passes in areas where wind tidal flats are infrequently inundated, bayside flats are exposed during low tide regimes, and wind tidal flats are infrequently inundated. The unit does not include densely vegetated habitat within these boundaries, but it includes all seagrass beds exposed at low tides. Specific habitat types within this unit include: estuarine (bayside) sandy shore/beach/sandbar that is irregularly or regularly, depending upon the location, inundated by tides; and

estuarine (bayside) sandy shore (beach/sandbar) and spoils irregularly inundated by tides. Lands within this unit include approximately 505 ac (205 ha) in State ownership and 218 ac (88 ha) in private/other ownership.

(ii) Map of Unit TX–5 follows:

Figure 104 to Rufa Red Knot paragraph (126)(ii)



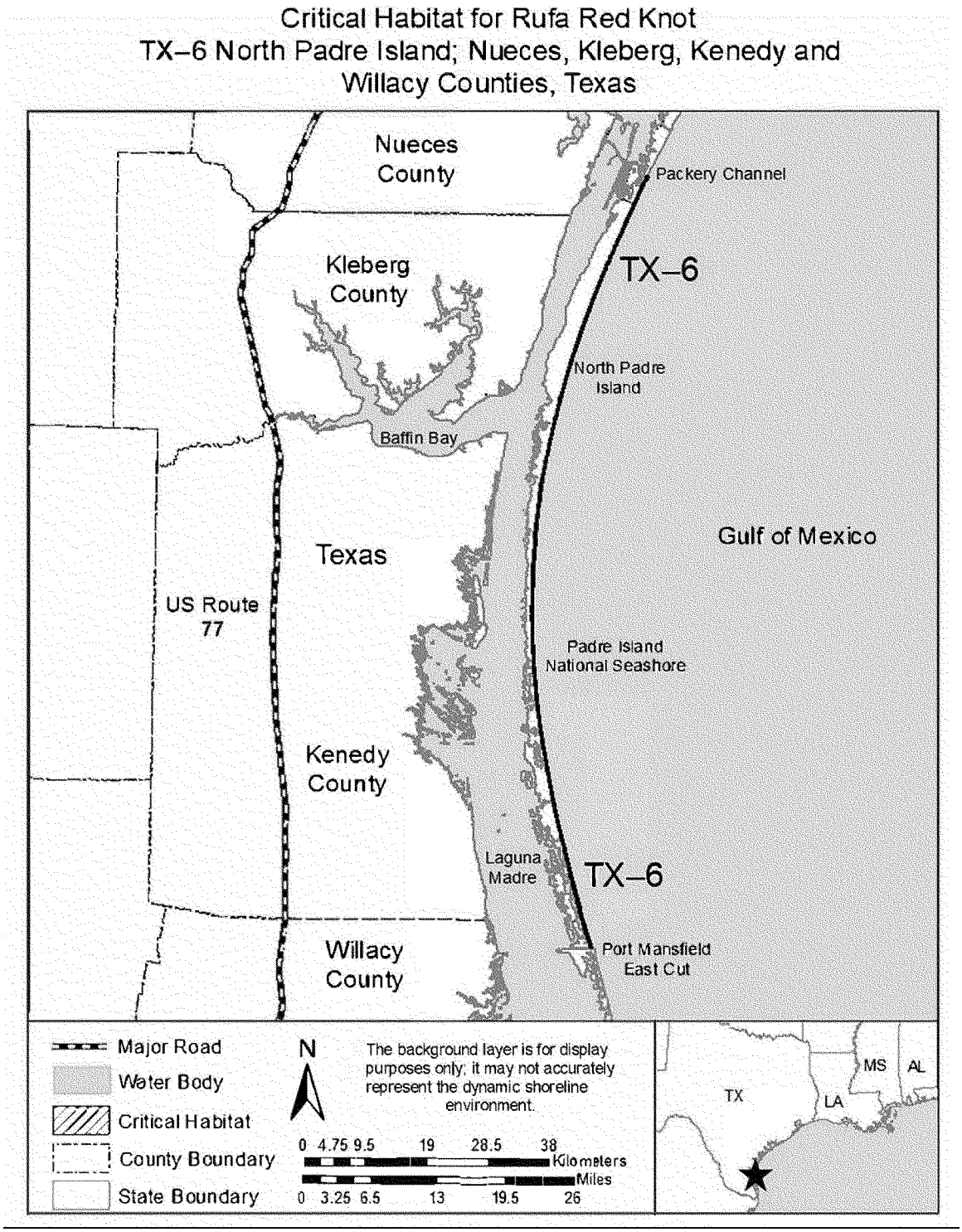
(127) Unit TX–6: North Padre Island, Texas.

(i) Unit TX–6 consists of approximately 2,817 ac (1,140 ha) of occupied habitat in Nueces, Kleberg, Kenedy, and Willacy Counties. The unit is along the gulf with boundaries from the MLLW up to the vegetation line, to include emergent lands and intertidal area characterized as highly dynamic beach/seashore that is covered at high tide and uncovered at low tide. The northern boundary is the south side of Packery Channel extending along the Gulf shoreline to Port Mansfield East Cut. Specific habitat types within this unit include marine sandy coastline beach that is irregularly or regularly

inundated by tides, depending upon the location. Lands within this unit include approximately 2,487 ac (1,007 ha) in Federal ownership (Padre Island National Seashore), 68 ac (27 ha) in State ownership, and 262 ac (106 ha) in private/other ownership.

(ii) Map of Unit TX–6 follows:

Figure 105 to Rufa Red Knot paragraph (127)(ii)



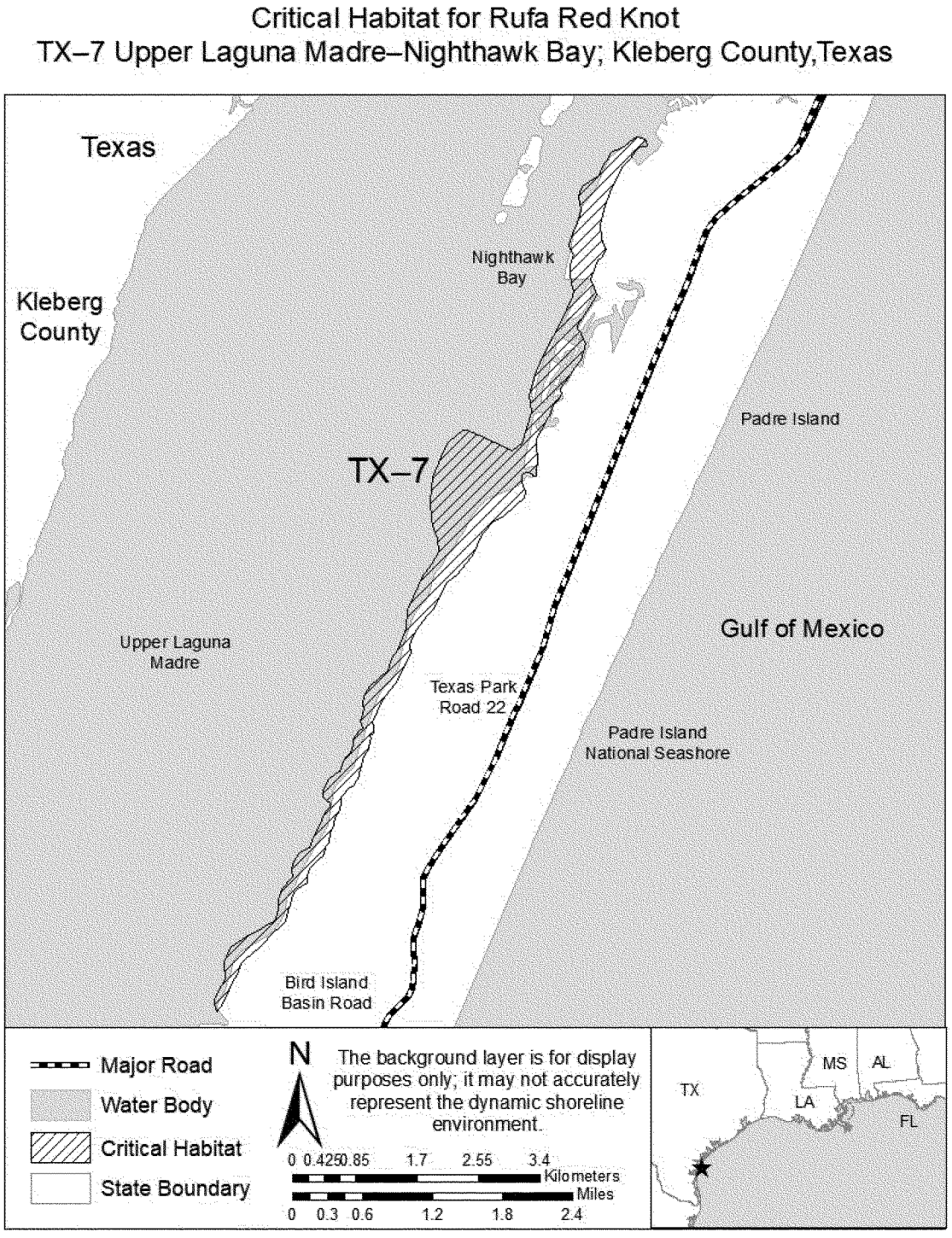
(128) Unit TX–7: Upper Laguna Madre–Nighthawk Bay, Texas.

(i) Unit TX–7 consists of approximately 1,157 ac (469 ha) of occupied habitat in Kleberg County. The unit is along the bayside of Texas Park Road 22. The northeastern boundary is the northern edge of the Kleberg County line in Nighthawk Bay, and the southwestern boundary ends bayside of Bird Island Basin Road. This unit includes a series of small flats along the

bayside of Padre Island in the Upper Laguna Madre. The unit includes bayside flats and seagrass beds that are exposed during low tide regimes and wind tidal flats that are infrequently inundated. Specific habitat types within this unit include: estuarine (bayside) seagrass mud or sand flats that are subtidal, seagrass flats that are nearly flat areas with rooted vascular plants (seagrass) growing below the water surface in subtidal mud or sand substrate; estuarine (bayside) sandy shore (beach/sandbar) rarely exposed due to tidal fluctuation; and estuarine (bayside) sandy shore (beach/sandbar) that is irregularly or regularly inundated by tide, depending upon the location. Lands within this unit include approximately 273 ac (111 ha) in Federal ownership (Padre Island National Seashore), 816 ac (330 ha) in State ownership, and 68 ac (28 ha) in private/other ownership.

(ii) Map of Unit TX–7 follows:

Figure 106 to Rufa Red Knot paragraph (128)(ii)

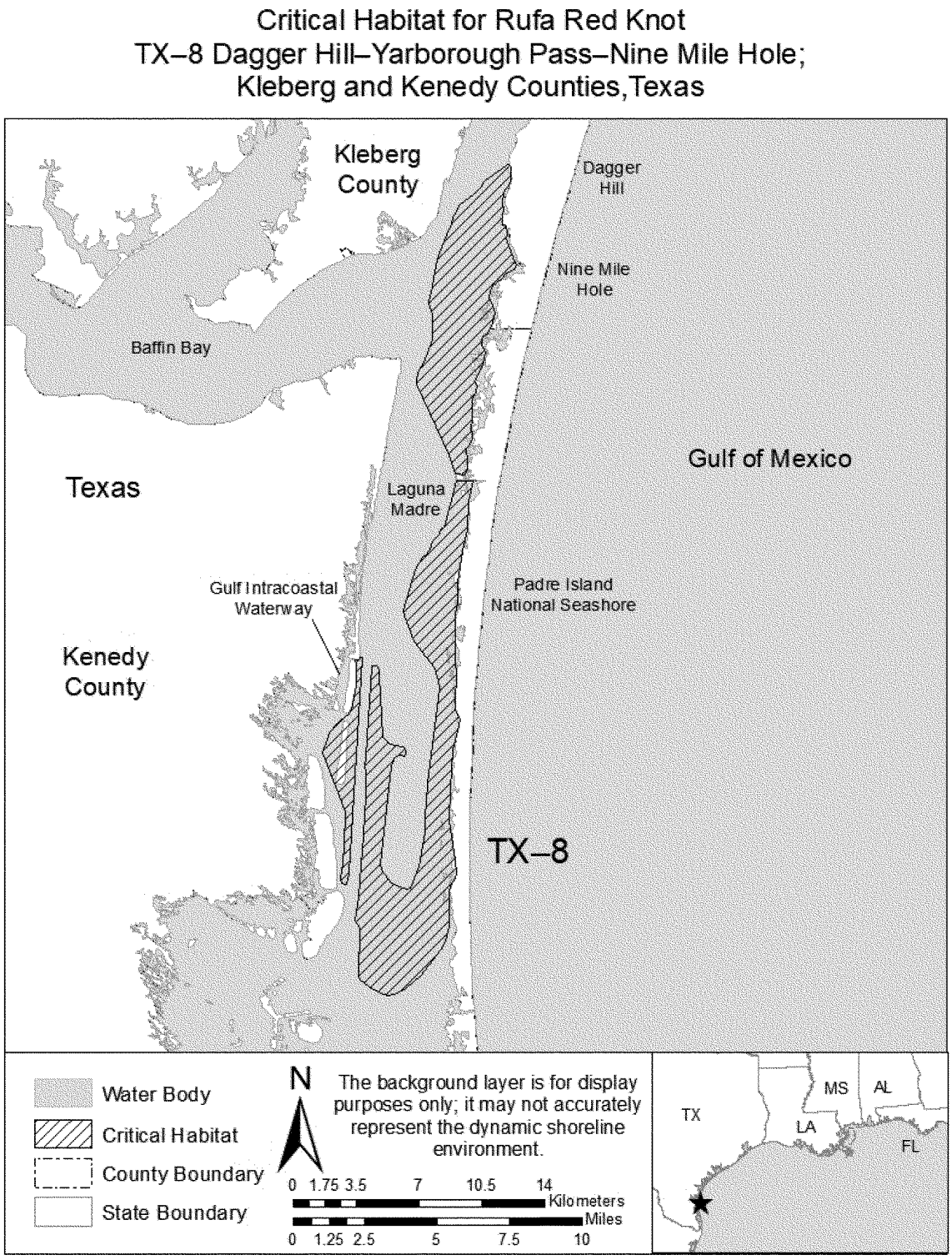


(129) Unit TX–8: Dagger Hill–Yarborough Pass–Nine Mile Hole, Texas.

(i) Unit TX–8 consists of approximately 32,773 ac (13,263 ha) of occupied habitat in Kleberg and Kenedy Counties. The unit is located bayside along and within the Laguna Madre adjacent to the west side of the Padre Island National Seashore. The northern boundary of the unit is Dagger Hill, and the southern boundary is approximately 6 mi (9.7 km) south of the land cut at Nine Mile Hole. The eastern boundary of this unit is the dense vegetation line on the bayside of the Padre Island National Seashore. The western boundary extends toward the Gulf Intracoastal Waterway to the MLLW (*i.e.,* the highly dynamic beach and emergent sand shoals that are covered at high tide and uncovered at low tide). The southern portion of this unit extends across the Gulf Intracoastal Waterway dredge spoil islands. The unit includes bayside flats and all seagrass beds that are exposed during low tide regimes and wind tidal flats that are infrequently inundated. Specific habitat types within this unit include: estuarine (bayside) seagrass mud or sand flats that are subtidal and are nearly flat areas with rooted vascular plants (seagrass) growing below the water surface in subtidal mud or sand substrate; estuarine (bayside) sandy shore (beach/sandbar) that is irregularly or regularly inundated by tides, depending upon the location; and estuarine (bayside) sandy shore (beach/sandbar) and spoils irregularly inundated by tides. Lands within this unit include approximately 9,731 ac (3,938 ha) in Federal ownership (Padre Island National Seashore) and 23,042 ac (9,325 ha) in State ownership.

(ii) Map of Unit TX–8 follows:

Figure 107 to Rufa Red Knot paragraph (129)(ii)



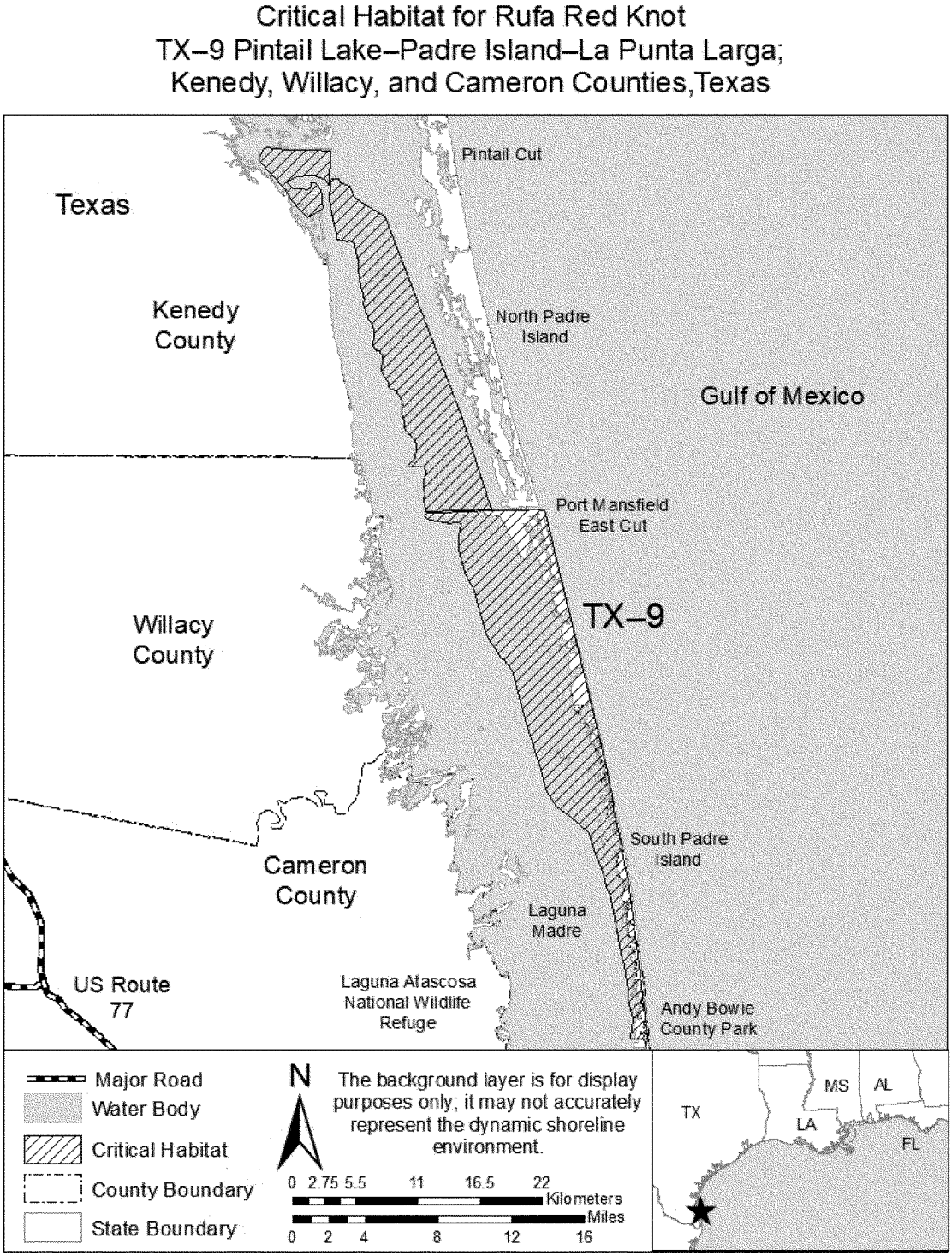
(130) Unit TX–9: Pintail Lake–Padre Island–La Punta Larga, Texas.

(i) Unit TX–9 consists of approximately 94,171 ac (38,110 ha) of occupied habitat in Kenedy, Willacy, and Cameron Counties. The northern boundary is Pintail Cut, extending south along the bay side of North Padre and South Padre Islands, with the southern boundary being Andy Bowie County Park. The center of the unit is approximately at Port Mansfield East Cut. North of the East Cut the western boundary is the MLLW (*i.e.,* the highly dynamic beach and emergent sand shoals that are covered at high tide and uncovered at low tide), and the eastern boundary is where dense vegetation begins. South of East Cut the western boundary is the MLLW, and the eastern boundary includes the beach side Gulf of Mexico out to the MLLW. The unit includes bayside flats and seagrass beds that are exposed during low tide regimes, and wind tidal flats that are infrequently inundated. Specific habitat types within this unit include: estuarine

(bayside) algal mud or sand flats irregularly inundated by tides; estuarine (bayside) sandy shore (beach/sandbar) regularly inundated by tides; and estuarine (bayside) sandy shore (beach/sandbar); and marine sandy coastline beach (irregularly or regularly inundated by tides, depending upon the location). Lands within this unit include approximately 25,881 ac (10,474 ha) in Federal ownership (Laguna Atascosa NWR), 34,165 ac (13,826 ha) in State ownership, and 34,125 ac (13,810 ha; 36 percent) in private/other ownership.

(ii) Map of Unit TX–9 follows:

Figure 108 to Rufa Red Knot paragraph (130)(ii)



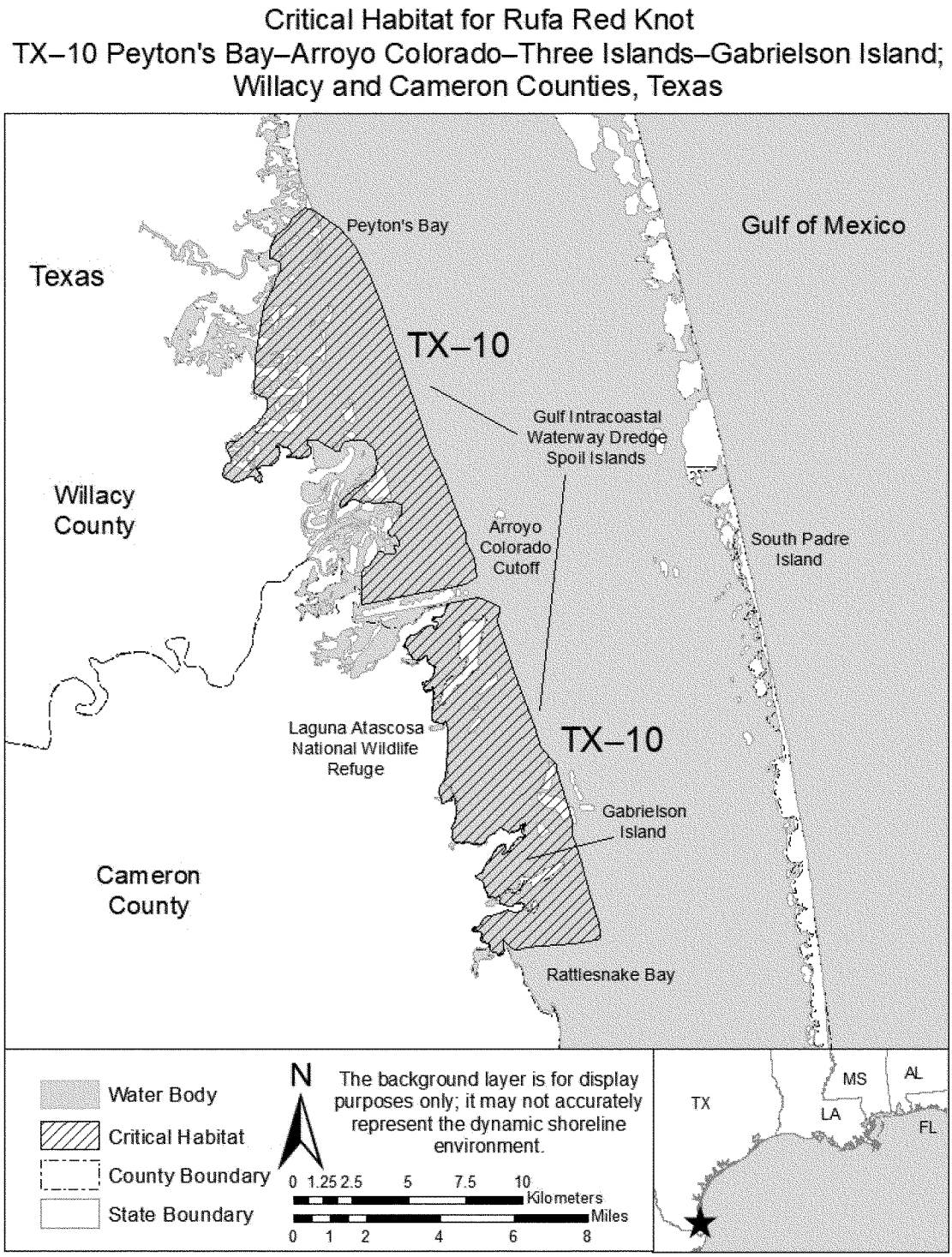
(131) Unit TX–10: Peyton's Bay–Arroyo Colorado–Three Island–Gabrielson Island, Texas.

(i) Unit TX–10 consists of approximately 35,651 ac (14,427 ha) of occupied habitat in Willacy and Cameron Counties. The northern boundary of this unit is approximately 11 mi (18 km) north of the Arroyo

Colorado Cutoff and encompasses Peyton's Bay (north being Chubby Island), and the southern boundary is approximately 9 mi (14 km) south of the Arroyo Colorado Cutoff encompassing Rattlesnake Bay (south edge near Gabrielson Island). The eastern boundary is the western side of the Gulf Intracoastal Waterway dredge spoil islands, and the western boundary is where dense vegetation begins. The unit includes bayside flats and seagrass beds that are exposed during low tide regimes and wind tidal flats that are infrequently inundated, and does not include densely vegetated habitat within these boundaries. Specific habitat types within this unit include: estuarine (bayside) seagrass mud or sand flats that are subtidal and are nearly flat areas with rooted vascular plants (seagrass) growing below the water surface in subtidal mud or sand substrate; estuarine (bayside) algal mud or sand flats regularly inundated by tides and that are nearly flat areas with a layer of algae growing on a moist mud or sand substrate and are otherwise devoid of vegetation; estuarine (bayside) algal mud or sand flats irregularly inundated by tides; estuarine (bayside) sandy shore (beach/sandbar) rarely exposed due to tidal fluctuation; estuarine (bayside) sandy shore (beach/sandbar) areas that are irregularly or regularly inundated by tides, depending upon the location; and estuarine (bayside) sandy shore (beach/sandbar), to include spoils irregularly inundated by tides. Lands within this unit include approximately 8,145 ac (3,296 ha) in Federal ownership (Laguna Atascosa NWR), 25,316 ac (10,245 ha) in State ownership, and 2,190 ac (886 ha) in private/other ownership.

(ii) Map of Unit TX–10 follows:

Figure 109 to Rufa Red Knot paragraph (131)(ii)



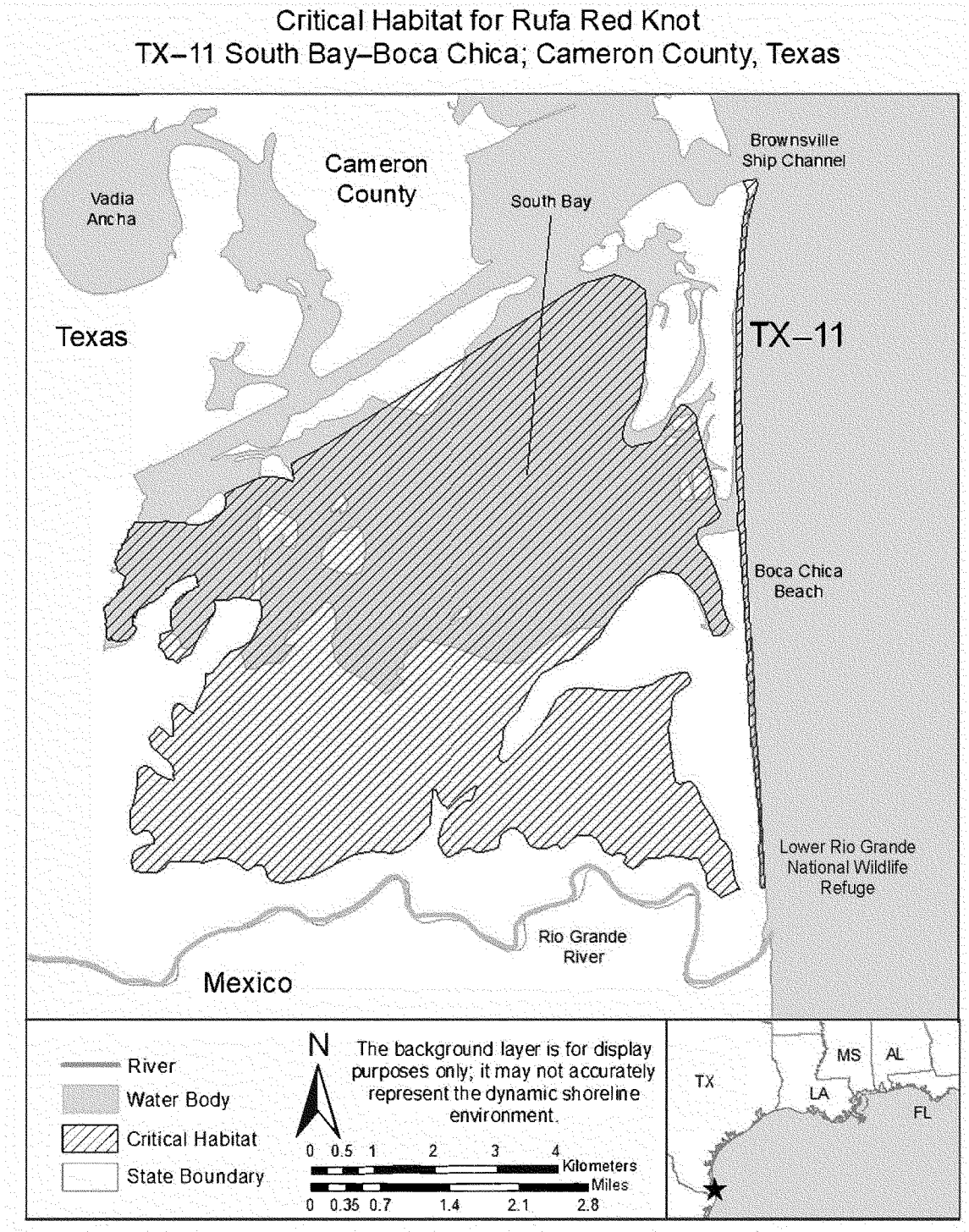
(132) Unit TX–11: South Bay–Boca Chica.

(i) Unit TX–11 consists of approximately 15,400 ac (6,236 ha) of occupied habitat in Cameron County. The Boca Chica gulf shoreline portion of this unit begins south of the Brownsville Ship Channel and extends approximately 6.5 mi (10 km) to the south. Within the South Bay, the northern boundary is south of Brownsville Ship Channel dredge spoil placement areas, and the southern boundary is north of the Rio Grande River. The eastern boundary is the bayside of the Boca Chica Beach (Gulf of Mexico) up to where dense vegetation begins, and the western boundary is west of the Loma islands up to where dense vegetation begins along the wind tidal flats. The unit includes wind tidal flats and all seagrass beds that are infrequently inundated and/or exposed at low tides, and the tidal flats within the area known as South Bay. Specific habitat types within this unit include: estuarine (bayside) seagrass mud or sand flats that are subtidal and are nearly flat areas with rooted vascular plants (seagrass) growing below the water surface in subtidal mud or sand substrate; estuarine (bayside) algal mud or sand flats regularly inundated by

tides and that are nearly flat areas with a layer of algae growing on a moist mud or sand substrate and are otherwise devoid of vegetation; estuarine (bayside) algal mud or sand flats irregularly inundated by tides; estuarine (bayside) sandy shore (beach/sandbar) rarely exposed due to tidal fluctuation; estuarine (bayside) sandy shore (beach/sandbar) irregularly or regularly inundated by tides, depending upon the location; estuarine (bayside) sandy shore (beach/sandbar) spoils irregularly inundated by tides; and marine sandy coastline (beach) irregularly or regularly inundated by tides, depending upon the location. Lands within this unit include approximately 5,536 ac (2,242 ha) in Federal ownership (Lower Rio Grande Valley NWR), 4,080 ac (1,652 ha) in State ownership, and 5,784 ac (2,342 ha) in private/other ownership.

(ii) Map of Unit TX–11 follows:

Figure 110 to Rufa Red Knot paragraph (132)(ii)



* * * * *

Martha Williams,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2023–06619 Filed 4–12–23; 8:45 am]

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Part III

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 217

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Empire Wind Project, Offshore New York; Proposed Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 217

[Docket No. 230404–0092]

RIN 0648–BL97

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Empire Wind Project, Offshore New York

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

ACTION: Proposed rule; proposed letter of authorization; request for comments.

SUMMARY: NMFS has received a request from Empire Offshore Wind, LLC (Empire Wind), a 50/50 joint venture between Equinor and BP p.l.c., for Incidental Take Regulations (ITR) and an associated Letter of Authorization (LOA). The requested regulations would govern the authorization of take, by Level A harassment and/or Level B harassment, of small numbers of marine mammals over the course of 5 years (2024–2029) incidental to construction of the Empire Wind Project offshore New York in a designated lease area on the Outer Continental Shelf (OCS–A–512). Project activities likely to result in incidental take include impact pile driving, vibratory pile driving and removal, and site assessment surveys using high-resolution geophysical (HRG) equipment. As required by the Marine Mammal Protection Act (MMPA), NMFS requests comments on its proposed rule. NMFS will consider public comments prior to making any final decision on the promulgation of the requested incidental take authorization (ITA) and issuance of the LOA; agency responses to public comments will be summarized in the final notice of our decision. The proposed regulations, if issued, would be effective January 22, 2024, through January 21, 2029.

DATES: Comments and information must be received no later than May 15, 2023.

ADDRESSES: Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov* and enter NOAA–NMFS–2023–0053 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Robert Pauline, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Availability

A copy of Empire Wind's 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-other-energy-activities-renewable.* In case of problems accessing these documents, please call the contact listed above (see **FOR FURTHER INFORMATION CONTACT**).

Purpose and Need for Regulatory Action

This proposed rule, if issued, would provide a framework under authority of the MMPA (16 U.S.C. 1361 *et seq.*) to allow for the authorization of take of marine mammals incidental to construction of the Empire Wind Project within the Bureau of Ocean Energy Management (BOEM) Renewable Energy Lease Area OCS–A 512 and along export cable corridors to two landfall locations in New York. NMFS received a request from Empire Wind requesting 5-year regulations and a LOA that would authorize take of individuals of 17 species of marine mammals (two species by Level A harassment and Level B harassment and 17 species by Level B harassment only) incidental to Empire Wind's construction activities. No mortality or serious injury is anticipated or proposed for authorization. Please see the Estimated Take of Marine Mammals section for definitions of harassment.

Legal Authority for the Proposed Action

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, regulations are promulgated (when required), and public notice and an opportunity for public comment are provided.

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 as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth. The definitions of all applicable MMPA statutory terms cited above are included below.

Section 101(a)(5)(A) of the MMPA and the implementing regulations at 50 CFR part 216, subpart I provide the legal basis for proposing and, if appropriate, issuing this rule containing five-year regulations and associated LOA. As directed by this legal authority, this proposed rule also establishes required mitigation, monitoring, and reporting requirements for Empire Wind's activities.

Summary of Major Provisions Within the Proposed Rule

The major provisions within this proposed rule are as follows:

- Establish a seasonal moratorium on impact pile driving during the months of highest North Atlantic right whale (*Eubalaena glacialis*) presence in the project area (January 1–April 30);
- Require both visual and passive acoustic monitoring by trained, NOAA Fisheries-approved Protected Species Observers (PSOs) and Passive Acoustic Monitoring (PAM) operators before, during, and after the in-water construction activities;
- Require the use of sound attenuation device(s) during all impact pile driving to reduce noise levels;
- Delay the start of pile driving if a North Atlantic right whale is observed at any distance by PSOs or acoustically detected;
- Delay the start of pile driving if other marine mammals are observed entering or within their respective clearance zones;

• Shut down pile driving (if feasible) if a North Atlantic right whale is observed or if other marine mammals enter their respective shut down zones;
• Implement sound field verification requirements during impact pile driving to measure in situ noise levels for comparison against the model results;
• Implement soft-starts for impact pile driving and use the least hammer energy possible;
• Require PSOs to continue to monitor for the presence of marine mammals for 30 minutes after any impact pile driving occurs;
• Implement ramp-up for HRG site characterization survey equipment;
• Increase awareness of North Atlantic right whale presence through monitoring of the appropriate networks and Channel 16, as well as reporting any sightings to the sighting network;
• Implement various vessel strike avoidance measures; and
• Implement best management practices during fisheries monitoring surveys such as removing gear from the water if marine mammals are considered at-risk or are interacting with gear.

Under Section 105(a)(1) of the MMPA, failure to comply with these requirements or any other requirements in a regulation or permit implementing the MMPA may result in civil monetary penalties. Pursuant to 50 CF 216.106, violations may also result in suspension or withdrawal of the Letter of Authorization (LOA) for the project. Knowing violations may result in criminal penalties, under Section 105(b) of the MMPA.

National Environmental Policy Act (NEPA)

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 evaluate the review our proposed action (*i.e.,* promulgation of regulations and subsequent issuance of a 5-year LOA) and alternatives with respect to potential impacts on the human environment.

Accordingly, NMFS proposes to adopt the Bureau of Ocean Energy Management's (BOEM's) Environmental Impact Statement (EIS), provided our independent evaluation of the document finds that it includes adequate information analyzing the effects of promulgating the proposed regulations and LOA issuance on the human environment. NMFS is a cooperating agency on BOEM's EIS. BOEM's draft EIS (Empire Wind Draft Environmental Impact Statement (DEIS) for Commercial Wind Lease OCS–A 512) was made available for public comment on November 18, 2022 (87 FR 69330), beginning the 60-day comment period ending on January 17, 2023. The draft EIS can be found at: *https://www.boem.gov/renewable-energy/state-activities/empire-wind.* Additionally, BOEM held three virtual public hearings on December 7, 2022, December 13, 2022 and December 15, 2022.

Information contained within Empire Wind's ITA application and this proposed rule collectively provide the environmental information related to these proposed regulations and associated 5-year LOA for public review and comment. NMFS will review all comments submitted in response to this proposed rule prior to concluding the NEPA process or making a final decision on the requested 5-year ITA and LOA.

Fixing America's Surface Transportation Act (FAST–41)

This project is covered under Title 41 of the Fixing America's Surface Transportation Act, or ''FAST–41''. FAST–41 includes a suite of provisions designed to expedite the environmental review for covered infrastructure projects, including enhanced interagency coordination as well as milestone tracking on the public-facing Permitting Dashboard. FAST–41 also places a 2-year limitations period on any judicial claim that challenges the validity of a Federal agency decision to issue or deny an authorization for a FAST–41 covered project. 42 U.S.C. 4370m–6(a)(1)(A).

Empire Wind's proposed project is listed on the Permitting Dashboard (*https://www.permits.performance.gov/),* where milestones and schedules related to the environmental review and permitting for the project can be found: *https://www.permits.performance.gov/permitting-project/empire-wind-energy-project.*

Summary of Request

On December 7, 2021, Empire Wind submitted a request for the promulgation of regulations and issuance of an associated 5-year LOA to take marine mammals incidental to construction activities associated with implementation of the Empire Wind Project offshore of New York in BOEM Lease Area OCS–A–0512. Empire Wind's request is for the incidental, but not intentional, taking of a small number of 17 marine mammal species (comprising 18 stocks) by Level B harassment (for all 18 stocks) and by Level A harassment (for two species or stocks). Neither Empire Wind, nor NMFS, expect serious injury or mortality to result from the specified activities nor is any proposed for authorization.

In response to our comments, and following extensive information exchange with NMFS, Empire Wind submitted a final, revised application on July 28, 2022, that NMFS deemed adequate and complete on August 11, 2022. In June 2022, new scientific information was released regarding marine mammal densities (Robert and Halpin, 2022). In response, Empire Wind submitted a final addendum to the application on January 25, 2023, which included revised marine mammal densities and take estimates based on Roberts and Halpin 2022. The addendum also identified a revision to the density calculation methodology. Both of these revisions were recommended by NMFS. Empire Wind requests the regulations and subsequent LOA be valid for 5 years beginning in the first quarter of 2024 (January 22) through the first quarter of 2029 (January 21). Neither Empire Wind nor NMFS expects serious injury or mortality to result from the specified activities. Empire Wind's complete application and associated addendum are available on NMFS' website at: *https://www.fisheries.noaa.gov/action/incidental-take-authorization-empire-offshore-wind-llc-construction-empire-wind-project-ew1?check_logged_in=1.*

On September 9, 2022, NMFS published a notice of receipt (NOR) of the application in the **Federal Register** (87 FR 55409), requesting comments and soliciting information related to Empire Wind's request during a 30-day public comment period. During the NOR public comment period, NMFS received comment letters from an environmental non-governmental organization (Responsible Offshore Development Alliance) and a corporate entity (Allco Renewable Energy Limited). NMFS has reviewed all submitted material and has taken these into consideration during the drafting of this proposed rulemaking.

NMFS previously issued three Incidental Harassment Authorizations (IHAs) to Equinor and its predecessors for the taking of marine mammals incidental to marine site characterization surveys (using HRG equipment) of the Empire Wind Lease Area (OCS–A 0512) and cable corridors (these were not issued to Empire Wind as this subsidiary of Equinor had not yet been established). On April 24, 2018, NMFS issued an IHA to Statoil Wind U.S. LLC, effective from April 24, 2018, through April 23, 2019 (83 FR 19532; May 3, 2018) which included Lease

Area OCS–A 512 and associated cable route corridors. Since the initial IHA was issued, Statoil Wind U.S. LLC changed the name under which the company operates to Equinor. A renewal IHA was issued to Equinor and was effective from April 25, 2019 through April 24, 2020 (84 FR 18801) which covered the same area. A new IHA was issued to Equinor on September 25, 2020 (85 FR 60424) and was effective from September 20, 2020, to September 19, 2021 which included OCS–A 512 and associated cable routes.

To date, Equinor, the parent company of Empire Wind, has complied with all IHA requirements (*e.g.,* mitigation, monitoring, and reporting) of these IHAs. Information regarding Equinor's take estimates and monitoring results may be found in the Estimated Take of Marine Mammals section, and the full monitoring reports can be found on NMFS' website: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable.*

On August 1, 2022, NMFS announced proposed changes to the existing North Atlantic right whale vessel speed regulations to further reduce the likelihood of mortalities and serious to endangered right whales from vessel collisions, which are a leading cause of the species' decline and a primary factor in an ongoing Unusual Mortality Event (87 FR 46921). Should a final vessel speed rule be issued and become effective during the effective period of this ITA (or any other MMPA incidental take authorization), the authorization holder would be required to comply with any and all applicable requirements contained within the final rule. Specifically, where measures in any final vessel speed rule are more protective or restrictive than those in this or any other MMPA authorization, authorization holders would be required to comply with the requirements of the rule. Alternatively, where measures in this or any other MMPA authorization are more restrictive or protective than those in any final vessel speed rule, the measures in the MMPA authorization would remain in place. The responsibility to comply with the applicable requirements of any vessel speed rule would become effective immediately upon the effective date of any final vessel speed rule and, when notice is published of the effective date, NMFS would also notify Empire Wind if the measures in the speed rule were to supersede any of the measures in the MMPA authorization such that they were not longer required.

Description of the Specified Activity

Overview

Empire Wind proposes to construct and operate two offshore wind projects within OCS–A 0512: Empire Wind 1 (EW 1; western portion of Lease Area) and Empire Wind 2 (EW 2; eastern portion of Lease Area) (Figure 1). Combined the two projects would produce a total of approximately 2,076 megawatts (MW) of renewable energy to New York. EW 1 (816 MW) and EW 2 (1,260 MW) will be electrically isolated and independent of each other and each will be connected to their own points of interconnection (POIs) via individual submarine export cable routes.

Empire Wind's project would consist of several different types of permanent offshore infrastructure, including wind turbine generators (WTGs) and associated foundations, offshore substations (OSSs), inter-array cables, submarine export cables and scour protection. Specifically, activities to construct the project include the installation of up to 147 WTGs and two OSSs by impact pile driving (total of 149 foundations). Additional activities would include cable installation, site preparation activities (*e.g.,* dredging), HRG surveys, installation of cofferdams or casing pipes supported by goal post piles, removal of berthing piles and performing marina bulkhead work; and conducting several types of fishery and ecological monitoring surveys. Multiple vessels would transit within the project area and between ports and the wind farm to perform the work and transport crew, supplies, and materials. All offshore cables will connect to onshore export cables, substations, and grid connections on Long Island and Brooklyn, New York. Marine mammals exposed to elevated noise levels during impact and vibratory pile driving or site characterization surveys may be taken by Level A harassment and/or Level B harassment depending on the specified activity.

Activities Not Considered in Empire Wind's Request for Authorization

During construction, Empire Wind will receive equipment and materials to be staged and loaded onto installation vessels at one or more existing third-party port facilities. Empire Wind not yet finalized the selection of all facilities, although they will include the South Brooklyn Marine Terminal (SBMT) in Brooklyn, New York. SBMT has been selected as the location for export cable landfall and the onshore substation for EW 1. Empire Wind also has leased portions of SBMT for EW 1 and EW 2 for laydown and staging of wind turbine blades, turbines, and nacelles; foundation transition pieces; or other facility parts during construction of the offshore wind farm.

The final port selection(s) for staging and construction will be determined based upon whether the ports are able to accommodate Empire Wind's schedule, workforce and equipment needs. Any port improvement construction activities to facilitate laydown and staging would be conducted by a separate entity and would serve the broader offshore wind industry in addition to the Empire Wind Project. Empire Wind would, therefore, not be the applicant for the authorization of marine mammal take incidental to these activities if an authorization for incidental take is warranted, and these activities are not analyzed further in this proposed rule.

Empire Wind is not planning on detonating any unexploded ordnance (UXO) or munitions and explosives of concern (MEC) during the effective period of the proposed rule, if issued. Hence, Empire Wind did not analyze or request take associated with this activity as it would not occur. Other means of removing UXO/MEC may occur (*e.g.,* lift and shift). As UXO/MEC detonation would not occur, it is not discussed further in this analysis.

Dates and Duration

Empire Wind anticipates that activities with the potential to result in harassment of marine mammals would occur throughout all five years of the proposed regulations which, if promulgated, would be effective from January 22, 2024 through January 21, 2029.

The estimated schedule, including dates and duration, for various activities is provided in Table 1. Detailed information about the activities themselves may be found in the Detailed Description of the Specific Activity subsection.

Empire Wind anticipates that 96 WTG monopiles will be installed in 2025 and the remaining 51 WTG monopiles will be installed in 2026. Specifically, installation of WTG monopiles is expected to begin in the second quarter of 2025 and end in the fourth quarter of 2025 for both EW 1 and EW 2. Installation of monopile foundations would resume in EW 2 in the second quarter of 2026 and end in the fourth quarter of that year. OSS foundation installation would occur in 2025 for both EW 1 and EW 2; however, topside work on the EW 2 OSS would occur in 2026 and 2025 and 2026 (EW 2). While Empire Wind currently anticipates adherence to this schedule, it is possible

that foundations could be installed in later time periods (but within the 5-year effective period of the LOA) should permitting or scheduling delays occur).

Installation of foundation piles would not occur from January 1–April 30 in any given year. In addition, impact pile driving is not planned from December 1 through December 31 but could only occur if unanticipated delays due to weather or technical problems arise that necessitate extending pile driving into December in which case Empire Wind would notify NOAA Fisheries and BOEM in advance writing by September 1 that circumstances are expected to necessitate pile driving in December. Given this uncertainty, Empire Wind has included December into its analysis to be precautionary; however, pile driving is currently planned for May through November. Each monopile pile will require up to 3.5 hours of impact pile driving and each pin pile will require up to 5 hours of impact pile driving.

Either cofferdams or casing pipe and goal post installation may occur as part of cable landfall activities, but not both. EW 1 cable landfall work would occur sometime between Q1 to Q4 in 2024 while EW 2 cable landfall work would occur sometime between Q1 2024–Q4 2025. Depending on the construction method chosen, each cable landfall site would require 7–30 days of work. Exact dates and durations could shift depending on factors such as weather delays, procurement, or contracting issues

The anticipated activity schedule for all activities is shown in Table 1. Empire Wind anticipates that WTGs in EW 1 would become operational late in Q2 or early Q3 in 2026 while those in EW 2 would become operational in Q4 of 2027. Turbines would be commissioned individually by personnel on location, so the number of commissioning teams would dictate how quickly turbines would become operational.

TABLE 1—ESTIMATED ACTIVITY SCHEDULE TO CONSTRUCT AND OPERATE THE EMPIRE WIND PROJECT

Project activity	Expected timing EW 1	Expected timing EW 2
Submarine Export Cables	Q3 2024; Q3 2025	Q3–Q4 2025.
Offshore Substation Jacket Foundation and Topside	Q2 [1]–Q4 2025	Q2 [1]–Q4 2025; Q2 [1]–Q4 2026. [2]
Monopile Foundation Installation	Q2 [1]–Q4 2025	Q2 [1]–Q4 2025; Q2 [1]–Q4 2026.
WTG Installation	Q4 2025–Q2 2026	Q4 2026–Q3 2027.
Interarray Cables	Q2–Q4 2025	Q2–Q3 2026.
HRG Surveys	Q1 2024–Q4 2028	Q1 2024–Q4 2028.
Cable Landfall Construction	Q1–Q4 2024 [3]	Q1 2024–Q4 2025. [3]
Marina Activities	n/a	Q1–Q4 2024.
Barnum Channel Cable Bridge Construction	n/a	Q4 2024–Q2 2025.

Note: Project activities are anticipated to start no earlier than Q1 2024.
[1] Impact driving of foundation piles is prohibited between January 1 and April 30. During Q2 such activities could not start until May 1.
[2] EW 2 OSS jacket installation is planned for 2025, only EW 2 topside work is planned for 2026.
[3] While cable landfall construction could occur at any time during the time period identified would only occur for approximately 30 days.

Specific Geographic Region

Empire Wind would conduct activities in state waters and Federal waters within the designated Lease Area OCS–A 0512 (which covers approximately 321 square kilometers (km^2; 79,350 acres) and New York state waters (See Figure 1)). The Lease Area is located in the New York Bight, approximately 14 miles (mi; 12 nautical miles (nm); 22 km) south of Long Island, New York, and 19.5 mi (16.9 nm; 31.4 km) east of Long Branch, New Jersey. The New York Bight is a section of the northwestern Atlantic Ocean that extends along the United States East Coast between Cape May, New Jersey in the southwest, to Montauk Point, New York in the northeast. It includes the waters over the continental shelf and offshore to the shelf break. It is part of the larger Mid-Atlantic Bight, which spans from Cape Hatteras, North Carolina to Cape Cod, Massachusetts. A number of estuaries drain into the New York Bight and provide spawning and nursery areas for many of the diadromous and marine species that utilize the New York Bight. Important geological features of the area include the Hudson Shelf Valley and Hudson Canyon, which provide habitat for deep-sea coral that shelters benthic invertebrates and fish. Nutrient-rich water created by water-column stratification from spring through fall, known as the cold pool, plays an essential role in the ecosystem and supports high biodiversity and phytoplankton productivity. The average temperature of the cold pool has increased due to changes to ocean circulation. The cold pool has been decreasing over the last several decades with the smallest sizes associated with warmer years while area fish distributions have shifted north or offshore (Zoidis *et al.,* 2021). The geology and geomorphology in the New York Bight region are diverse with glacial deposits as a result of the Pleistocene Epoch sea level falls and rises, and more recent Flandrian transgression of sea level (Messina and Stoffer, 1996). Analysis of geophysical and geotechnical survey data collected across the Lease Area indicates the current geological conditions underlying the Lease Area are generally flat.

Water depths vary within the Lease Area from 24 m (78 ft) to 44 m (144 ft), with deeper water depths in the southeast portion of the Lease Area. From June to September, the average temperature of the upper (10–15 m) water column is higher, which can lead to a surface layer of increased sound speeds (Kusel *et al.* 2022). This creates a downward refracting environment in which propagating sound interacts with the seafloor more than in a well-mixed environment. Increased wind mixing combined with a decrease in solar energy during winter, from December through March, results in a sound speed profile that is more uniform with depth.

Sediments in the project area are characterized as predominantly sands and fine sands in the New York Bight area, which includes the Lease Area and most of the submarine export cable routes, to predominantly clays and silts in New York Bay, which includes a section of the EW 1 submarine export cable route. Impact pile driving would occur in a continental shelf environment characterized by predominantly fine to coarse grained sandy seabed sediments, with some clay content.

The EW 1 submarine export cable route exits the Lease Area from the northwestern edge of the Lease Area and will travel northwest through Raritan Bay to the EW 1 export cable landfall in

Brooklyn, New York. Current geological conditions underlying the EW 1 submarine export cable route trend with shoaling towards the shore, and with more significant variation in the bathymetry closer to shore, where dredging patterns influence the seabed. Water depths vary along the EW 1 submarine export cable route from 5.9 m (19.4 ft) to 31.7 m (104.0 ft). Several channels exist along the submarine export cable route, both natural and anthropogenic. The general gradient along the cable is less than 1 degree, although isolated gradients of up to five degrees exist along the near shore portion of the route.

The EW 2 submarine export cable route exits the Lease Area from the central portion of the Lease Area and travels in a northwestern direction in a relatively straight line until turning north to the EW 2 export cable landfall in Long Beach, New York. Conditions along the EW 2 submarine export cable route exhibit a general trend of shoaling towards the shore. Water depth variations range, in the current surveyed and interpreted portion of the route, from 21.5 m (70 ft) to 35.5 m (116 ft). The slope gradient along the EW 2 submarine export cable route reaches a maximum of 1 degree.

Impact pile driving activities to install monopile and the piled jacket foundations will occur within the proposed WTG and offshore substation layout within EW 1 (Figure 3 in application). The WTGs and offshore substations will be located in the Wind Farm Development Area (WFDA), which is a subset of the Lease Area. EW 1 is located in the northwest portion of the WFDA. Additionally, impact pile driving activities to install monopile and the piled jacket foundations will occur within the proposed WTG and offshore substation layout within EW 2 (Figure 3 in application). EW 2 is located in the southeast portion of the WFDA.

Cable Landfall activities for EW 1 would occur at the South Brooklyn Marine Terminal in Brooklyn, NY along the waterfront and adjacent to 1st Avenue/2nd Avenue (Figure 1 in Application). The EW 1 submarine export siting corridor itself begins on the northern edge of the EW 1 portion of the WFDA and extends northwest for approximately 40 nm (74 km). EW 2 landfall locations would occur at one of the following locations: Landfall A (Riverside Boulevard); EW 2 Landfall B (Monroe Boulevard); EW 2 Landfall C (Lido Beach West Town Park); or Landfall E (Laurelton Boulevard). The final location is still being determined. The EW 2 submarine export siting corridor itself begins on the northwest corner of the EW 2 portion of the WFDA and extends northwest for approximately 26 nm (48 km).

All marina activities, both the berthing pile removal and bulkhead work, would be conducted at the Onshore Substation C location along inshore Long Island on the Wreck Lead Channel. Wreck Lead Channel adjoins Reynolds Channel. Reynolds Channel's median salinity is 30–32 practical salinity units (PSU) and dissolved oxygen levels range from 6–12 milligrams per decilitre (mg/dL), decreasing seasonally with warming temperatures. The sediments in the New York Bight, outer harbor, and barrier islands region are composed primarily of sand, gravel, silt, and clay. Currents in the area are minimal and are expected to be similar to those reported at Rockaway Inlet, which vary between 0.0 and 1.0 knots.

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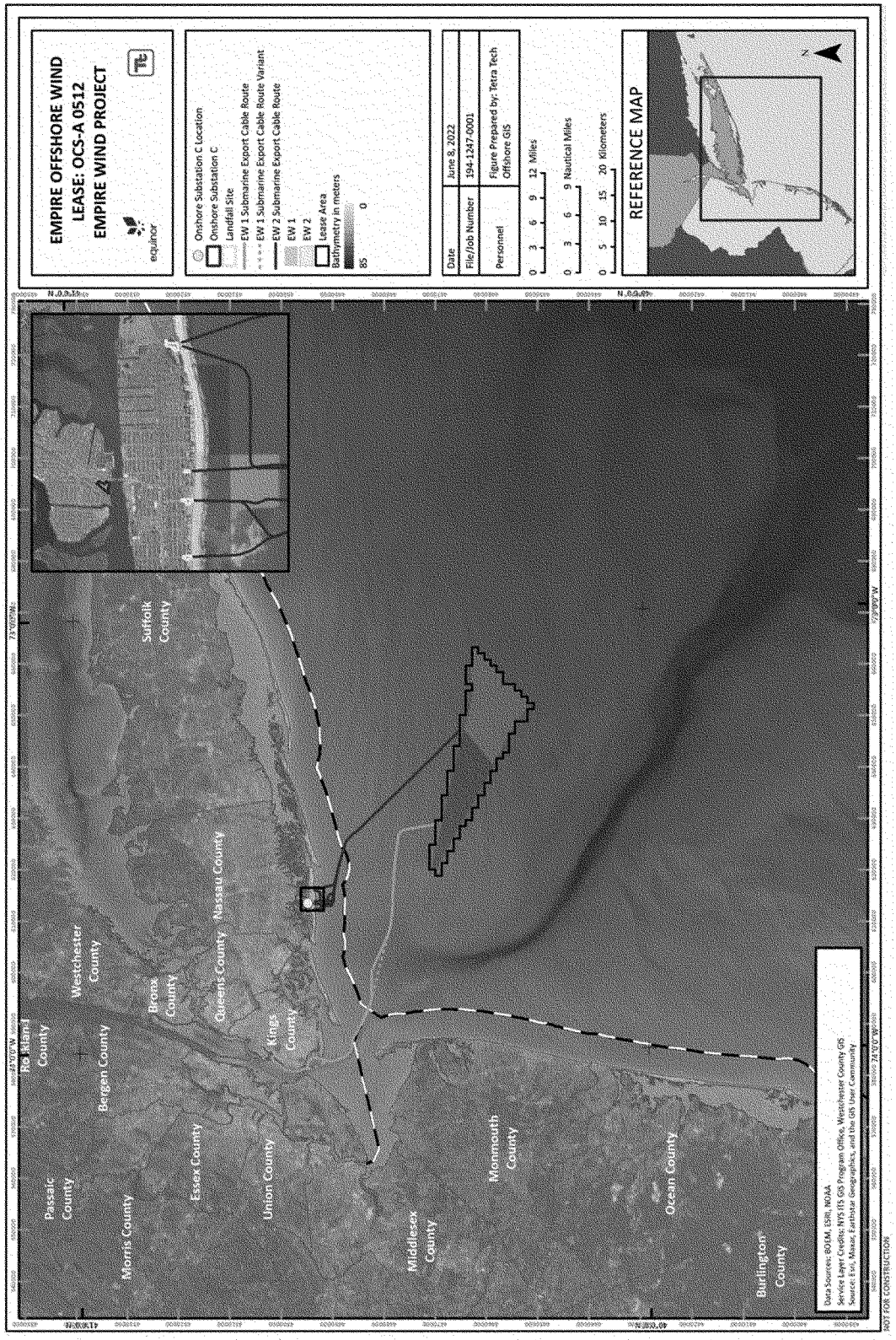


Figure 1. Empire Wind Project Location

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Detailed Description of Specific Activity

Below, we provide detailed descriptions of Empire Wind's activities, explicitly noting those that are anticipated to result in the take of marine mammals and for which incidental take authorization is requested. Additionally, a brief explanation is provided for those activities that are not expected to result in the take of marine mammals.

WTG and OSS Foundation Installation

As described above, Empire Wind would construct two independent

projects under these proposed regulations: EW 1 and EW 2. In total, 147 WTGs would be installed. Turbine size includes either 9.6 or 11-m diameter piles driven to a penetration depth of 38 m or 55 m respectively. Both of the 9.6-m and 11-m piles would be installed using a 5,500 kilojoule (kJ) impact pile driver, although only up to 5,225 kJ would be necessary for the 9.6-m piles and up to 2,500 kJ would be used for 11-m piles. Empire Wind anticipates installing up to 57 WTG monopile foundations and 1 OSS jacket foundation for EW 1 and up to 90 WTG monopile foundations and 1 OSS jacket foundation for EW 2. Only one foundation is proposed to be installed via pile driving at a given time (*i.e.,* no concurrent foundation-specific pile driving activities are proposed) and there would be no overlap in pile driving activities between EW 1 and EW 2. WTGs turbines would be installed in clearly marked rows aligned with the dominant trawl directions when feasible. Minimum spacing of no less than 0.65 nm (1.2 km) in a north-south orientation will be maintained between WTGs. Additionally, the layout maintains a 1 nm setback from existing shipping lanes.

Monopile installation techniques are as follows. Once the installation vessel is in place, the steel pile is lifted into a vertical position and lowered onto the seabed. The steel pile is then driven into the seabed. Pile driving is conducted with the use of a large crane mounted hydraulic impact hammer being dropped, or driven, onto the top of a foundation pile, and driving it into the ground to a penetration depth of up to 38 m for 9.6-m piles and 55 m for 11-m piles. Each monopile pile will require a maximum of up to 3.5 hours of impact pile driving. All monopiles would be installed using impact hammers capable of reaching 5,500 kJ of energy. Typically, 9.6-m piles would require a maximum energy level of 2,300 kJ; however, there may be positions (up to 17) wherein the pile is difficult to drive due to seabed conditions. These difficult-to-drive piles would require hammer energies up to 5,225 kJ. Typically, 11-m piles require an energy level of up to 2,500 kJ. An additional hammer energy schedule was generated for difficult-to-drive monopiles (the difficult-to-drive hammer energy schedule was generated only for the 9.6-m diameter scenario as larger diameter monopiles could not be driven in difficult-to-drive conditions).

Installation of each monopile will include a 20-minute soft-start where lower hammer energy is used at the beginning of each pile installation. Following pile driving, the transition piece and secondary ancillary equipment are installed onto the steel pile. Only one foundation is proposed to be installed via pile driving at a given time and there will be no overlap in pile driving activities between EW 1 and EW 2.

Installation of the OSS foundations would be similar to WTG foundation installation. Pin piles (2.5 m) for jacket foundations would be installed via impact driving and would require the installation of up to 12 pin piles per OSS. Once the installation vessel is in place, the jacket structure is lifted from the vessel and lowered onto the seabed. The support piles are placed in the jacket structure and then driven into the seabed. The piles will be driven using the same methodology as described for monopiles. Each pin pile will require a maximum of up to 4.2 hours of impact pile driving. Pin piles at both OSSs would require use of a hammer with an energy level of 4,000 kJ. However, the maximum energy level would be 3,200 kJ at each location. The OSS 1 location would have a penetration depth of 56 m while OSS 2 would have a penetration depth of 47 m. Installation of each pin pile would include a 20-minute soft-start where lower hammer energy is used at the beginning of each pile installation. Following pile driving of the pin piles, the jacket structure is secured to the driven piles.

Seabed preparation will include installation of a filter layer prior to monopile installation and an armor layer after cable installation on each WTG location. The filter layer and armor layer are rock layers installed on the seabed to prevent scour due to flow increase around the monopiles. This activity would not have any impacts on marine mammals.

Foundation installation is scheduled for May through November in 2025 and 2026. Pile driving in December would not occur unless unforeseen circumstances arise. Foundation installation pile driving would not occur January 1–April 30 of any year. Pile driving would occur during daylight hours, only extending into night if Empire Wind starts installing a pile 1.5 hours prior to civil sunset.

Installation of WTG monopile foundations and OSS pin piles are anticipated to result in the take of marine mammals due to noise generated during pile driving. Therefore, Empire Wind has requested, and NMFS proposes to authorize, take (by Level A harassment and Level B harassment) of marine mammals incidental to foundation installation.

Cable Landfall Construction

To connect the offshore export cable to the onshore cable, Empire Wind proposes to conduct construction related activities at two cable landfall sites. The export cable landfall for the EW 1 export cables will occur at SBMT, located along the Brooklyn waterfront and adjacent to 1st Avenue/2nd Avenue. The cable landfall site for EW2 has not yet been chosen but will occur somewhere between Jones Beach to Long Beach, NY. Installation of the export cable landfall will be accomplished using a horizontal directional drilling (HDD) methodology. HDD operations for an export cable landfall originate from an onshore landfall location and exit a certain distance offshore, which is determined by the water depth contour, as well as total length considerations. To support this installation, both onshore and offshore work areas are required. The onshore work areas are typically located within the landfall parcels. Target transition depths of landfall HDD paths vary by the length of the HDD, up to approximately 80 ft (24 m). Once the onshore work area is set up, the HDD activities commence using a rig that drills a borehole underneath the surface. Once the drill for the HDDs exits onto the seafloor, the ducts in which the submarine cable will be installed are floated out to sea and then pulled back onshore within the drilled borehole. The offshore exit locations require some seafloor preparation to collect any drilling fluids that localize during HDD completion. Preparation will include excavation of pits at each offshore exit location. To facilitate the retaining of drilling fluids, Empire Wind may utilize a casing pipe supported by goal posts on the exit side from a jack-up barge or cofferdams (but not both). The jack-up barge will also house the drill rig.

If Empire Wind installs temporary cofferdams to facilitate transition of the export cable to the onshore cable, up to five cofferdams would be required (up to two cofferdams for EW 1 and three cofferdams for EW 2). Each cofferdam would be installed using vibratory driving over 3 days and removed over 3 days for a total of 6 days for each cofferdam (or 30 days total (5 cofferdams $\times$ 6 days of pile driving per cofferdam)). Empire Wind anticipates only 1 hour of pile driving would be required each day (30 hours total). The temporary offshore cofferdams will be constructed by installing up to 60 0.61-m (24-inch) steel sheet piles per cofferdam in a tight configuration around an area of up to 30 m by 30 m (100 ft by 100 ft). A total of up to five

temporary cofferdams may be constructed (two cofferdams for EW 1 and three cofferdams for EW 2). Variation in the final cofferdam design is possible, with designs ranging from 30 to 40 sheet piles per cofferdam. To be conservative, up to 60 sheet piles per cofferdam have been accounted for in the modeling (see Estimated Take of Marine Mammals section). Sheet piles would be installed with a vibratory hammer. Vibratory pile drivers install piling into the ground by applying a rapidly alternating force to the pile. This is generally accomplished by rotating eccentric weights about shafts. Each rotating eccentric produces a force acting in a single plane and directed toward the centerline of the shaft. The weights are set off-center of the axis of rotation by the eccentric arm. If only one eccentric is used, in one revolution a force will be exerted in all directions, giving the system a good deal of lateral whip. To avoid this problem, the eccentrics are paired so the lateral forces cancel each other, leaving only axial force for the pile.

Seabed preparation may also be completed with installation of a cofferdam for each HDD and an excavation pit to remove material from the cofferdam. The pit would likely be excavated using a bucket—there are no acoustic impacts from this activity if it were to occur and therefore no potential for take.

An alternative to the use of cofferdams for the cable landfall would be the use of a casing pipe supported by up to 3 goal posts. The casing pipe at each landfall location would likely be a 42″ pipe installed with a pneumatic hammer. Empire Wind estimates it would take approximately 4 hours to install the casing pipe with a strike rate of 180 strikes/minute. Each goal post would consist of two piles for a total of 18 piles at each landfall location. Each goal post pile would be installed with an impact hammer requiring up to 2,000 strikes per pile over 2 hours. In total, up to 36 hours (18 piles × 2 hours per pile) of impact pile driving to install three goal posts may occur.

For the goal post installation process, a barge with necessary support equipment is first mobilized and anchored into position. The support equipment on the barge will include at least one crane, a hydraulic impact hammer mounted at the end of the crane hook or load block, and the piles to be driven. An additional crane or similar equipment may also be located on the support barge to aid in the handling of the goal post piles. For each HDD installation, it is estimated that three goal posts will need to be installed to support the casing pipe. Therefore, for each HDD installation there could be up to ten 12-inch piles. For each goal post, a total of two 12-inch steel piles must be driven to complete a single goal post installation, with 2,000 strikes per pile. The piles are installed by attaching the hydraulic hammer to the end of the pile, and lifting the hydraulic hammer with the crane, and swinging the pile into place for the goal post installation. The hydraulic hammer then drives the pile into the subsea floor by repeated percussive blows until the pile reaches a sufficient depth where enough strength to support the casing pipe is achieved. This process is repeated until all piles necessary for the goal post are installed.

HRG Surveys

Empire Wind would conduct HRG surveys in the EW 1 and EW 2 marine environment of the approximately 321 km² (79,350 acres) Lease Area and along the submarine export cable route corridors, inter-array cable locations, and export cable landfall sites. The HRG survey activities will include the following equipment summarized in Table 2, or comparable sources. HRG site characterization surveys would occur annually throughout the five years the rule and LOA would be effective.

Empire Wind would conduct HRG surveys within the lease area and the export cable corridor, including the cable landfall sites. The estimated distance of the daily vessel track line was determined using the estimated average speed of the vessel and the 24-hour operational period within each of the corresponding survey segments. Empire Wind proposes to use up to three vessels to conduct the surveys. The estimated daily vessel track for all vessels is approximately 177.792 km (110.475 mi) for 24-hour operations with a daily ensonified area of 17.8 km². The number of active survey vessel days ranges from 41 (in 2024) to 191 (in 2025). There would be an anticipated 483 survey days over the 5-year LOA period covering 85,872 km. The duration of each survey varies as described in Table 11 in the application. The survey schedule is based on 24-hour operations and includes estimated weather down time.

These surveys may utilize active acoustic equipment such as multibeam echosounders, side scan sonars, shallow penetration sub-bottom profilers (SBPs) (*e.g.,* Compressed High-Intensity Radiated Pulses (CHIRPs) non-parametric SBP), medium penetration sub-bottom profilers (*e.g.,* sparkers and boomers), ultra-short baseline positioning equipment, and marine magnetometers, some of which are expected to result in the take of marine mammals. Surveys would occur annually, with durations dependent on the activities occurring in that year (*i.e.,* construction years versus operational years).

Of the HRG equipment types proposed for use, only Shallow penetration sub-bottom profilers (SBPs) have the potential to result in take. SBPs would be used to map the near-surface stratigraphy (top 0 to 5 m (0 to 16 ft) of sediment below seabed). A CHIRP system emits sonar pulses that increase in frequency over time. The pulse length frequency range can be adjusted to meet project variables. These are typically mounted on the hull of the vessel or from a side pole. Boomers and sparkers would not be used during HRG surveys.

Table 2 identifies all the representative survey equipment that operate below 180 kilohertz (kHz) (*i.e.,* at frequencies that are audible and have the potential to disturb marine mammals) that may be used in support of planned geophysical survey activities. Equipment with operating frequencies above 180 kHz (*e.g.,* SSS, MBES) and equipment that does not have an acoustic output (*e.g.,* magnetometers) will also be used but are not discussed further because they are outside the general hearing range of marine mammals likely to occur in the project area. No harassment exposures can be reasonably expected from the operation of these sources; therefore, they are not considered further in this proposed action.

TABLE 2—SUMMARY OF REPRESENTATIVE HRG SURVEY EQUIPMENT

Representative HRG equipment [a]	Operating frequencies (kHz)	RMS source level	Peak source level	Primary beamwidth (degrees)	Pulse duration (milliseconds (ms))	Pulse repetition (Hz)
Kongsberg HiPAP 501/502 USBL	21—31	190	207	Omni	2	0.5–2

TABLE 2—SUMMARY OF REPRESENTATIVE HRG SURVEY EQUIPMENT—Continued

Representative HRG equipment [a]	Operating frequencies (kHz)	RMS source level	Peak source level	Primary beamwidth (degrees)	Pulse duration (milliseconds (ms))	Pulse repetition (Hz)
iXblue, IxSea GAPS Beacon System	8–16	188	194	Omni	10	1
Sonardyne Ranger 2 and Mini Ranger 2 USBL HPT 3000/5/7000	19–34	200	206	Omni	5	1
Reson Seabat T20P multibeam echosounder [a]	200–400	221	227	90	0.253	
Reson 7111	100	224	228	6	1.35	
Kongsberg EM2040Quad	200–400	-	-	-	-	
R2 Sonic 2026	170–450	191	221	1	1.115	
R2 Sonic 2024	200–700	-	-	-	-	
Klein 3900 SSS [a]	445–900	200	226	1.8	0.1	
EdgeTech DW106	1 to 6	194	197	Omni	<66	8
EdgeTech 424 [a]	4–20	180	186	122	4.8	
Innomar, SES–2000 compact	85–115	232	238	4	40	1
Innomar, SES–2000 Light & Light Plus	85–115	232	238	4	40	1
Innomar, SES–2000 Standard & Standard Plus	85–115	234	240	1–3.5	60	1.5
Innomar, SES–2000 Smart	90–110	229	235	5	40	0.5
Innomar, SES–2000 Medium–70	60–80	240	246	3	40	5
Teledyne Benthos Chirp III–TTV 170	2 to 7	219	225	100	60	15
Coda Octopus 3D	240–300	-	-	-	-	20

Note:
[a] Equipment specifications found in the 2016 Crocker and Fratantonio Report. Equipment selected would be the same or similar.
"-" indicates Empire Wind was unable to provide this information; however, it is not relevant to the analysis herein.

Based on the operating frequencies of some types of HRG survey equipment and the hearing ranges of the marine mammals that have the potential to occur in the Project Area, HRG survey activities will have the potential to result in Level B harassment of marine mammals. No Level A harassment is anticipated as a result of HRG survey activities.

Onshore Substation C Marina Activities

Construction activities will also be completed to facilitate the connection of the cables to Onshore Substation C, located inshore Long Island on the Wreck Lead Channel, as shown in Figure 1. Work includes removing berthing piles and bulkhead repair. Up to 130 12-inch diameter timber berthing piles would be removed using a combination of a crane and vibratory hammer, depending on the condition of the piles. Two piles would be removed each hour with up to 15 piles per day (7–8 hours per day) with approximately 130 piles removed over the course of two weeks for a total of approximately 65 hours. Vibratory installation of 24-inch z-type steel sheet piles would also occur at the marina bulkheads, consisting of 20 piles per day, with installation occurring for approximately 1 hour of noise generation time per day for 35 days.

The onshore substation will be used to transform and prepare the power received by the export cables from EW 2 for connection to the points of interconnection (POIs) in New York. SMBT Vibratory installation of sheet piles would also occur at the marina bulkheads, consisting of 20 piles per day, with installation occurring for approximately 1 hour of noise generation time per day for 35 days for a total of 700 sheet piles between Q1–Q4 for EW 1 and EW 2 in 2024 and between Q1–Q4 for EW 2 in 2025.

Barnums Channel Cable Bridge Activities

The cable bridge structure for EW 2 only requires two support columns (pile caps) located within the waterway to support the truss system, which will hold the cables above water. The support may be installed by a hammer, but other methods are under consideration. There could be up to six 1.5 ft (0.5 meter) diameter steel pipe piles per cap for a total of 12 steel pipe piles. The location is in an inland waterway near the Barrett Generation Station in an industrialized section of the island, where water depths are only 1 meter, therefore, marine mammals, including seals, are not expected. Sightings data support this assumption, as no sightings of seals have been recorded in the vicinity (OBIS 2023). No take is anticipated from this activity.

Cable Laying and Installation

Submarine export cables will be installed from specialized installation vessels/barges, which will install the cables from a turntable on the lay vessel/barge. One or several vessels might be used for the installation of the cables depending on a number of factors, such as seabed depth, depth of cable protection, distance to shore, and cable protection method to be used. There are several cable installation and burial methods being considered. Some activities will be performed before the installation of the cables, some during the installation of the cables, and some after the installation of the cables. Cable pre-lay activities may include pre-installation grapnel run, route clearance and boulder removal, pre-sweeping, dredging and pre-trenching. The cable burial methods being considered are plowing, jetting, trenching, and dredging. The equipment selected will depend on seabed conditions, the required burial depths, as well as the results of various cable burial studies. More than one installation and burial method may be selected per route and has the potential to be used pre-installation, during installation, and/or post-installation.

Installation of the submarine export cables is expected to take approximately four months for the EW 1 submarine export cables and approximately four months for the EW 2 submarine export cables. The actual installation schedule will be subject to seabed characteristics, installation vessel availability, seasonal restriction windows for protected species, and weather. Installation of the EW 1 and EW 2 submarine export cables may occur at the same time; however,

any overlap in installation activities would not occur at the same stage (*i.e.,* pre-installation activities may commence for EW 2 while the cable lay and burial for EW 1 is being completed).

The noise levels generated from cable laying and installation work are low so the potential for take of marine mammals to result is discountable. Empire Wind is not requesting, and NMFS is not proposing to authorize, take associated with cable laying activities. Therefore, cable laying activities are not analyzed further in this document.

Vessel Operation

Multiple vessels will be in use during construction and operations. Empire Wind estimates that the Project will require approximately 18 vessels for construction of EW 1 and approximately 18 vessels for construction of EW 2. Vessels including barges, tugboats, crew transfer vessels, heavy transport vessels, and various supply vessels are expected to be utilized. Helicopters may also be used to provide site support (Table 3).

TABLE 3—PRELIMINARY SUMMARY OF OFFSHORE VESSELS FOR CONSTRUCTION

Foundations				Wind turbines	Offshore Substation Topside & Foundation / Substation Topside & Foundation	Submarine Export Cables	Interarray Cables	Scour Protection
Vessel	Description	Monopile	Piled Jacket					
Heavy lift vessel	Vessel for installation of foundations.	X	X		X			
Monopile supply vessel	Vessel for transport of monopile foundations.	X						
Wind turbine installation vessel.	Vessel for installation of wind turbine components.			X				
Wind turbine supply vessel	Vessel for transport of wind turbine components.			X				
Cable lay vessel/barge	Vessel for installation of submarine cables.					X	X	
Heavy transport vessel	Vessel for transport of offshore substation topside.	X	X		X			
Cable lay support vessel	Support vessel for cable lay operations.					X	X	
Pre-lay grapnel run vessel	Vessel for seabed clearance along cable routes.					X	X	
Fall pipe vessel	Vessel for installation of scour protection.	X	X		X	X	X	X
Crew transfer vessel	Vessel for transporting workers to and from shore.	X	X	X	X	X	X	
Accommodation vessel	Vessel for worker accommodations.				X			
Construction support vessel	Vessel for general construction support.	X	X			X	X	
Tugboat	Vessel for transporting and maneuvering barges.	X	X	X	X	X		
Barge	Vessel for transport of construction materials.	X	X	X	X			
Safety vessel	Vessel for protection of construction areas.	X	X			X	X	

Fisheries and Benthic Monitoring

Empire Wind will engage in various fisheries and benthic monitoring surveys that have been designed for the Project in accordance with recommendations set forth in ''Guidelines for Providing Information on Fisheries for Renewable Energy Development on the Atlantic Outer Continental Shelf'' (BOEM 2019). Empire Wind would conduct a number of surveys including trawl surveys, baited underwater video surveys, and hard bottom monitoring surveys.

Because the gear types and equipment used for benthic habitat monitoring, and Habcam surveys do not have components with which marine mammals are likely to interact (*i.e.,* become entangled in or hooked by), these activities are unlikely to have any impacts on marine mammals. Only trawl surveys, in general, have the potential to result in harassment to marine mammals. Empire Wind did not propose to implement mitigation measures to avoid take of marine mammals incidental to trawl surveys; however, NMFS has included them in this proposed rule (see Proposed Mitigation). With the implementation of those measures, NMFS does not anticipate, and is not proposing to authorize, take associated with fisheries and benthic monitoring surveys.

Description of Marine Mammals in the Area of Specified Activities

Thirty-eight marine mammal species under NMFS' jurisdiction have geographic ranges within the western North Atlantic OCS (Hayes *et al.,* 2022). However, for reasons described below, Empire Wind has requested, and NMFS proposes to authorize, take of 17 species (comprising 18 stocks) of marine mammals. Sections 3 and 4 of Empire Wind's application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species (Empire Wind, 2022). NMFS fully considered all of this information, and we refer the reader to these descriptions in the application, incorporated here by reference, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS's 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's website (*https://www.fisheries.noaa.gov/find-species).*

Of the 38 marine mammal species in the Atlantic OCS under NMFS' jurisdiction, 21 are not expected to be present or are considered rare or unexpected in the project area based on sighting and distribution data; they are, therefore, not discussed further beyond the explanation provided here. The following species are not expected to occur in the project area due to the location of preferred habitat outside the Empire Wind project area based on the best scientific information available: blue whale (*Balaenoptera musculus*), dwarf and pygmy sperm whales (*Kogia sima and K. breviceps*), northern bottlenose whale (*hyperoodon ampullatus*), cuvier's beaked whale (*Ziphius cavirostris*), four species of Mesoplodont beaked whales (*Mesoplodon densitostris, M. europaeus, M. mirus, and M. bidens*), killer whale (*Orcinus orca*), false killer whale (*Pseudorca crassidens*), pygmy killer whale (*Feresa attenuate*), melon-headed whale (*Peponocephala electra*), white-beaked dolphin (*Lagenorhynchus albirotris*), pantropical spotted dolphin (*Stenella attenuata*), Clymene dolphin (*Stenella clymene*), striped dolphin (*Stenella coeruleoalba*), spinner dolphin (*Stenella longirostris*), Fraser's dolphin (*Lagenodelphis hosei*), and rough-toothed dolphin (*Steno bredanensis*) and the hooded seal (*Cystophora cristata*).

In addition, Florida manatees (*Trichechus manatus;* a sub-species of the West Indian manatee) have been previously documented as an occasional visitor to the Northeast region during summer months. However, manatees are managed by the U.S. Fish and Wildlife Service and are not considered further in this document.

In anticipation of the Empire Wind Project, Equinor (prior to establishing its subsidiary, Empire Wind) conducted 12 monthly aerial digital surveys of Empire Wind Lease Area OCS–A 0512 in the New York Bight between November 2017 and October 2018 using APEM Inc.'s high-resolution camera system to capture digital still imagery. Raw counts and design-based abundance estimates of all species and incidental observations recorded during the surveys are presented here as well as information on species distribution, flight height and flight direction. The key findings from each of the monthly aerial digital surveys are summarized below. (Normandeau-APEM, 2019). Common dolphins were the most abundant marine mammal species recorded, with a peak count (n=68) in the May survey, followed by bottlenose dolphins, with a peak raw count (n=22) in the June survey. Harbor porpoises, minke whales and a single humpback whale were also recorded, as were three unidentified dolphins and three unidentified marine mammals. Marine mammals were recorded in peak numbers in spring. Equinor's required marine mammal monitoring report as part of HRG surveys covering Lease Area OCS–A 0512 and the associate export cable routes from September 20, 2020 through September 19, 2021 reported sightings of humpback whales, bottlenose dolphins, common dolphins, unidentifiable dolphin species, and harbor seals. Between April 19, 2019 through July 22, 2019, Equinor also observed fin whales, humpback whales, unidentified whales, common bottlenose dolphins, unidentifiable dolphins, and gray seals during HRG surveys. The lack of detections of any of the 22 species listed above during these surveys reinforces the fact that they are not expected to occur in the project area. As these species are not expected to occur in the project area during the proposed activities, Equinor did not request, and NMFS does not propose to authorize, take of these species, and they are not discussed further in this document.

Table 4 lists all species and stocks for which take is expected and proposed to be authorized for this action, 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 (16 U.S.C. 1362(20)), as described in NMFS's SARs. While no mortality is anticipated or proposed to be authorized, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species 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's 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's U.S. Atlantic and Gulf of Mexico SARs. All values presented in Table 4 are the most recent available at the time of publication and are available in NMFS' final 2021 SARs (Hayes *et al.,* 2022) and draft 2022 SARs available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports.*

TABLE 4—MARINE MAMMAL SPECIES LIKELY TO OCCUR NEAR THE PROJECT AREA THAT MAY BE TAKEN BY EMPIRE WIND'S ACTIVITIES

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Order Artiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)						
Family Balaenidae:						
North Atlantic right whale	Eubalaena glacialis	Western Atlantic	E, D, Y	338 (0; 332; 2020) [5] ..	0.7	8.1
Family Balaenopteridae (rorquals):						
Fin whale	*Balaenoptera physalus*	Western North Atlantic	E, D, Y	6,802 (0.24; 5,573; 2016)	11	1.8
Sei whale	*Balaenoptera borealis*	Nova Scotia	E, D, Y	6,292 (1.02; 3,098; 2016)	6.2	0.8
Minke whale	*Balaenoptera acutorostrata*	Canadian Eastern Coastal	-, -, N	21,968 (0.31; 17,002; 2016).	170	10.6
Humpback whale	*Megaptera novaeangliae*	Gulf of Maine	-, -, Y	1,396 (0; 1,380; 2016)	22	12.15

TABLE 4—MARINE MAMMAL SPECIES LIKELY TO OCCUR NEAR THE PROJECT AREA THAT MAY BE TAKEN BY EMPIRE WIND'S ACTIVITIES—Continued

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Physeteridae:						
Sperm whale	*Physeter macrocephalus*	North Atlantic	E, D, Y	4,349 (0.28; 3,451; 2016)	3.9	0
Family Delphinidae:						
Atlantic white-sided dolphin	*Lagenorhynchus acutus*	Western North Atlantic	-, -, N	93,233 (0.71; 54,433; 2016).	544	27
Atlantic spotted dolphin	*Stenella frontalis*	Western North Atlantic	-, -, N	39,921 (0.27; 32,032; 2016).	320	0
Common bottlenose dolphin	*Tursiops truncatus*	Western North Atlantic Offshore	-, -, N	62,851 (0.23; 51,914; 2016).	519	28
		Migratory Coastal	-, -, N	6,639 (0.41; 4,759; 2016)	48	12.2–21.5
Long-finned pilot whales	*Globicephala melas*	Western North Atlantic	-, -, N	39,215 (0.3; 30,627; 2016).	306	29
Short-finned pilot whales	*Globicephala macrorhynchus*	Western North Atlantic	-, -, N	28,924 (0.24; 23,637; 2016).	236	136
Risso's dolphin	*Grampus griseus*	Western North Atlantic	-, -, N	35,215 (0.19; 30,051; 2016).	301	34
Common dolphin (short-beaked).	*Delphinus delphis*	Western North Atlantic	-, -, N	172,897 (0.21; 145,216; 2016).	1,452	390
Family Phocoenidae (porpoises):						
Harbor porpoise	*Phocoena phocoena*	Gulf of Maine/Bay of Fundy	-, -, N	95,543 (0.31; 74,034; 2016).	851	16
Order Carnivora—Superfamily Pinnipedia						
Family Phocidae (earless seals):						
Gray seal [4]	*Halichoerus grypus*	Western North Atlantic	-, -, N	27,300 (0.22; 22,785; 2016).	1,458	4,453
Harbor seal	*Phoca vitulina*	Western North Atlantic	-, -, N	61,336 (0.08; 57,637; 2018).	1,729	339
Harp seal [6]	*Pagophilus grownlandicus*	Western North Atlantic	-, -, N	7,600,000 (UNK, 7,100,000.	426,000	178,573

[1] 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.

[2] NMFS marine mammal stock assessment reports online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments* (Hayes *et al.,* 2022). CV is the coefficient of variation; Nmin is the minimum estimate of stock abundance. In some cases, CV is not applicable.

[3] These values, found in NMFS' SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike).

[4] NMFS' stock abundance estimate (and associated PBR value) applies to the U.S. population only. Total stock abundance (including animals in Canada) is approximately 451,431. The annual M/SI value given is for the total stock.

[5] On Monday, October 24, 2022, the North Atlantic Right Whale Consortium announced that the North Atlantic right whale population estimate for 2021 was 340 individuals. NMFS' website also indicates that less than 350 animals remain (*https://www.fisheries.noaa.gov/species/north-atlantic-right-whale*).

[6] Harp seals are rare in the region; however, stranding data suggest this species may be present during activities that may take marine mammals.

As indicated above, all 17 species and 18 stocks in Table 4 temporally and spatially co-occur with the activity to the degree that there is a potential for take. Four of the marine mammal species for which take is requested are listed as threatened or endangered under the ESA, including North Atlantic right, fin, sei, and sperm whales. In addition to what is included in Sections 3 and 4 of Empire Wind's application (*https://www.fisheries.noaa.gov/action/incidental-take-authorization-empire-offshore-wind-llc-construction-empire-wind-project-ew1?check_logged_in=1*), the SARs (*https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*), and NMFS' website (*https://www.fisheries.noaa.gov/species-directory/marine-mammals*), we provide further detail below informing the baseline for select species (*e.g.,* information regarding current Unusual Mortality Events (UME) and known important habitat areas, such as Biologically Important Areas (BIAs) (Van Parijs, 2015). There is no ESA-designated critical habitat for any species within the project area.

Under the MMPA, a UME is defined as ''a stranding that is unexpected; involves a significant die-off of any marine mammal population; and demands immediate response'' (16 U.S.C. 1421h(6)). As of January 24, 2023, five UMEs in total are considered active, with four of these occurring along the U.S. Atlantic coast for various marine mammal species; of these, the most relevant to the Empire Wind Project are the right whale, humpback whale, and northeast pinniped UMEs, given the prevalence of these species in the project area. More information on UMEs, including all active, closed, or pending, can be found on NMFS' website at *https://www.fisheries.noaa.gov/national/marine-life-distress/active-and-closed-unusual-mortality-events.*

Below we include additional information for a subset of the species that presently have an active or recently closed UME occurring along the Atlantic coast, or for which there is information available related to areas of biological significance. For the majority of species potentially present in the specific geographic region, NMFS has designated only a single generic stock (*e.g.,* ''western North Atlantic'') for management purposes. This includes the ''Canadian east coast'' stock of minke whales, which includes all minke whales found in U.S. waters and is also

a generic stock for management purposes. For humpback and sei whales, NMFS defines stocks on the basis of feeding locations, *i.e.,* Gulf of Maine and Nova Scotia, respectively. However, references to humpback whales and sei whales in this document refer to any individuals of the species that are found in the specific geographic region. Any areas of known biological importance (including the BIAs identified in La Brecque *et al.,* 2015) that overlap spatially with the project area are addressed in the species sections below.

North Atlantic Right Whale

The North Atlantic right whale has been listed as Endangered since the ESA was enacted in 1973. They were recently uplisted from Endangered to Critically Endangered on the International Union for Conservation of Nature (IUCN) Red List of Threatened Species (Cooke, 2020). The uplisting was due to a decrease in population size (Pace *et al.,* 2017), an increase in vessel strikes and entanglements in fixed fishing gear (Daoust *et al.,* 2017; Davis & Brillant, 2019; Knowlton *et al.,* 2012; Knowlton *et al.,* 2022; Moore *et al.,* 2021; Sharp *et al.,* 2019), and a decrease in birth rate (Pettis *et al.,* 2021; Reed *et al.,* 2022). The Western Atlantic stock is considered depleted under the MMPA (Hayes *et al.* 2022). There is a recovery plan (NOAA Fisheries 2005) for the North Atlantic right whale, and NMFS completed 5-year reviews of the species in 2012, 2017, and 2022 which concluded no change to the listing status is warranted.

The North Atlantic right whale population had only a 2.8 percent recovery rate between 1990 and 2011, and an overall abundance decline of 29.7 percent from 2011–2020 (Hayes *et al.* 2022). Since 2010, the North Atlantic right whale population has been in decline (Pace *et al.,* 2017; Pace *et al.,* 2021), with a 40 percent decrease in calving rate (Kraus *et al.,* 2016; Moore *et al.,* 2021). North Atlantic right whale calving rates dropped from 2017 to 2020, with zero births recorded during the 2017–2018 season. The 2020–2021 calving season had the first substantial calving increase in five years, with 20 calves born, followed by 15 calves during the 2021–2022 calving season. However, mortalities continue to outpace births, and best estimates indicate fewer than 100 reproductively active females remain in the population.

The project area both spatially and temporally overlaps a portion of the migratory corridor BIA within which right whales migrate south to calving grounds generally in November and December, followed by a northward migration into feeding areas east and north of the project area in March and April (LaBrecque *et al.,* 2015; Van Parijs *et al.,* 2015).

In late fall (*i.e.,* November), a portion of the right whale population (including pregnant females) typically departs the feeding grounds in the North Atlantic, moves south along the migratory corridor BIA, including through the project area, to right whale calving grounds off Georgia and Florida. However, recent research indicates understanding of their movement patterns remains incomplete and not all of the population undergoes a consistent annual migration (Davis *et al.,* 2017; Gowan *et al.,* 2019; Krzystan *et al.,* 2018). The results of multistate temporary emigration capture-recapture modeling, based on sighting data collected over the past 22 years, indicate that non-calving females may remain in the feeding grounds, during the winter in the years preceding and following the birth of a calf to increase their energy stores (Gowen *et al.,* 2019).

Right whales are anticipated to occur in the proposed survey area year-round but with lower levels in the summer from July-September. (Estabrook *et al.,* 2021). Recent aerial surveys in the New York Bight showed right whales near the proposed survey area with the highest sighting rate in spring, followed by winter, preferring deeper waters near the shelf break (right whales observed in depths ranging from 33–1,041 m), but were observed throughout the survey area. No right whales were observed in summer months (Normandeau Associates and APEM, 2020; Zoidis *et al.,* 2021). Similarly, passive acoustic data collected from 2018 to 2020 in the New York Bight showed detections of right whales throughout the year. During the Year 3 survey period, North Atlantic right whales were detected in each month, except in February, March, and October 2020, with the most detections occurring in late fall through early spring. Seasonally, North Atlantic right whale acoustic presence was highest in the fall at sites that were closer to New York Harbor and during spring months at sites farthest from the Harbor (Zoidis *et al.,* 2021).

North Atlantic right whales present in the Empire Wind project area are primarily migrating through. Some opportunistic foraging may occur although core foraging habitat is located north of the project area in Southern New England, Gulf of Maine and Gulf of St. Lawrence. Right whales feed primarily on the copepod *Calanus finmarchicus,* a species whose availability and distribution has changed both spatially and temporally over the last decade due to an oceanographic regime shift that has been ultimately linked to climate change (Meyer-Gutbrod *et al.,* 2021; Record *et al.,* 2019; Sorochan *et al.,* 2019). This distribution change in prey availability has led to shifts in right whale habitat-use patterns within the region over the same time period (Davis *et al.,* 2020; Meyer-Gutbrod *et al.,* 2022; Quintano-Rizzo *et al.,* 2021, O'Brien *et al.,* 2022).

Elevated right whale mortalities have occurred since June 7, 2017, along the U.S. and Canadian coast, with the leading category for the cause of death for this UME determined to be ''human interaction,'' specifically from entanglements or vessel strikes. As of February, 2023, there have been 36 confirmed mortalities and 22 seriously injured free-swimming whales for a total of 58. The UME also considers animals with sublethal injury or illness, also known as morbidity cases. There have been 39 bringing the total number of whales in the UME to 97. 2021), likely contributing to smaller body sizes at maturation, making them more susceptible to threats and reducing fecundity (Moore *et al.,* 2021; Reed *et al.,* 2022; Stewart *et al.,* 2022). More information about the North Atlantic right whale UME is available online at: *https://www.fisheries.noaa.gov/national/marine-life-distress/2017-2023-north-atlantic-right-whale-unusual-mortality-event.*

NMFS' regulations at 50 CFR part 224.105 designated nearshore waters of the Mid-Atlantic Bight as Mid-Atlantic U.S. Seasonal Management Areas (SMAs) for right whales in 2008. These specific SMAs were developed to reduce the threat of collisions between ships and right whales around their migratory route and calving grounds. The SMA southeast of Ports of New York/New Jersey is currently active from November 1 through April 30 of each year and may be used by right whales for feeding. As noted above, NMFS is proposing changes to the North Atlantic right whale speed rule (87 FR 46921; August 1, 2022). In addition, Dynamic Management Areas (DMAs) are areas of temporary protection established by NOAA Fisheries for particular marine mammal species, in an effort to respond to movements of high-risk whale species (such as right whale). These DMAs are determined by sighting reports made through vessel traffic in the larger Northern Atlantic and are communicated through marine communication systems and published on their website. The Right Whale Sighting Advisory System, a statutory

requirement to reduce the risk of right whale collisions, is in place for any DMA. As noted above, NMFS is proposing changes to the North Atlantic right whale speed rule (87 FR 46921; August 1, 2022).

Fin Whale

Fin whales typically feed in the Gulf of Maine and the waters surrounding New England, but their mating and calving (and general wintering) areas are largely unknown (Hain *et al.* 1992, Hayes *et al.* 2022). Recordings from Massachusetts Bay, New York Bight, and deep-ocean areas have detected some level of fin whale singing from September through June (Watkins *et al.* 1987, Clark and Gagnon 2002, Morano *et al.* 2012). These acoustic observations from both coastal and deep-ocean regions support the conclusion that male fin whales are broadly distributed throughout the western North Atlantic for most of the year (Hayes *et al.* 2022).

There are no fin whale BIAs in the immediate vicinity of the project area although a small feeding BIA is located approximately 140 km to the northeast offshore of Montauk Point, from March to October (Hain *et al.,* 1992; LaBrecque *et al.,* 2015).

Minke Whale

Minke whales are among the most widely distributed of all the baleen whales. They occur in the North Atlantic and North Pacific, from tropical to polar waters. Generally, they inhabit warmer waters during winter and travel north to colder regions in summer, while some animals migrate as far as the ice edge. There appears to be a strong seasonal component to minke whale distribution in the survey areas, in which spring to fall are times of relatively widespread and common occurrence while during winter the species appears to be largely absent (Waring *et al.,* 2016). Recent aerial surveys in the New York Bight area found that minke whales were observed throughout the survey area, with highest numbers sighting in the spring months (Normandeau Associates and APEM). Minke whales are primarily documented near the continental shelf offshore of New Jersey (Schwartz, 1962; Mead, 1975; Potter, 1979; Rowlett, 1980; Potter, 1984; Winn *et al.,* 1985, DoN, 2005). Acoustic recordings of minke whales have been detected north of the Lease survey area within the New York Bight during the fall (August to December) and winter (February to May) (Biedron *et al.,* 2009). Minke whales are most common off New Jersey in coastal waters in the spring and early summer as they move north to feeding ground in New England and fall as they migrate south (Geo-Marine, 2010). Geo-Marine (2010) observed four minke whales near the survey area and surrounding waters during winter and spring. A juvenile minke whale was sighted northwest of the Lease survey area near the New York Harbor in April 2007 (Hamazaki, 2002). Minke whale sightings off the coast of New Jersey were within water depths of 36 ft to 79 ft (11 m to 24 m) and temperatures ranging from 5.4 to 11.5 °C (47 °F) (Geo-Marine, 2010).

There are no minke whale BIAs in or near the project area. The closest is a feeding BIA identified in the southern and southwestern section of the Gulf of Maine from March through November, annually (LeBrecque *et al.,* 2015). A migratory route for minke whales transiting between northern feeding grounds and southern breeding areas may exist to the east of the proposed project area, as minke whales may track warmer waters along the continental shelf while migrating (Risch *et al.,* 2014).

Since January 2017, elevated minke whale mortalities detected along the Atlantic coast from Maine through South Carolina resulted in the declaration of a UME. However, that UME is now nonactive with closure pending. During the active phase of the UME, a total of 140 strandings had been reported with 21 occurring in New York and 11 in New Jersey. Previous minke whale UMEs occurred in 2003 and 2005 (NOAA Fisheries 2018c). Full or partial necropsy examinations were conducted on more than 60 percent of the whales. Preliminary findings in several of the whales have shown evidence of human interactions or infectious disease, but these findings are not consistent across all of the whales examined, so more research is needed. More information is available at: *https://www.fisheries.noaa.gov/national/marine-life-distress/2017-2022-minke-whale-unusual-mortality-event-along-atlantic-coast.*

Humpback Whale

Humpback whales are a cosmopolitan species, found worldwide in all oceans, but were listed as endangered under the Endangered Species Conservation Act (ESCA) in June 1970. In 1973, the ESA replaced the ESCA, and humpbacks continued to be listed as endangered.

On September 8, 2016, NMFS divided the once single species into 14 distinct population segments (DPS), removed the species-level listing, and, in its place, listed four DPSs as endangered and one DPS as threatened (81 FR 62259; September 8, 2016). The remaining nine DPSs were not listed. The West Indies DPS, which is not listed under the ESA, is the only DPS of humpback whales that is expected to occur in the project area. Bettridge *et al.* (2015) estimated the size of the West Indies DPS population at 12,312 (95 percent CI 8,688–15,954) whales in 2004–05, which is consistent with previous population estimates of approximately 10,000–11,000 whales (Stevick *et al.,* 2003; Smith *et al.,* 1999) and the increasing trend for the West Indies DPS (Bettridge *et al.,* 2015).

The project area does not overlap any designated critical habitat, nor any identified BIAs or other known important areas, for the humpback whales. A humpback whale feeding BIA extends throughout the Gulf of Maine, Stellwagen Bank, and Great South Channel from May through December, annually (LeBrecque *et al.,* 2015). However, this BIA is located further east and north of, and thus does not overlap, the project area.

Four decades ago, humpback whales were infrequently sighted off the US mid-Atlantic states (USMA, New York, New Jersey, Delaware, Maryland, Virginia and North Carolina, CeTAP, 1982), but they are now regular visitors. Humpback whales are now frequently seen inside the New York-New Jersey harbor estuary and in the greater New York Bight (Brown *et al.,* 2018, 2019; King *et al.,* 2021; Zoidis *et al.,* 2021; Smith *et al.,* 2022). Based on a 2012–2018 dataset, mean occurrence was low (2.5 days), mean occupancy was 37.6 days, and 31.3 percent of whales returned from one year to the next (Brown *et al.,* 2022). Sightings of mother-calf pairs are rare in the New York Bight Area, suggesting that maternally directed fidelity may not be responsible for the presence of young whales in this area (Brown *et al.,* 2022).

Humpback whales belonging to the West Indies DPS typically feed in the waters between the Gulf of Maine and Newfoundland during spring, summer, and fall, but they have been observed feeding in other areas, such as off the coast of New York and New Jersey, including in close-proximity to the entrance of the Port of New York and New Jersey (Sieswerda *et al.,* 2015, Brown *et al.,* 2019).

Recent aerial surveys in the New York Bight observed humpback whales in the spring and winter, but sightings were reported year round in the area (Normandeau Associates and APEM, 2020). During 36 line-transect aerial surveys conducted systematically nearshore out to 120 nm from March 2017 to February 2020. Humpback whales preferred deeper waters near the shelf break, but were observed throughout the area. Additionally,

passive acoustic data recorded humpback whales in the New York Bight throughout the year, but the presence was highest in the fall and summer months (Estabrook *et al.,* 2021). In addition, recent research has demonstrated a higher occurrence and foraging use of the New York Bight area by humpback whales than previously known.

Since January 2016, elevated humpback whale mortalities along the Atlantic coast from Maine to Florida led to the declaration of a UME. A total of 27 and 36 strandings have been reported in the waters off New Jersey and New York, respectively. Partial or full necropsy examinations have been conducted on approximately half of the 189 known cases (as of February 2023). Of the whales examined, about 50 percent had evidence of human interaction, either ship strike or entanglement. While a portion of the whales have shown evidence of pre-mortem vessel strike, this finding is not consistent across all whales examined and more research is needed. NOAA is consulting with researchers that are conducting studies on the humpback whale populations, and these efforts may provide information on changes in whale distribution and habitat use that could provide additional insight into how these vessel interactions occurred. More information is available at: *https://www.fisheries.noaa.gov/national/marine-life-distress/2016-2023-humpback-whale-unusual-mortality-event-along-atlantic-coast.*

Since December 1, 2022, the number of humpback strandings along the mid-Atlantic coast, including New York, has been elevated. In some cases, the cause of death is not yet known. In others, vessel strike has been deemed the cause of death. As the humpback whale population has grown, they are seen more often in the Mid-Atlantic. Along the New York/New Jersey shore, these whales may be following their prey which are reportedly close to shore this winter. These prey also attract fish that are of interest to recreational and commercial fishermen. This increases the number of boats in these areas. More whales in the water in areas traveled by boats of all sizes increases the risk of vessel strikes. Vessel strikes and entanglement in fishing gear are the greatest human threats to large whales.

Phocid Seals

Since June 2022, elevated numbers of harbor seal and gray seal mortalities have occurred across the southern and central coast of Maine. This event has been declared a UME. Preliminary testing of samples has found some harbor and gray seals positive for highly pathogenic avian influenza. While the UME is not occurring in the Empire Wind project area, the populations affected by the UME are the same as those potentially affected by the project.

The above event was preceded by a different UME, occurring from 2018–2020 (closure of the 2018–2020 UME is pending). Beginning in July 2018, elevated numbers of harbor seal and gray seal mortalities occurred across Maine, New Hampshire, and Massachusetts. Additionally, stranded seals have shown clinical signs as far south as Virginia, although not in elevated numbers, therefore the UME investigation encompassed all seal strandings from Maine to Virginia. A total of 3,152 reported strandings (of all species) occurred from July 1, 2018, through March 13, 2020. Full or partial necropsy examinations have been conducted on some of the seals and samples have been collected for testing. Based on tests conducted thus far, the main pathogen found in the seals is phocine distemper virus. NMFS is performing additional testing to identify any other factors that may be involved in this UME, which is pending closure. Information on this UME is available online at: *www.fisheries.noaa.gov/new-england-mid-atlantic/marine-life-distress/2018–2020-pinniped-unusual-mortality-event-along.*

There are several seal haul-out sites in New York. Harbor seals generally predominate in the onshore haul-out sites but gray seals intermix and are present as well. There are 26 known haul-out sites on Long Island, New York (CRESLI, 2019). During surveys from 2004–2019, a total of 18,321 harbor seals were documented using these sites (CRESLI, 2019). While there are no known haul-out sites directly at or near the proposed nearshore activities (*i.e.,* cable landfall construction, marine activities), harbor seals will occur throughout the New York coastline and have potential to haul out at many beach sites. The only known and consistently used gray seal haul out locations are along the sandy shoals located closer to Monomoy Refuge and on Nantucket, both in Massachusetts (Kenney and Vigness-Raposa 2010). This species has been reported with greater frequency in waters south of Cape Cod in recent years, likely due to a population rebound in the Mid-Atlantic (Kenney and Vigness-Raposa 2010).

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. Current data indicate that 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) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 5.

TABLE 5—MARINE MAMMAL HEARING GROUPS

[NMFS, 2018]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.

TABLE 5—MARINE MAMMAL HEARING GROUPS—Continued

[NMFS, 2018]

Hearing group	Generalized hearing range *
High-frequency (HF) cetaceans (true porpoises, Kogia, river dolphins, cephalorhynchid, Lagenorhynchus cruciger & L. australis).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 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 are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information. Seventeen marine mammal species (14 cetacean species (6 mysticetes and 8 odontocetes) and 3 pinniped species (both phocid)) have the reasonable potential to co-occur with the proposed project activities (Table 4).

NMFS notes that in 2019, Southall *et al.* recommended new names for hearing groups that are widely recognized. However, this new hearing group classification does not change the weighting functions or acoustic thresholds (*i.e.,* the weighting functions and thresholds in Southall *et al.* (2019) are identical to NMFS 2018 Revised Technical Guidance). When NMFS updates our Technical Guidance, we will be adopting the updated Southall *et al.* (2019) hearing group classification.

Acoustic Habitat

Acoustic habitat is defined as distinguishable soundscapes inhabited by individual animals or assemblages of species, inclusive of both the sounds they create and those they hear (NOAA, 2016). All of the sound present in a particular location and time, considered as a whole, comprises a ''soundscape'' (Pijanowski *et al.,* 2011). When examined from the perspective of the animals experiencing it, a soundscape may also be referred to as ''acoustic habitat'' (Clark *et al.,* 2009, Moore *et al.,* 2012, Merchant *et al.,* 2015). High value acoustic habitats, which vary spectrally, spatially, and temporally, support critical life functions (feeding, breeding, and survival) of their inhabitants. Thus, it is important to consider acute (*e.g.,* stress or missed feeding/breeding opportunities) and chronic effects (*e.g.,* masking) of noise on important acoustic habitats. Effects that accumulate over long periods can ultimately result in detrimental impacts on the individual, stability of a population, or ecosystems that they inhabit.

Potential Effects to Marine Mammals and Their Habitat

This section includes a summary and discussion of the ways that 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 how those impacts on individuals are likely to impact marine mammal species or stocks. General background information on marine mammal hearing was provided previously (see the Description of Marine Mammals in the Area of the Specified Activities section). Here, the potential effects of sound on marine mammals are discussed.

Empire Wind has requested, and NMFS proposes to authorize, the taking of marine mammals incidental to construction activities associated with in the EW 1 and EW 2 project area. In their application, Empire Wind presented analyses of potential impacts to marine mammals from use of acoustic sources. NMFS both carefully reviewed the information provided by Empire Wind, as well as independently reviewed applicable scientific research and literature and other information to evaluate the potential effects of Empire Wind's activities on marine mammals.

The proposed activities would result in placement of up to 147 permanent monopiles foundations and two OSS jacket foundations in the marine environment. There are a variety of the types and degrees of effects to marine mammals, prey species, and habitat that could occur as a result from the project. Below we provide a brief description of the types of sound sources that would be generated by the project, the general impacts from these types of activities, and an analysis of the anticipated impacts on marine mammals from the project, with consideration of the proposed mitigation measures.

Description of Sound Sources

This section contains a brief technical background on sound, on the characteristics of certain sound types, and on metrics used in this proposal inasmuch as the information is relevant to the specified activity and to a discussion of the potential effects of the specified activity on marine mammals found later in this document. For general information on sound and its interaction with the marine environment, please see, *e.g.,* Au and Hastings (2008); Richardson *et al.* (1995); Urick (1983) as well as the Discovery of Sound in the Sea (DOSITS) website at *https://dosits.org/.*

Sound is a vibration that travels as an acoustic wave through a medium such as a gas, liquid or solid. Sound waves alternately compress and decompress the medium as the wave travels. These compressions and decompressions are detected as changes in pressure by aquatic life and man-made sound receptors such as hydrophones (underwater microphones). In water, sound waves radiate in a manner similar to ripples on the surface of a pond and may be either directed in a beam (narrow beam or directional sources) or sound beams may radiate in all directions (omnidirectional sources).

Sound travels in water more efficiently than almost any other form of energy, making the use of acoustics ideal for the aquatic environment and its inhabitants. In seawater, sound travels at roughly 1500 meters per second (m/s). In-air, sound waves travel much more slowly, at about 340 m/s. However, the speed of sound can vary by a small amount based on

characteristics of the transmission medium, such as water temperature and salinity. Sound travels in water more efficiently than almost any other form of energy, making the use of acoustics ideal for the aquatic environment and its inhabitants. In seawater, sound travels at roughly 1500 m/s. In-air, sound waves travel much more slowly, at about 340 m/s. However, the speed of sound can vary by a small amount based on characteristics of the transmission medium, such as water temperature and salinity.

The basic components of a sound wave are frequency, wavelength, velocity, and amplitude. Frequency is the number of pressure waves that pass by a reference point per unit of time and is measured in Hz or cycles per second. Wavelength is the distance between two peaks or corresponding points of a sound wave (length of one cycle). Higher frequency sounds have shorter wavelengths than lower frequency sounds, and typically attenuate (decrease) more rapidly, except in certain cases in shallower water. The intensity (or amplitude) of sounds are measured in decibels (dB), which are a relative unit of measurement that is used to express the ratio of one value of a power or field to another. Decibels are measured on a logarithmic scale, so a small change in dB corresponds to large changes in sound pressure. For example, a 10-dB increase is a ten-fold increase in acoustic power. A 20-dB increase is then a 100-fold increase in power and a 30-dB increase is a 1000-fold increase in power. However, a ten-fold increase in acoustic power does not mean that the sound is perceived as being ten times louder. Decibels are a relative unit comparing two pressures, therefore a reference pressure must always be indicated. For underwater sound, this is 1 microPascal (µPa). For in-air sound, the reference pressure is 20 microPascal (µPa). The amplitude of a sound can be presented in various ways; however, NMFS typically considers three metrics. In this proposed rule, all decibel levels referenced to 1µPa.

Sound exposure level (SEL) represents the total energy in a stated frequency band over a stated time interval or event, and considers both amplitude and duration of exposure (represented as dB re 1 μPa^2-s). SEL is a cumulative metric; it can be accumulated over a single pulse (for pile driving this is often referred to as single-strike SEL; SEL_{ss}), or calculated over periods containing multiple pulses (SEL_{cum}). Cumulative SEL represents the total energy accumulated by a receiver over a defined time window or during an event. The SEL metric is useful because it allows sound exposures of different durations to be related to one another in terms of total acoustic energy. The duration of a sound event and the number of pulses, however, should be specified as there is no accepted standard duration over which the summation of energy is measured.

Root mean square (rms) is the quadratic mean sound pressure over the duration of an impulse. Root mean square is calculated by squaring all of the sound amplitudes, averaging the squares, and then taking the square root of the average (Urick, 1983). Root mean square accounts for both positive and negative values; squaring the pressures makes all values positive so that they may be accounted for in the summation of pressure levels (Hastings and Popper, 2005). This measurement is often used in the context of discussing behavioral effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak pressures.

Peak sound pressure (also referred to as zero-to-peak sound pressure or 0-pk) is the maximum instantaneous sound pressure measurable in the water at a specified distance from the source, and is represented in the same units as the rms sound pressure. Along with SEL, this metric is used in evaluating the potential for PTS (permanent threshold shift) and TTS (temporary threshold shift).

Sounds can be either impulsive or non-impulsive. The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing *(e.g.,* Ward, 1997 in Southall *et al.,* 2007). Please see NMFS *et al.* (2018) and Southall *et al.* (2007, 2019) for an in-depth discussion of these concepts. Impulsive sound sources (*e.g.,* airguns, explosions, gunshots, sonic booms, impact pile driving) produce signals that are brief (typically considered to be less than one second), broadband, atonal transients (ANSI, 1986, 2005; Harris, 1998; NIOSH, 1998; ISO, 2003) and occur either as isolated events or repeated in some succession. Impulsive sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features. Impulsive sounds are typically intermittent in nature.

Non-impulsive sounds can be tonal, narrowband, or broadband, brief or prolonged, and may be either continuous or intermittent (ANSI, 1995; NIOSH, 1998). Some of these non-impulsive sounds can be transient signals of short duration but without the essential properties of pulses (*e.g.,* rapid rise time). Examples of non-impulsive sounds include those produced by vessels, aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems.

Sounds are also characterized by their temporal component. Continuous sounds are those whose sound pressure level remains above that of the ambient sound, with negligibly small fluctuations in level (NIOSH, 1998; ANSI, 2005), while intermittent sounds are defined as sounds with interrupted levels of low or no sound (NIOSH, 1998). NMFS identifies Level B harassment thresholds based on if a sound is continuous or intermittent.

Even in the absence of sound from the specified activity, the underwater environment is typically loud due to ambient sound, which is defined as environmental background sound levels lacking a single source or point (Richardson *et al.,* 1995). The sound level of a region is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (*e.g.,* wind and waves, earthquakes, ice, atmospheric sound), biological (*e.g.,* sounds produced by marine mammals, fish, and invertebrates), and anthropogenic (*e.g.,* vessels, dredging, construction) sound. A number of sources contribute to ambient sound, including wind and waves, which are a main source of naturally occurring ambient sound for frequencies between 200 Hz and 50 kHz (ICES, 1995). In general, ambient sound levels tend to increase with increasing wind speed and wave height. Precipitation can become an important component of total sound at frequencies above 500 Hz, and possibly down to 100 Hz during quiet times. Marine mammals can contribute significantly to ambient sound levels, as can some fish and snapping shrimp. The frequency band for biological contributions is from approximately 12 Hz to over 100 kHz. Sources of ambient sound related to human activity include transportation (surface vessels), dredging and construction, oil and gas drilling and production, geophysical surveys, and sonar. Vessel noise typically dominates the total ambient sound for frequencies between 20 and 300 Hz. In general, the frequencies of anthropogenic sounds are below 1 kHz and, if higher frequency sound levels are created, they attenuate rapidly.

The sum of the various natural and anthropogenic sound sources that comprise ambient sound at any given location and time depends not only on the source levels (as determined by current weather conditions and levels of biological and human 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 10–20 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. Human-generated sound is a significant contributor to the acoustic environment in the project location.

Potential Effects of Underwater Sound on Marine Mammals

Anthropogenic sounds cover a broad range of frequencies and sound levels and can have a range of highly variable impacts on marine life, from none or minor to potentially severe responses, depending on received levels, duration of exposure, behavioral context, and various other factors. Broadly, underwater sound from active acoustic sources such as those in the Empire Wind Project can potentially result in one or more of the following: temporary or permanent hearing impairment, non-auditory physical or physiological effects (*e.g.,* stress), behavioral disturbance, and masking (Richardson *et al.,* 1995; Gordon *et al.,* 2003; Nowacek *et al.,* 2007; Southall *et al.,* 2007; Götz *et al.,* 2009). Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to high level underwater sound or as a secondary effect of extreme behavioral reactions (*e.g.,* change in dive profile as a result of an avoidance reaction) caused by exposure to sound include neurological effects, bubble formation, resonance effects, and other types of organ or tissue damage (Cox *et al.,* 2006; Southall *et al.,* 2007; Zimmer and Tyack, 2007; Tal *et al.,* 2015).

In general, the degree of effect of an acoustic exposure is intrinsically related to the signal characteristics, received level, distance from the source, and duration of the sound exposure, in addition to the contextual factors of the receiver (*e.g.,* behavioral state at time of exposure, age class, etc). In general, sudden, high level sounds can cause hearing loss as can longer exposures to lower level sounds. Moreover, any temporary or permanent loss of hearing will occur almost exclusively for noise within an animal's hearing range. We describe below the specific manifestations of acoustic effects that may occur based on the activities proposed by Empire Wind.

Richardson *et al.* (1995) described zones of increasing intensity of effect that might be expected to occur, in relation to distance from a source and assuming that the signal is within an animal's hearing range. First (at the greatest distance) is the area within which the acoustic signal would be audible (potentially perceived) to the animal but not strong enough to elicit any overt behavioral or physiological response. The next zone (closer to the receiving animal) corresponds with the area where the signal is audible to the animal and of sufficient intensity to elicit behavioral or physiological responsiveness. The third is a zone within which, for signals of high intensity, the received level is sufficient to potentially cause discomfort or tissue damage to auditory or other systems. Overlaying these zones to a certain extent is the area within which masking (*i.e.,* when a sound interferes with or masks the ability of an animal to detect a signal of interest that is above the absolute hearing threshold) may occur; the masking zone may be highly variable in size.

Below, we provide additional detail regarding potential impacts on marine mammals and their habitat from noise in general, as well as from the specific activities Empire Wind plans to conduct, to the degree it is available (noting that there is limited information regarding the impacts of offshore wind construction on marine mammals or cetaceans).

Hearing Threshold Shift

Marine mammals exposed to high-intensity sound, or to lower-intensity sound for prolonged periods, can experience hearing threshold shift (TS), which NMFS defines 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, expressed in decibels (NMFS, 2018). Threshold shifts can be permanent (permanent threshold shift; PTS), in which case there is an irreversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range, or temporary (temporary threshold shift; TTS), in which there is reversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range and the animal's hearing threshold would fully recover over time (Southall *et al.,* 2019). Repeated sound exposure that leads to TTS could cause PTS.

When PTS occurs, there can be physical damage to the sound receptors in the ear (*i.e.,* tissue damage), whereas TTS represents primarily tissue fatigue and is reversible (Henderson *et al.,* 2008). In addition, other investigators have suggested that TTS is within the normal bounds of physiological variability and tolerance and does not represent physical injury (*e.g.,* Ward, 1997; Southall *et al.,* 2019). Therefore, NMFS does not consider TTS to constitute auditory injury.

Relationships between TTS and PTS thresholds have not been studied in marine mammals, and there is no PTS data for cetaceans, but such relationships are assumed to be similar to those in humans and other terrestrial mammals. Noise exposure can result in either a permanent shift in hearing thresholds from baseline (PTS; a 40 dB threshold shift approximates a PTS onset; *e.g.,* Kryter *et al.,* 1966; Miller, 1974; Henderson *et al.,* 2008) or a temporary, recoverable shift in hearing that returns to baseline (a 6 dB threshold shift approximates a TTS onset; *e.g.,* Southall *et al.,* 2019). Based on data from terrestrial mammals, a precautionary assumption is that the PTS thresholds, expressed in the unweighted peak sound pressure level metric (PK), for impulsive sounds (such as impact pile driving pulses) are at least 6 dB higher than the TTS thresholds and the weighted PTS cumulative sound exposure level thresholds are 15 (impulsive sound) to 20 (non-impulsive sounds) dB higher than TTS cumulative sound exposure level thresholds (Southall *et al.,* 2019). Given the higher level of sound or longer exposure duration necessary to cause PTS as compared with TTS, PTS is less likely to occur as a result of these activities, but it is possible and a small amount has been proposed for authorization for several species.

TTS is the mildest form of hearing impairment that can occur during exposure to sound, with a TTS of 6 dB considered the minimum threshold shift 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; Finneran *et al.,* 2002). 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. There is data on sound levels and durations necessary to elicit mild TTS for marine mammals but recovery is complicated to predict and dependent on multiple factors.

Currently, TTS data only exist for four species of cetaceans (bottlenose dolphin, beluga whale (*Delphinapterus leucas*), harbor porpoise, and Yangtze finless porpoise (*Neophocoena asiaeorientalis*)) and six species of pinnipeds (northern elephant seal (*Mirounga angustirostris*), harbor seal, ring seal, spotted seal, bearded seal, and California sea lion (*Zalophus californianus*)) that were exposed to a limited number of sound sources (*i.e.,* mostly tones and octave-band noise with limited number of exposure to impulsive sources such as seismic airguns or impact pile driving) in laboratory settings (Southall *et al.,* 2019). There is currently no data available on noise-induced hearing loss for mysticetes. For summaries of data on TTS or PTS in marine mammals or for further discussion of TTS or PTS onset thresholds, please see Southall *et al.* (2019), and NMFS (2018).

Recent studies with captive odontocete species (bottlenose dolphin, harbor porpoise, beluga, and false killer whale) have observed increases in hearing threshold levels when individuals received a warning sound prior to exposure to a relatively loud sound (Nachtigall and Supin, 2013, 2015, Nachtigall *et al.,* 2016 a,b,c, Finneran, 2018, Nachtigall *et al.,* 2018). These studies suggest that captive animals have a mechanism to reduce hearing sensitivity prior to impending loud sounds. Hearing change was observed to be frequency dependent and Finneran (2018) suggests hearing attenuation occurs within the cochlea or auditory nerve. Based on these observations on captive odontocetes, the authors suggest that wild animals may have a mechanism to self-mitigate the impacts of noise exposure by dampening their hearing during prolonged exposures of loud sound, or if conditioned to anticipate intense sounds (Finneran, 2018, Nachtigall *et al.,* 2018).

Marine mammal hearing plays a critical role in communication with conspecifics, and interpretation of environmental cues for purposes such as predator avoidance and prey capture. 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 depending on the degree of interference of marine mammals hearing. 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 occurs during a time 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 time when communication is critical (*e.g.,* for successful mother/calf interactions, consistent detection of prey) could have more serious impacts.

Behavioral Effects

Exposure of marine mammals to sound sources can result in, but is not limited to, no response or any of the following observable responses: Increased alertness; orientation or attraction to a sound source; vocal modifications; cessation of feeding; cessation of social interaction; alteration of movement or diving behavior; habitat abandonment (temporary or permanent); and, in severe cases, panic, flight, stampede, or stranding, potentially resulting in death (Southall *et al.,* 2007). A review of marine mammal responses to anthropogenic sound was first conducted by Richardson (1995). More recent reviews (Nowacek *et al.,* 2007; DeRuiter *et al.,* 2012 and 2013; Ellison *et al.,* 2012; Gomez *et al.,* 2016; Southall *et al.,* 2021)) address studies conducted since 1995 and focused on observations where the received sound level of the exposed marine mammal(s) was known or could be estimated. Gomez *et al.* (2016) conducted a review of the literature considering the contextual information of exposure in addition to received level and found that higher received levels were not always associated with more severe behavioral responses and vice versa. Southall *et al.* (2021) states that results demonstrate that some individuals of different species display clear yet varied responses, some of which have negative implications, while others appear to tolerate high levels, and that responses may not be fully predictable with simple acoustic exposure metrics (*e.g.,* received sound level). Rather, the authors state that differences among species and individuals along with contextual aspects of exposure (*e.g.,* behavioral state) appear to affect response probability. Behavioral responses to sound are highly variable and context-specific. Many different variables can influence an animal's perception of and response to (nature and magnitude) an acoustic event. An animal's prior experience with a sound or sound source affects whether it is less likely (habituation) or more likely (sensitization) to respond to certain sounds in the future (animals can also be innately predisposed to respond to certain sounds in certain ways) (Southall *et al.,* 2019). Related to the sound itself, the perceived nearness of the sound, bearing of the sound (approaching vs. retreating), the similarity of a sound to biologically relevant sounds in the animal's environment (*i.e.,* calls of predators, prey, or conspecifics), and familiarity of the sound may affect the way an animal responds to the sound (Southall *et al.,* 2007; DeRuiter *et al.,* 2013). Individuals (of different age, gender, reproductive status, *etc.*) among most populations will have variable hearing capabilities, and differing behavioral sensitivities to sounds that will be affected by prior conditioning, experience, and current activities of those individuals. Often, specific acoustic features of the sound and contextual variables (*i.e.,* proximity, duration, or recurrence of the sound or the current behavior that the marine mammal is engaged in or its prior experience), as well as entirely separate factors such as the physical presence of a nearby vessel, may be more relevant to the animal's response than the received level alone.

Overall, the variability of responses to acoustic stimuli depends not only on the species receiving the sound and the sound source, but also on the social, behavioral, or environmental contexts of exposure (*e.g.,* DeRuiter *et al.,* 2012). For example, Goldbogen *et al.* (2013) demonstrated that individual behavioral state was critically important in determining response of blue whales to sonar, noting that some individuals engaged in deep (greater than 50 m) feeding behavior had greater dive responses than those in shallow feeding or non-feeding conditions. Some blue whales in the Goldbogen *et al.* (2013) study that were engaged in shallow feeding behavior demonstrated no clear changes in diving or movement even when received levels were high (~160 dB re 1µPa) for exposures to 3–4 kHz sonar signals, while deep feeding and non-feeding whales showed a clear response at exposures at lower received levels of sonar and pseudorandom noise. Southall *et al.* 2011 found that blue whales had a different response to sonar exposure depending on behavioral state, more pronounced when deep

feeding/travel modes than when engaged in surface feeding.

With respect to distance influencing disturbance, DeRuiter *et al.* (2013) examined behavioral responses of Cuvier's beaked whales to MF sonar and found that whales responded strongly at low received levels (89–127 dB *re 1*μ*Pa*) by ceasing normal fluking and echolocation, swimming rapidly away, and extending both dive duration and subsequent non-foraging intervals when the sound source was 3.4–9.5 km away. Importantly, this study also showed that whales exposed to a similar range of received levels (78–106 dB *re 1*μ*Pa*) from distant sonar exercises (118 km away) did not elicit such responses, suggesting that context (in this case, distance) may moderate reactions. Thus, distance from the source is an important variable in influencing the type and degree of behavioral response and this is variable is independent of the effect of received levels (*e.g.,* DeRuiter *et al.,* 2013; Dunlop *et al.,* 2017a; Dunlop *et al.,* 2017b; Falcone *et al.,* 2017; Dunlop *et al.,* 2018; Southall *et al.,* 2019).

Ellison *et al.* (2012) outlined an approach to assessing the effects of sound on marine mammals that incorporates contextual-based factors. The authors recommend considering not just the received level of sound, but also the activity the animal is engaged in at the time the sound is received, the nature and novelty of the sound (*i.e.,* is this a new sound from the animal's perspective), and the distance between the sound source and the animal. They submit that this ''exposure context,'' as described, greatly influences the type of behavioral response exhibited by the animal. Forney *et al.* (2017) also point out that an apparent lack of response (*e.g.,* no displacement or avoidance of a sound source) may not necessarily mean there is no cost to the individual or population, as some resources or habitats may be of such high value that animals may choose to stay, even when experiencing stress or hearing loss. Forney *et al.* (2017) recommend considering both the costs of remaining in an area of noise exposure such as TTS, PTS, or masking, which could lead to an increased risk of predation or other threats or a decreased capability to forage, and the costs of displacement, including potential increased risk of vessel strike, increased risks of predation or competition for resources, or decreased habitat suitable for foraging, resting, or socializing. This sort of contextual information is challenging to predict with accuracy for ongoing activities that occur over large spatial and temporal expanses. However, distance is one contextual factor for which data exists to potentially quantitatively inform a take estimate. Other factors are often considered qualitatively in the analysis of the likely consequences of sound exposure, where supporting information is available.

Friedlaender *et al.* (2016) provided the first integration of direct measures of prey distribution and density variables incorporated into across-individual analyses of behavior responses of blue whales to sonar, and demonstrated a five-fold increase in the ability to quantify variability in blue whale diving behavior. These results illustrate that responses evaluated without such measurements for foraging animals may be misleading, which again illustrates the context-dependent nature of the probability of response.

The following subsections provide examples of behavioral responses that give an idea of the variability in behavioral responses that would be expected given the differential sensitivities of marine mammal species to sound, contextual factors, and the wide range of potential acoustic sources to which a marine mammal may be exposed. Behavioral responses that could occur for a given sound exposure should be determined from the literature that is available for each species, or extrapolated from closely related species when no information exists, along with contextual factors.

Avoidance and Displacement

Avoidance is the displacement of an individual from an area or migration path as a result of the presence of a sound or other stressors and is one of the most obvious manifestations of disturbance in marine mammals (Richardson *et al.,* 1995). For example, gray whales or humpback whales are known to change direction—deflecting from customary migratory paths—in order to avoid noise from airgun surveys (Malme *et al.,* 1984; Dunlop *et al.,* 2018). Avoidance is qualitatively different from the flight response, but also differs in the magnitude of the response (*i.e.,* directed movement, rate of travel, etc.). Avoidance may be short-term, with animals returning to the area once the noise has ceased (*e.g.,* Bowles *et al.,* 1994; Goold, 1996; Stone *et al.,* 2000; Morton and Symonds, 2002; Gailey *et al.,* 2007; Dähne *et al.,* 2013; Russel *et al.,* 2016; Malme *et al.,* 1984). Longer-term displacement is possible, however, which may lead to changes in abundance or distribution patterns of the affected species in the affected region if habituation to the presence of the sound does not occur (*e.g.,* Blackwell *et al.,* 2004; Bejder *et al.,* 2006; Teilmann *et al.,* 2006; Forney *et al.,* 2017). Avoidance of marine mammals during the construction of offshore wind facilities (specifically, impact pile driving) has been documented previously noted in the literature, with some significant variation in the temporal and spatial degree of avoidance effects, and with most studies focused on harbor porpoises as one of the most common marine mammals in European waters (*e.g.,* Tougaard *et al.,* 2009; Dähne *et al.,* 2013; Thompson *et al.,* 2013; Russell *et al.,* 2016; Brandt *et al.,* 2018).

Available information on impacts to marine mammals from pile driving associated with offshore wind is limited to information on harbor porpoises and seals, as the vast majority of this research has occurred at European offshore wind projects where large whales and other odontocete species are uncommon. Harbor porpoises and harbor seals are considered to be behaviorally sensitive species (*e.g.,* Southall *et al.,* 2007) and the effects of wind farm construction in Europe on these species has been well documented. These species have received particular attention in European waters due to their abundance in the North Sea (Hammond *et al.,* 2002; Nachtsheim *et al.,* 2021). A summary of the literature on documented effects of wind farm construction on harbor porpoise and harbor seals is described below.

Brandt *et al.* (2016) summarized the effects of the construction of eight offshore wind projects within the German North Sea (*i.e.,* Alpha Ventus, BARD Offshore I, Borkum West II, DanTysk, Global Tech I, Meerwind Süd/Ost, Nordsee Ost, and Riffgat) between 2009 and 2013 on harbor porpoises, combining PAM data from 2010–2013 and aerial surveys from 2009–2013 with data on noise levels associated with pile driving. Results of the analysis revealed significant declines in porpoise detections during pile driving when compared to 25–48 hours before pile driving began, with the magnitude of decline during pile driving clearly decreasing with increasing distances to the construction site. During the majority of projects, significant declines in detections (by at least 20 percent) were found within at least 5–10 km of the pile driving site, with declines at up to 20–30 km of the pile driving site documented in some cases. Similar results demonstrating the long-distance displacement of harbor porpoises (18–25 km) and harbor seals (up to 40 km) during impact pile driving have also been observed during the construction at multiple other European wind farms

(Haleters *et al.,* 2015; Lucke *et al.,* 2012; Dähne *et al.,* 2013; Tougaard *et al.,* 2009; Bailey *et al.,* 2010).

While harbor porpoises and seals tend to move several kilometers away from wind farm construction activities, the duration of displacement has been documented to be relatively temporary. In two studies on impact driving at Horns Rev II in the North Sea near Denmark, harbor porpoise returned within 1–2 days following cessation of pile driving (Tougaard *et al.,* 2009, Brandt *et al.,* 2011). Similar recovery periods have been noted for harbor seals off of England during the construction of four wind farms (Carroll *et al.,* 2010; Hamre *et al.,* 2011; Hastie *et al.,* 2015; Russell *et al.,* 2016; Brasseur *et al.,* 2010). For example, although there was no significant displacement during construction as a whole, Russell *et al.* (2016) found that displacement did occur during active pile driving at predicted received levels between 168 and 178 dB re 1µ$Pa_{(p-p)}$; however seal distribution returned to the pre-piling condition within two hours of cessation of pile driving. In some cases, an increase in harbor porpoise activity has been documented inside wind farm areas following construction (*e.g.,* Lindeboom *et al.,* 2011). Other studies have noted longer term impacts after impact pile driving. Near Dogger Bank in Germany, harbor porpoises continued to avoid the area for over two years after construction began (Gilles *et al.* 2009). Approximately ten years after construction of the Nysted wind farm, harbor porpoise abundance had not recovered to the original levels previously seen, although the echolocation activity was noted to have been increasing when compared to the previous monitoring period (Teilmann and Carstensen, 2012). However, overall, there are no indications for a population decline of harbor porpoises in European waters (*e.g.,* Brandt *et al.,* 2016). Notably, where significant differences in displacement and return rates have been identified for these species, the occurrence of secondary project-specific influences such as use of mitigation measures (*e.g.,* bubble curtains, acoustic deterrent devices (ADDs)) or the manner in which species use the habitat in the project area are likely the driving factors of this variation.

NMFS notes the aforementioned studies from Europe involve pile driving much smaller piles than Empire Wind proposes to install and therefore we anticipate noise levels from impact pile driving to be louder. For this reason, we anticipate that the greater distances of displacement observed in harbor porpoise and harbor seals documented in Europe are likely to occur off of New York. However, we do not anticipate any greater severity of response due to harbor porpoise and harbor seal habitat use off of New York or population level consequences, similar to European findings. In many cases, harbor porpoises and harbor seals are resident to the areas where European wind farms have been constructed. However, off of New York, harbor porpoises are transient (with higher abundances in winter when impact pile driving would not occur) and a very small percentage of the large harbor seal population are only seasonally present with no rookeries established. In summary, we anticipate that harbor porpoise and harbor seals will likely respond to pile driving by moving several kilometers away from the source but return to typical habitat use patterns when pile driving ceases.

Some avoidance behavior of other marine mammal species has been documented to be dependent on distance from the source. As described above, DeRuiter *et al.* (2013) noted that distance from a sound source may moderate marine mammal reactions in their study of Cuvier's beaked whales (an acoustically sensitive species), which showed the whales swimming rapidly and silently away when a sonar signal was 3.4–9.5 km away while showing no such reaction to the same signal when the signal was 118 km away even though the received levels were similar. Tyack *et al.* (1983) conducted playback studies of SURTASS low frequency active (LFA) sonar in a gray whale migratory corridor off California. Similar to North Atlantic right whales, gray whales migrate close to shore (approximately +2 kms) and are low frequency hearing specialists. The LFA sonar source was placed within the gray whale migratory corridor (approximately 2 km offshore) and offshore of most, but not all, migrating whales (approximately 4 km offshore). These locations influenced received levels and distance to the source. For the inshore playbacks, not unexpectedly, the louder the source level of the playback (*i.e.,* the louder the received level), whale avoided the source at greater distances. Specifically, when the source level was 170 dB rms and 178 dB rms, whales avoided the inshore source at ranges of several hundred meters, similar to avoidance responses reported by Malme *et al.* (1983, 1984). Whales exposed to source levels of 185 dB rms demonstrated avoidance levels at ranges of +1 km. Responses to the offshore source broadcasting at source levels of 185 and 200 dB, avoidance responses were greatly reduced. While there was observed deflection from course, in no case did a whale abandon its migratory behavior.

The signal context of the noise exposure has been shown to play an important role in avoidance responses. In a 2007–2008 Bahamas study, playback sounds of a potential predator—a killer whale—resulted in a similar but more pronounced reaction in beaked whales (an acoustically sensitive species), which included longer inter-dive intervals and a sustained straight-line departure of more than 20 km from the area (Boyd *et al.,* 2008; Southall *et al.,* 2009; Tyack *et al.,* 2011). Empire Wind does not anticipate, and NMFS is not proposing to authorize take of beaked whales and, moreover, the sounds produced by Empire Wind do not have signal characteristics similar to predators. Therefore we would not expect such extreme reactions to occur. Southall *et al.* 2011 found that blue whales had a different response to sonar exposure depending on behavioral state, more pronounced when deep feeding/travel modes than when engaged in surface feeding.

One potential consequence of behavioral avoidance is the altered energetic expenditure of marine mammals because energy is required to move and avoid surface vessels or the sound field associated with active sonar (Frid and Dill, 2002). Most animals can avoid that energetic cost by swimming away at slow speeds or speeds that minimize the cost of transport (Miksis-Olds, 2006), as has been demonstrated in Florida manatees (Miksis-Olds, 2006). Those energetic costs increase, however, when animals shift from a resting state, which is designed to conserve an animal's energy, to an active state that consumes energy the animal would have conserved had it not been disturbed. Marine mammals that have been disturbed by anthropogenic noise and vessel approaches are commonly reported to shift from resting to active behavioral states, which would imply that they incur an energy cost.

Forney *et al.* (2017) detailed the potential effects of noise on marine mammal populations with high site fidelity, including displacement and auditory masking, noting that a lack of observed response does not imply absence of fitness costs and that apparent tolerance of disturbance may have population-level impacts that are less obvious and difficult to document. Avoidance of overlap between disturbing noise and areas and/or times of particular importance for sensitive

species may be critical to avoiding population-level impacts because (particularly for animals with high site fidelity) there may be a strong motivation to remain in the area despite negative impacts. Forney *et al.* (2017) stated that, for these animals, remaining in a disturbed area may reflect a lack of alternatives rather than a lack of effects.

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; Frid and Dill, 2002). 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, beaked whale strandings (Cox *et al.,* 2006; D'Amico *et al.,* 2009). 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. Flight responses of marine mammals have been documented in response to mobile high intensity active sonar (*e.g.,* Tyack *et al.,* 2011; DeRuiter *et al.,* 2013; Wensveen *et al.,* 2019), and more severe responses have been documented when sources are moving towards an animal or when they are surprised by unpredictable exposures (Watkins 1986; Falcone *et al.,* 2017). Generally speaking, however, marine mammals would be expected to be less likely to respond with a flight response to either stationery pile driving (which they can sense is stationery and predictable) or significantly lower-level HRG surveys, unless they are within the area ensonified above behavioral harassment thresholds at the moment the source is turned on (Watkins, 1986; Falcone *et al.,* 2017).

Diving and Foraging

Changes in dive behavior in response to noise exposure can vary widely. They 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). Variations in dive behavior may reflect interruptions in biologically significant activities (*e.g.,* foraging) or they may be of little biological significance. Variations in dive behavior may also expose an animal to potentially harmful conditions (*e.g.,* increasing the chance of ship-strike) or may serve as an avoidance response that enhances survivorship. The impact of a variation in diving resulting from an acoustic exposure depends on what the animal is doing at the time of the exposure, the type and magnitude of the response, and the context within which the response occurs (*e.g.,* the surrounding environmental and anthropogenic circumstances).

Nowacek *et al.* (2004) reported disruptions of dive behaviors in foraging North Atlantic right whales when exposed to an alerting stimulus, an action, they noted, that could lead to an increased likelihood of ship strike. The alerting stimulus was in the form of an 18 minute exposure that included three 2-minute signals played three times sequentially. This stimulus was designed with the purpose of providing signals distinct to background noise that serve as localization cues. However, the whales did not respond to playbacks of either right whale social sounds or vessel noise, highlighting the importance of the sound characteristics in producing a behavioral reaction. Although source levels for the proposed pile driving activities may exceed the received level of the alerting stimulus described by Nowacek *et al.* (2004), proposed mitigation strategies (further described in the Proposed Mitigation section) will reduce the severity of response to proposed pile driving activities. Converse to the behavior of North Atlantic right whales, Indo-Pacific humpback dolphins have been observed to dive for longer periods of time in areas where vessels were present and/or approaching (Ng and Leung, 2003). In both of these studies, the influence of the sound exposure cannot be decoupled from the physical presence of a surface vessel, thus complicating interpretations of the relative contribution of each stimulus to the response. Indeed, the presence of surface vessels, their approach, and speed of approach, seemed to be significant factors in the response of the Indo-Pacific humpback dolphins (Ng and Leung, 2003). Low frequency signals of the Acoustic Thermometry of Ocean Climate (ATOC) sound source were not found to affect dive times of humpback whales in Hawaiian waters (Frankel and Clark, 2000) or to overtly affect elephant seal dives (Costa *et al.,* 2003). They did, however, produce subtle effects that varied in direction and degree among the individual seals, illustrating the equivocal nature of behavioral effects and consequent difficulty in defining and predicting them.

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 cessation of secondary indicators of foraging (*e.g.,* bubble nets or sediment plumes), or changes in dive behavior. 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.,* 2006a; Yazvenko *et al.,* 2007; Southall *et al.,* 2019b). An understanding 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 can facilitate the assessment of whether foraging disruptions are likely to incur fitness consequences (Goldbogen *et al.,* 2013; Farmer *et al.,* 2018; Pirotta *et al.,* 2018; Southall *et al.,* 2019; Pirotta *et al.,* 2021).

Impacts on marine mammal foraging rates from noise exposure have been documented, though there is little data regarding the impacts of offshore turbine construction specifically. Several broader examples follow, and it is reasonable to expect that exposure to noise produced during the 5-years the proposed rule would be effective could have similar impacts.

Visual tracking, passive acoustic monitoring, and movement recording tags were used to quantify sperm whale behavior prior to, during, and following exposure to air gun arrays at received levels in the range 140–160 dB at distances of 7–13 km, following a phase-in of sound intensity and full array exposures at 1–13 km (Madsen *et al.,* 2006a; Miller *et al.,* 2009). Sperm whales did not exhibit horizontal avoidance behavior at the surface. However, foraging behavior may have been affected. The sperm whales exhibited 19 percent less vocal (buzz) rate during full exposure relative to post exposure, and the whale that was approached most closely had an extended resting period and did not resume foraging until the air guns had ceased firing. The remaining whales continued to execute foraging dives throughout exposure; however, swimming movements during foraging dives were six percent lower during exposure than control periods (Miller *et al.,* 2009). Miller *et al.* (2009) noted that

more data are required to understand whether the differences were due to exposure or natural variation in sperm whale behavior.

Balaenopterid whales exposed to moderate low-frequency signals similar to the ATOC sound source demonstrated no variation in foraging activity (Croll *et al.,* 2001), whereas five out of six North Atlantic right whales exposed to an acoustic alarm interrupted their foraging dives (Nowacek *et al.,* 2004). Although the received SPLs were similar in the latter two studies, the frequency, duration, and temporal pattern of signal presentation were different. These factors, as well as differences in species sensitivity, are likely contributing factors to the differential response. Though the area ensonified by the HRG sources is significantly smaller than from construction, the source levels of both the proposed construction and HRG activities exceed the source levels of the signals described by Nowacek *et al.,* (2004) and Croll *et al.,* (2001), and noise generated by Empire Wind's activities at least partially overlap in frequency with the described signals. Blue whales exposed to mid-frequency sonar in the Southern California Bight were less likely to produce low frequency calls usually associated with feeding behavior (Melcón *et al.,* 2012). However, Melcón *et al.* (2012) were unable to determine if suppression of low frequency calls reflected a change in their feeding performance or abandonment of foraging behavior and indicated that implications of the documented responses are unknown. Further, it is not known whether the lower rates of calling actually indicated a reduction in feeding behavior or social contact since the study used data from remotely deployed, passive acoustic monitoring buoys. Results from the 2010–2011 field season of a behavioral response study in Southern California waters indicated that, in some cases and at low received levels, tagged blue whales responded to mid-frequency sonar but that those responses were mild and there was a quick return to their baseline activity (Southall *et al.,* 2011; Southall *et al.,* 2012b, Southall *et al.,* 2019b).

Information on or estimates of the energetic requirements of the individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal will help better inform a determination of whether foraging disruptions incur fitness consequences. Foraging strategies may impact foraging efficiency, such as by reducing foraging effort and increasing success in prey detection and capture, in turn promoting fitness and allowing individuals to better compensate for foraging disruptions. Surface feeding blue whales did not show a change in behavior in response to mid-frequency simulated and real sonar sources with received levels between 90 and 179 dB *re 1* µ*Pa,* but deep feeding and non-feeding whales showed temporary reactions including cessation of feeding, reduced initiation of deep foraging dives, generalized avoidance responses, and changes to dive behavior (DeRuiter *et al.,* 2017; Goldbogen *et al.,* 2013b; Sivle *et al.,* 2015). Goldbogen *et al.* (2013b) indicate that disruption of feeding and displacement could impact individual fitness and health. However, for this to be true, we would have to assume that an individual whale could not compensate for this lost feeding opportunity by either immediately feeding at another location, by feeding shortly after cessation of acoustic exposure, or by feeding at a later time. There is no indication that individual fitness and health would be impacted, particularly since unconsumed prey would likely still be available in the environment in most cases following the cessation of acoustic exposure.

Similarly, while the rates of foraging lunges decrease in humpback whales due to sonar exposure, there was variability in the response across individuals, with one animal ceasing to forage completely and another animal starting to forage during the exposure (Sivle *et al.,* 2016). In addition, almost half of the animals that demonstrated avoidance were foraging before the exposure but the others were not; the animals that avoided while not feeding responded at a slightly lower received level and greater distance than those that were feeding (Wensveen *et al.,* 2017). These findings indicate the behavioral state of the animal and foraging strategies play a role in the type and severity of a behavioral response. For example, when the prey field was mapped and used as a covariate in examining how behavioral state of blue whales is influenced by mid-frequency sound, the response in blue whale deep-feeding behavior was even more apparent, reinforcing the need for contextual variables to be included when assessing behavioral responses (Friedlaender *et al.,* 2016).

Vocalizations and Auditory Masking

Marine mammals vocalize for different purposes and across multiple modes, such as whistling, production of echolocation clicks, calling, and singing. Changes in vocalization behavior in response to anthropogenic noise can occur for any of these modes and may result directly from increased vigilance (also see the *Potential Effects of Behavioral Disturbance on Marine Mammal Fitness* section) or a startle response, or from a need to compete with an increase in background noise (see Erbe *et al.,* 2016 review on communication masking), the latter of which is described more below.

For example, in the presence of potentially masking signals, humpback whales and killer whales have been observed to increase the length of their songs (Miller *et al.,* 2000; Fristrup *et al.,* 2003; Foote *et al.,* 2004) and blue increased song production (Di Iorio and Clark, 2009), while North Atlantic right whales have been observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.,* 2007). In some cases, animals may cease or reduce sound production during production of aversive signals (Bowles *et al.,* 1994; Thode *et al.,* 2020; Cerchio *et al.,* (2014); McDonald *et al.,* (1995)). Blackwell *et al.* (2015) showed that whales increased calling rates as soon as air gun signals were detectable before ultimately decreasing calling rates at higher received levels.

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, or navigation) (Richardson *et al.,* 1995; Erbe and Farmer, 2000; Tyack, 2000; Erbe *et al.,* 2016). 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.,* 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 these acoustic signals can disturb the behavior of individual animals, groups of animals, or entire populations. Masking can lead to behavioral changes including vocal changes (*e.g.,* Lombard

effect, increasing amplitude, or changing frequency), cessation of foraging or lost foraging opportunities, and leaving an area, to both signalers and receivers, in an attempt to compensate for noise levels (Erbe *et al.,* 2016) or because sounds that would typically have triggered a behavior were not detected. In humans, significant masking of tonal signals occurs as a result of exposure to noise in a narrow band of similar frequencies. As the sound level increases, though, the detection of frequencies above those of the masking stimulus decreases also. This principle is expected to apply to marine mammals as well because of common biomechanical cochlear properties across taxa.

Therefore, when the coincident (masking) sound is man-made, it may be considered harassment when disrupting behavioral patterns. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which only occurs during the sound exposure. Because masking (without resulting in threshold shift) is not associated with abnormal physiological function, it is not considered a physiological effect, but rather a potential behavioral effect.

The frequency range of the potentially masking sound is important in determining any potential behavioral impacts. For example, low-frequency signals may have less effect on high-frequency echolocation sounds produced by odontocetes but are more likely to affect detection of mysticete communication calls and other potentially important natural sounds such as those produced by surf and some prey species. The masking of communication signals by anthropogenic noise may be considered as a reduction in the communication space of animals (*e.g.,* Clark *et al.,* 2009; Matthews *et al.,* 2016) and may result in energetic or other costs as animals change their vocalization behavior (*e.g.,* Miller *et al.,* 2000; Foote *et al.,* 2004; Parks *et al.,* 2007; Di Iorio and Clark, 2009; Holt *et al.,* 2009). Masking can be reduced in situations where the signal and noise come from different directions (Richardson *et al.,* 1995), through amplitude modulation of the signal, or through other compensatory behaviors (Houser and Moore, 2014). Masking can be tested directly in captive species (*e.g.,* Erbe, 2008), but in wild populations it must be either modeled or inferred from evidence of masking compensation. There are few studies addressing real-world masking sounds likely to be experienced by marine mammals in the wild (*e.g.,* Branstetter *et al.,* 2013; Cholewiak *et al.,* 2018).

The echolocation calls of toothed whales are subject to masking by high-frequency sound. Human data indicate low-frequency sound can mask high-frequency sounds (*i.e.,* upward masking). Studies on captive odontocetes by Au *et al.* (1974, 1985, 1993) indicate that some species may use various processes to reduce masking effects (*e.g.,* adjustments in echolocation call intensity or frequency as a function of background noise conditions). There is also evidence that the directional hearing abilities of odontocetes are useful in reducing masking at the high-frequencies these cetaceans use to echolocate, but not at the low-to-moderate frequencies they use to communicate (Zaitseva *et al.,* 1980). A study by Nachtigall and Supin (2008) showed that false killer whales adjust their hearing to compensate for ambient sounds and the intensity of returning echolocation signals.

Impacts on signal detection, measured by masked detection thresholds, are not the only important factors to address when considering the potential effects of masking. As marine mammals use sound to recognize conspecifics, prey, predators, or other biologically significant sources (Branstetter *et al.,* 2016), it is also important to understand the impacts of masked recognition thresholds (often called ''informational masking''). Branstetter *et al.* (2016) measured masked recognition thresholds for whistle-like sounds of bottlenose dolphins and observed that they are approximately 4 dB above detection thresholds (energetic masking) for the same signals. Reduced ability to recognize a conspecific call or the acoustic signature of a predator could have severe negative impacts. Branstetter *et al.* (2016) observed that if ''quality communication'' is set at 90 percent recognition the output of communication space models (which are based on 50 percent detection) would likely result in a significant decrease in communication range.

As marine mammals use sound to recognize predators (Allen *et al.,* 2014; Cummings and Thompson, 1971; Curé *et al.,* 2015; Fish and Vania, 1971), the presence of masking noise may also prevent marine mammals from responding to acoustic cues produced by their predators, particularly if it occurs in the same frequency band. For example, harbor seals that reside in the coastal waters off British Columbia are frequently targeted by mammal-eating killer whales. The seals acoustically discriminate between the calls of mammal-eating and fish-eating killer whales (Deecke *et al.,* 2002), a capability that should increase survivorship while reducing the energy required to attend to all killer whale calls. Similarly, sperm whales (Curé *et al.,* 2016; Isojunno *et al.,* 2016), long-finned pilot whales (Visser *et al.,* 2016), and humpback whales (Curé *et al.,* 2015) changed their behavior in response to killer whale vocalization playbacks; these findings indicate that some recognition of predator cues could be missed if the killer whale vocalizations were masked. The potential effects of masked predator acoustic cues depends on the duration of the masking noise and the likelihood of a marine mammal encountering a predator during the time that detection and recognition of predator cues are impeded.

Redundancy and context can also facilitate detection of weak signals. These phenomena may help marine mammals detect weak sounds in the presence of natural or manmade noise. Most masking studies in marine mammals present the test signal and the masking noise from the same direction. The dominant background noise may be highly directional if it comes from a particular anthropogenic source such as a ship or industrial site. Directional hearing may significantly reduce the masking effects of these sounds by improving the effective signal-to-noise ratio.

Masking affects both senders and receivers of acoustic signals and, at higher levels and longer duration, can potentially have long-term chronic effects on marine mammals at the population level as well as at the individual level. Low-frequency ambient sound levels have increased by as much as 20 dB (more than three times in terms of SPL) in the world's ocean from pre-industrial periods, with most of the increase from distant commercial shipping (Hildebrand, 2009; Cholewiak *et al.,* 2018). All anthropogenic sound sources, but especially chronic and lower-frequency signals (*e.g.,* from commercial vessel traffic), contribute to elevated ambient sound levels, thus intensifying masking.

In addition to making it more difficult for animals to perceive and recognize acoustic cues in their environment, anthropogenic sound presents separate challenges for animals that are vocalizing. When they vocalize, animals are aware of environmental conditions that affect the ''active space'' (or communication space) of their vocalizations, which is the maximum area within which their vocalizations can be detected before it drops to the level of ambient noise (Brenowitz, 2004; Brumm *et al.,* 2004; Lohr *et al.,* 2003).

Animals are also aware of environmental conditions that affect whether listeners can discriminate and recognize their vocalizations from other sounds, which is more important than simply detecting that a vocalization is occurring (Brenowitz, 1982; Brumm *et al.,* 2004; Dooling, 2004; Marten and Marler, 1977; Patricelli *et al.,* 2006). Most species that vocalize have evolved with an ability to make adjustments to their vocalizations to increase the signal-to-noise ratio, active space, and recognizability/distinguishability of their vocalizations in the face of temporary changes in background noise (Brumm *et al.,* 2004; Patricelli *et al.,* 2006). Vocalizing animals can make adjustments to vocalization characteristics such as the frequency structure, amplitude, temporal structure, and temporal delivery (repetition rate), or ceasing to vocalize.

Many animals will combine several of these strategies to compensate for high levels of background noise. Anthropogenic sounds that reduce the signal-to-noise ratio of animal vocalizations, increase the masked auditory thresholds of animals listening for such vocalizations, or reduce the active space of an animal's vocalizations impair communication between animals. Most animals that vocalize have evolved strategies to compensate for the effects of short-term or temporary increases in background or ambient noise on their songs or calls. Although the fitness consequences of these vocal adjustments are not directly known in all instances, like most other trade-offs animals must make, some of these strategies likely come at a cost (Patricelli *et al.,* 2006; Noren *et al.,* 2017; Noren *et al.,* 2020). Shifting songs and calls to higher frequencies may also impose energetic costs (Lambrechts, 1996).

Marine mammals are also known to make vocal changes in response to anthropogenic noise. In cetaceans, vocalization changes have been reported from exposure to anthropogenic noise sources such as sonar, vessel noise, and seismic surveying (see the following for examples: Gordon *et al.,* 2003; Di Iorio and Clark, 2009; Hatch *et al.,* 2012; Holt *et al.,* 20098; Holt *et al.,* 2011; Lesage *et al.,* 1999; McDonald *et al.,* 2009; Parks *et al.,* 2007, Risch *et al.,* 2012, Rolland *et al.,* 2012), as well as changes in the natural acoustic environment (Dunlop *et al.,* 2014). Vocal changes can be temporary, or can be persistent. For example, model simulation suggests that the increase in starting frequency for the North Atlantic right whale upcall over the last 50 years resulted in increased detection ranges between right whales. The frequency shift, coupled with an increase in call intensity by 20 dB, led to a call detectability range of less than 3 km to over 9 km (Tennessen and Parks, 2016). Holt *et al.* (2009) measured killer whale call source levels and background noise levels in the one to 40 kHz band and reported that the whales increased their call source levels by one dB SPL for every one dB SPL increase in background noise level. Similarly, another study on St. Lawrence River belugas reported a similar rate of increase in vocalization activity in response to passing vessels (Scheifele *et al.,* 2005). Di Iorio and Clark (2009) showed that blue whale calling rates vary in association with seismic sparker survey activity, with whales calling more on days with surveys than on days without surveys. They suggested that the whales called more during seismic survey periods as a way to compensate for the elevated noise conditions.

In some cases, these vocal changes may have fitness consequences, such as an increase in metabolic rates and oxygen consumption, as observed in bottlenose dolphins when increasing their call amplitude (Holt *et al.,* 2015). A switch from vocal communication to physical, surface-generated sounds such as pectoral fin slapping or breaching was observed for humpback whales in the presence of increasing natural background noise levels, indicating that adaptations to masking may also move beyond vocal modifications (Dunlop *et al.,* 2010).

While these changes all represent possible tactics by the sound-producing animal to reduce the impact of masking, the receiving animal can also reduce masking by using active listening strategies such as orienting to the sound source, moving to a quieter location, or reducing self-noise from hydrodynamic flow by remaining still. The temporal structure of noise (*e.g.,* amplitude modulation) may also provide a considerable release from masking through comodulation masking release (a reduction of masking that occurs when broadband noise, with a frequency spectrum wider than an animal's auditory filter bandwidth at the frequency of interest, is amplitude modulated) (Branstetter and Finneran, 2008; Branstetter *et al.,* 2013). Signal type (*e.g.,* whistles, burst-pulse, sonar clicks) and spectral characteristics (*e.g.,* frequency modulated with harmonics) may further influence masked detection thresholds (Branstetter *et al.,* 2016; Cunningham *et al.,* 2014).

Masking is more likely to occur in the presence of broadband, relatively continuous noise sources such as vessels. Several studies have shown decreases in marine mammal communication space and changes in behavior as a result of the presence of vessel noise. For example, right whales were observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.,* 2007) as well as increasing the amplitude (intensity) of their calls (Parks, 2009; Parks *et al.,* 2011). Clark *et al.* (2009) observed that right whales' communication space decreased by up to 84 percent in the presence of vessels. Cholewiak *et al.* (2018) also observed loss in communication space in Stellwagen National Marine Sanctuary for North Atlantic right whales, fin whales, and humpback whales with increased ambient noise and shipping noise. Although humpback whales off Australia did not change the frequency or duration of their vocalizations in the presence of ship noise, their source levels were lower than expected based on source level changes to wind noise, potentially indicating some signal masking (Dunlop, 2016). Multiple delphinid species have also been shown to increase the minimum or maximum frequencies of their whistles in the presence of anthropogenic noise and reduced communication space (for examples see: Holt *et al.,* 20098; Holt *et al.,* 2011; Gervaise *et al.,* 2012; Williams *et al.,* 2013; Hermannsen *et al.,* 2014; Papale *et al.,* 2015; Liu *et al.,* 2017). While masking impacts are not a concern from lower intensity, higher frequency HRG surveys, some degree of masking would be expected in the vicinity of turbine pile driving and concentrated support vessel operation. However, pile driving is an intermittent sound and would not be continuous throughout a day.

Habituation and Sensitization

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.,* 2003). 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 having a neutral or positive outcome (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. Both habituation and sensitization require an ongoing learning process. As noted, 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; NRC, 2003; Wartzok *et al.,* 2003; Southall *et al.,* 2019b). Controlled experiments with captive marine mammals have shown pronounced behavioral reactions, including avoidance of loud sound sources (*e.g.,* Ridgway *et al.,* 1997; Finneran *et al.,* 2003; Houser *et al.,* 2013a,b; Kastelein *et al.,* 2018). Observed responses of wild marine mammals to loud impulsive sound sources (typically airguns or acoustic harassment devices) have been varied but often consist of avoidance behavior or other behavioral changes suggesting discomfort (Morton and Symonds, 2002; see also Richardson *et al.,* 1995; Nowacek *et al.,* 2007; Tougaard *et al.,* 2009; Brandt *et al.,* 2011, Brandt *et al.,* 2012, Dähne *et al.,* 2013; Brandt *et al.,* 2014; Russell *et al.,* 2016; Brandt *et al.,* 2018). Stone (2015a) reported data from at-sea observations during 1,196 airgun surveys from 1994 to 2010. When large arrays of airguns (considered to be 500 in 3 or more) were firing, lateral displacement, more localized avoidance, or other changes in behavior were evident for most odontocetes. However, significant responses to large arrays were found only for the minke whale and fin whale. Behavioral responses observed included changes in swimming or surfacing behavior with indications that cetaceans remained near the water surface at these times. Behavioral observations of gray whales during an air gun survey monitored whale movements and respirations pre-, during-, and post-seismic survey (Gailey *et al.,* 2016). Behavioral state and water depth were the best 'natural' predictors of whale movements and respiration and after considering natural variation, none of the response variables were significantly associated with survey or vessel sounds. Many delphinids approach low-frequency airgun source vessels with no apparent discomfort or obvious behavioral change (*e.g.,* Barkaszi *et al.,* 2012), indicating the importance of frequency output in relation to the species' hearing sensitivity.

Physiological 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 sufficiently 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.,* 2002b) and, more rarely, studied in wild populations (*e.g.,* Lusseau and Bejder, 2007; Romano *et al.,* 2002a; Rolland *et al.,* 2012). 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, 2017).

Respiration naturally varies with different behaviors and variations in respiration rate as a function of acoustic exposure can be expected to co-occur with other behavioral reactions, such as a flight response or an alteration in diving. However, respiration rates in and of themselves may be representative of annoyance or an acute stress response. Mean exhalation rates of gray whales at rest and while diving were found to be unaffected by seismic surveys conducted adjacent to the whale feeding grounds (Gailey *et al.,* 2007). Studies with captive harbor porpoises show increased respiration rates upon introduction of acoustic alarms (Kastelein *et al.,* 2001; Kastelein *et al.,* 2006a) and emissions for underwater data transmission (Kastelein *et al.,* 2005). However, exposure of the same acoustic alarm to a striped dolphin under the same conditions did not elicit a response (Kastelein *et al.,* 2006a), again highlighting the importance in understanding species differences in the tolerance of underwater noise when determining the potential for impacts resulting from anthropogenic sound exposure.

Potential Effects of Disturbance on Marine Mammal Fitness

The different ways that marine mammals respond to sound are sometimes indicators of the ultimate effect that exposure to a given stimulus will have on the well-being (survival, reproduction, etc.) of an animal. There is little quantitative marine mammal data relating the exposure of marine mammals from sound to effects on reproduction or survival, though data exists for terrestrial species to which we can draw comparisons for marine mammals. Several authors have reported that disturbance stimuli may cause animals to abandon nesting and foraging sites (Sutherland and Crockford, 1993); may cause animals to increase their activity levels and suffer premature deaths or reduced reproductive success when their energy expenditures exceed their energy budgets (Daan *et al.,* 1996; Feare, 1976; Mullner *et al.,* 2004); or may cause animals to experience higher predation rates when they adopt risk-prone foraging or migratory strategies (Frid

and Dill, 2002). Each of these studies addressed the consequences of animals shifting from one behavioral state (*e.g.,* resting or foraging) to another behavioral state (*e.g.,* avoidance or escape behavior) because of human disturbance or disturbance stimuli.

Attention is the cognitive process of selectively concentrating on one aspect of an animal's environment while ignoring other things (Posner, 1994). Because animals (including humans) have limited cognitive resources, there is a limit to how much sensory information they can process at any time. The phenomenon called ''attentional capture'' occurs when a stimulus (usually a stimulus that an animal is not concentrating on or attending to) ''captures'' an animal's attention. This shift in attention can occur consciously or subconsciously (for example, when an animal hears sounds that it associates with the approach of a predator) and the shift in attention can be sudden (Dukas, 2002; van Rij, 2007). Once a stimulus has captured an animal's attention, the animal can respond by ignoring the stimulus, assuming a ''watch and wait'' posture, or treat the stimulus as a disturbance and respond accordingly, which includes scanning for the source of the stimulus or ''vigilance'' (Cowlishaw *et al.,* 2004).

Vigilance is an adaptive behavior that helps animals determine the presence or absence of predators, assess their distance from conspecifics, or to attend cues from prey (Bednekoff and Lima, 1998; Treves, 2000). Despite those benefits, however, vigilance has a cost of time; when animals focus their attention on specific environmental cues, they are not attending to other activities such as foraging or resting. These effects have generally not been demonstrated for marine mammals, but studies involving fish and terrestrial animals have shown that increased vigilance may substantially reduce feeding rates (Saino, 1994; Beauchamp and Livoreil, 1997; Fritz *et al.,* 2002; Purser and Radford, 2011). Animals will spend more time being vigilant, which may translate to less time foraging or resting, when disturbance stimuli approach them more directly, remain at closer distances, have a greater group size (*e.g.,* multiple surface vessels), or when they co-occur with times that an animal perceives increased risk (*e.g.,* when they are giving birth or accompanied by a calf).

The primary mechanism by which increased vigilance and disturbance appear to affect the fitness of individual animals is by disrupting an animal's time budget and, as a result, reducing the time they might spend foraging and resting (which increases an animal's activity rate and energy demand while decreasing their caloric intake/energy). In a study of northern resident killer whales off Vancouver Island, exposure to boat traffic was shown to reduce foraging opportunities and increase traveling time (Holt *et al.,* 2021). A simple bioenergetics model was applied to show that the reduced foraging opportunities equated to a decreased energy intake of 18 percent while the increased traveling incurred an increased energy output of 3–4 percent, which suggests that a management action based on avoiding interference with foraging might be particularly effective.

On a related note, many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (24-hr cycle). Behavioral reactions to noise exposure (such as disruption of critical life functions, displacement, or avoidance of important habitat) are more likely to be significant for fitness if they last more than one diel cycle or recur on subsequent days (Southall *et al.,* 2007). Consequently, a behavioral response lasting less than one day and not recurring on subsequent days is not considered particularly severe unless it could directly affect reproduction or survival (Southall *et al.,* 2007). It is important to note the difference between behavioral reactions lasting or recurring over multiple days and anthropogenic activities lasting or recurring over multiple days. For example, just because certain activities last for multiple days does not necessarily mean that individual animals will be either exposed to those activity-related stressors (*i.e.,* sonar) for multiple days or further exposed in a manner that would result in sustained multi-day substantive behavioral responses. However, special attention is warranted where longer-duration activities overlay areas in which animals are known to congregate for longer durations for biologically important behaviors.

As noted above, there are few studies that directly illustrate the impacts of disturbance on marine mammal populations. Lusseau and Bejder (2007) present data from three long-term studies illustrating the connections between disturbance from whale-watching boats and population-level effects in cetaceans. In Shark Bay, Australia, the abundance of bottlenose dolphins was compared within adjacent control and tourism sites over three consecutive 4.5-year periods of increasing tourism levels. Between the second and third time periods, in which tourism doubled, dolphin abundance decreased by 15 percent in the tourism area and did not change significantly in the control area. In Fiordland, New Zealand, two populations (Milford and Doubtful Sounds) of bottlenose dolphins with tourism levels that differed by a factor of seven were observed and significant increases in traveling time and decreases in resting time were documented for both. Consistent short-term avoidance strategies were observed in response to tour boats until a threshold of disturbance was reached (average 68 minutes between interactions), after which the response switched to a longer-term habitat displacement strategy. For one population, tourism only occurred in a part of the home range. However, tourism occurred throughout the home range of the Doubtful Sound population and once boat traffic increased beyond the 68-minute threshold (resulting in abandonment of their home range/preferred habitat), reproductive success drastically decreased (increased stillbirths) and abundance decreased significantly (from 67 to 56 individuals in a short period).

In order to understand how the effects of activities may or may not impact species and stocks of marine mammals, it is necessary to understand not only what the likely disturbances are going to be but how those disturbances may affect the reproductive success and survivorship of individuals and then how those impacts to individuals translate to population-level effects. Following on the earlier work of a committee of the U.S. National Research Council (NRC, 2005), New *et al.* (2014), in an effort termed the Potential Consequences of Disturbance (PCoD), outline an updated conceptual model of the relationships linking disturbance to changes in behavior and physiology, health, vital rates, and population dynamics. This framework is a four-step process progressing from changes in individual behavior and/or physiology, to changes in individual health, then vital rates, and finally to population-level effects. In this framework, behavioral and physiological changes can have direct (acute) effects on vital rates, such as when changes in habitat use or increased stress levels raise the probability of mother-calf separation or predation; indirect and long-term (chronic) effects on vital rates, such as when changes in time/energy budgets or increased disease susceptibility affect health, which then affects vital rates; or no effect to vital rates (New *et al.,* 2014). Since this general framework was outlined and the relevant supporting

literature compiled, multiple studies developing state-space energetic models for species with extensive long-term monitoring (*e.g.,* southern elephant seals, North Atlantic right whales, Ziphiidae beaked whales, and bottlenose dolphins) have been conducted and can be used to effectively forecast longer-term, population-level impacts from behavioral changes. While these are very specific models with very specific data requirements that cannot yet be applied broadly to project-specific risk assessments for the majority of species, they are a critical first step towards being able to quantify the likelihood of a population level effects. Since New *et al.* (2014), several publications have described models developed to examine the long-term effects of environmental or anthropogenic disturbance of foraging on various life stages of selected species (*e.g.,* sperm whale, Farmer *et al.* (2018); California sea lion, McHuron *et al.* (2018); blue whale, Pirotta *et al.* (2018a); humpback whale, Dunlop *et al.* (2021)). These models continue to add to refinement of the approaches to the PCoD framework. Such models also help identify what data inputs require further investigation. Pirotta *et al.* (2018b) provides a review of the PCoD framework with details on each step of the process and approaches to applying real data or simulations to achieve each step.

Despite its simplicity, there are few complete PCoD models available for any marine mammal species due to a lack of data available to parameterize many of the steps. To date, no PCoD model has been fully parameterized with empirical data (Pirotta *et al.,* 2018a) due to the fact they are data intensive and logistically challenging to complete. Therefore, most complete PCoD models include simulations, theoretical modeling, and expert opinion to move through the steps. For example, PCoD models have been developed to evaluate the effect of wind farm construction on the North Sea harbor porpoise populations (*e.g.,* King *et al.,* 2015; Nabe-Nielsen *et al.,* 2018). These models include a mix of empirical data, expert elicitation (King *et al.,* 2015) and simulations of animals' movements, energetics, and/or survival (New *et al.,* 2014; Nabe-Nielsen *et al.,* 2018).

PCoD models may also be approached in different manners. Dunlop *et al.* (2021) modeled migrating humpback whale mother-calf pairs in response to seismic surveys using both a forwards and backwards approach. While a typical forwards approach can determine if a stressor would have population-level consequences, Dunlop *et al.* demonstrated that working backwards through a PCoD model can be used to assess the ''worst case'' scenario for an interaction of a target species and stressor. This method may be useful for future management goals when appropriate data becomes available to fully support the model. In another example, harbor porpoise PCoD model investigating the impact of seismic surveys on harbor porpoise included an investigation on underlying drivers of vulnerability. Harbor porpoise movement and foraging were modeled for baseline periods and then for periods with seismic surveys as well; the models demonstrated that temporal (*i.e.,* seasonal) variation in individual energetics and their link to costs associated with disturbances was key in predicting population impacts (Gallagher *et al.*, 2021).

Behavioral change, such as disturbance manifesting in lost foraging time, in response to anthropogenic activities is often assumed to predict a biologically significant effect on a population of concern. However, as described above, individuals may be able to compensate for some types and degrees of shifts in behavior, preserving their health and thus their vital rates and population dynamics. For example, New *et al.,* (2013) developed a model simulating the complex social, spatial, behavioral and motivational interactions of coastal bottlenose dolphins in the Moray Firth, Scotland, to assess the biological significance of increased rate of behavioral disruptions caused by vessel traffic. Despite a modeled scenario in which vessel traffic increased from 70 to 470 vessels a year (a sixfold increase in vessel traffic) in response to the construction of a proposed offshore renewables' facility, the dolphins' behavioral time budget, spatial distribution, motivations and social structure remain unchanged. Similarly, two bottlenose dolphin populations in Australia were also modeled over five years against a number of disturbances, (Reed *et al.,* 2020) and results indicated that habitat/noise disturbance had little overall impact on population abundances in either location, even in the most extreme impact scenarios modeled. By integrating different sources of data (*e.g.,* controlled exposure data, activity monitoring, telemetry tracking, and prey sampling) into a theoretical model to predict effects from sonar on a blue whale's daily energy intake, Pirotta *et al.* (2021) found that tagged blue whales' activity budgets, lunging rates, and ranging patterns caused variability in their predicted cost of disturbance. This method may be useful for future management goals when appropriate data becomes available to fully support the model. Harbor porpoise movement and foraging were modeled for baseline periods and then for periods with seismic surveys as well; the models demonstrated that the seasonality of the seismic activity was an important predictor of impact (Gallagher *et al.,* 2021).

Nearly all PCoD studies and experts agree that infrequent exposures of a single day or less are unlikely to impact individual fitness, let alone lead to population level effects (Booth *et al.,* 2016; Booth *et al.,* 2017; Christiansen and Lusseau 2015; Farmer *et al.,* 2018; Wilson *et al.,* 2020; Harwood and Booth 2016; King *et al.,* 2015; McHuron *et al.,* 2018; NAS 2017; New *et al.,* 2014; Pirotta *et al.,* 2018; Southall *et al.,* 2007; Villegas-Amtmann *et al.,* 2015). As described through this proposed rule, NMFS expects that any behavioral disturbance that would occur due to animals being exposed to construction activity would be of a relatively short duration, with behavior returning to a baseline state shortly after the acoustic stimuli ceases or the animal moves far enough away from the source. Given this, and NMFS' evaluation of the available PCoD studies, and the required mitigation discussed later, any such behavioral disturbance resulting from Empire Wind's activities is not expected to impact individual animals' health or have effects on individual animals' survival or reproduction, thus no detrimental impacts at the population level are anticipated. Marine mammals may temporarily avoid the immediate area but are not expected to permanently abandon the area or their migratory or foraging behavior. Impacts to breeding, feeding, sheltering, resting, or migration are not expected nor are shifts in habitat use, distribution, or foraging success.

Vessel Strike

Vessel collisions with marine mammals, also referred to as vessel strikes or ship strikes, can result in death or serious injury of the animal. Wounds resulting from ship strike may include massive trauma, hemorrhaging, broken bones, or propeller lacerations (Knowlton and Kraus, 2001). An animal at the surface could be struck directly by a vessel, a surfacing animal could hit the bottom of a vessel, or an animal just below the surface could be cut by a vessel's propeller. Superficial strikes may not kill or result in the death of the animal. Lethal interactions are typically associated with large whales, which are occasionally found draped across the

bulbous bow of large commercial ships upon arrival in port. Although smaller cetaceans are more maneuverable in relation to large vessels than are large whales, they may also be susceptible to strike. The severity of injuries typically depends on the size and speed of the vessel (Knowlton and Kraus, 2001; Laist *et al.,* 2001; Vanderlaan and Taggart, 2007; Conn and Silber, 2013). Impact forces increase with speed, as does the probability of a strike at a given distance (Silber *et al.,* 2010; Gende *et al.,* 2011).

The most vulnerable marine mammals are those that spend extended periods of time at the surface in order to restore oxygen levels within their tissues after deep dives (*e.g.,* the sperm whale). In addition, some baleen whales seem generally unresponsive to vessel sound, making them more susceptible to vessel collisions (Nowacek *et al.,* 2004). These species are primarily large, slow moving whales. Marine mammal responses to vessels may include avoidance and changes in dive pattern (NRC, 2003).

An examination of all known ship strikes from all shipping sources (civilian and military) indicates vessel speed is a principal factor in whether a vessel strike occurs and, if so, whether it results in injury, serious injury, or mortality (Knowlton and Kraus, 2001; Laist *et al.,* 2001; Jensen and Silber, 2003; Pace and Silber, 2005; Vanderlaan and Taggart, 2007; Conn and Silber 2013). In assessing records in which vessel speed was known, Laist *et al.* (2001) found a direct relationship between the occurrence of a whale strike and the speed of the vessel involved in the collision. The authors concluded that most deaths occurred when a vessel was traveling in excess of 13 knots.

Jensen and Silber (2003) detailed 292 records of known or probable ship strikes of all large whale species from 1975 to 2002. Of these, vessel speed at the time of collision was reported for 58 cases. Of these 58 cases, 39 (or 67 percent) resulted in serious injury or death (19 of those resulted in serious injury as determined by blood in the water, propeller gashes or severed tailstock, and fractured skull, jaw, vertebrae, hemorrhaging, massive bruising or other injuries noted during necropsy and 20 resulted in death). Operating speeds of vessels that struck various species of large whales ranged from 2 to 51 knots. The majority (79 percent) of these strikes occurred at speeds of 13 knots or greater. The average speed that resulted in serious injury or death was 18.6 knots. Pace and Silber (2005) found that the probability of death or serious injury increased rapidly with increasing vessel speed. Specifically, the predicted probability of serious injury or death increased from 45 to 75 percent as vessel speed increased from 10 to 14 knots, and exceeded 90 percent at 17 knots. Higher speeds during collisions result in greater force of impact and also appear to increase the chance of severe injuries or death. While modeling studies have suggested that hydrodynamic forces pulling whales toward the vessel hull increase with increasing speed (Clyne, 1999; Knowlton *et al.,* 1995), this is inconsistent with Silber *et al.* (2010), which demonstrated that there is no such relationship (*i.e.,* hydrodynamic forces are independent of speed).

In a separate study, Vanderlaan and Taggart (2007) analyzed the probability of lethal mortality of large whales at a given speed, showing that the greatest rate of change in the probability of a lethal injury to a large whale as a function of vessel speed occurs between 8.6 and 15 knots. The chances of a lethal injury decline from approximately 80 percent at 15 knots to approximately 20 percent at 8.6 knots. At speeds below 11.8 knots, the chances of lethal injury drop below 50 percent, while the probability asymptotically increases toward 100 percent above 15 knots.

The Jensen and Silber (2003) report notes that the Large Whale Ship Strike Database represents a minimum number of collisions, because the vast majority probably goes undetected or unreported. In contrast, Empire Wind's personnel are likely to detect any strike that does occur because of the required personnel training and lookouts, along with the inclusion of Protected Species Observers (as described in the Proposed Mitigation section), and they are required to report all ship strikes involving marine mammals.

Given the extensive mitigation and monitoring measures (see the Proposed Mitigation and Proposed Monitoring and Reporting section) that would be required of Empire Wind, NMFS believes that a vessel strike is not likely to occur.

Potential Effects to Marine Mammal Habitat

Empire Wind's proposed activities could potentially affect marine mammal habitat through the introduction of impacts to the prey species of marine mammals (through noise, oceanographic processes, or reef effects), acoustic habitat (sound in the water column), water quality, and biologically important habitat for marine mammals. NMFS has preliminarily determined that the proposed project would not have adverse or long-term impacts on marine mammal habitat that would be expected to affect the reproduction or survival of any marine mammals.

Effects on Prey

Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (*e.g.,* crustaceans, cephalopods, fish, and zooplankton). Marine mammal prey varies by species, season, and location and, for some, is not well documented. 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). The most likely effects on fishes exposed to loud, intermittent, low-frequency sounds are behavioral responses (*i.e.,* flight or avoidance). Short duration, sharp sounds (such as pile driving or air guns) can cause overt or subtle changes in fish behavior and local distribution. The reaction of fish to acoustic sources depends on the physiological state of the fish, past exposures, motivation (*e.g.,* feeding, spawning, migration), and other environmental factors. Key impacts to fishes may include behavioral responses, hearing damage, barotrauma (pressure-related injuries), and mortality. While it is clear that the behavioral responses of individual prey, such as displacement or other changes in distribution, can have direct impacts on the foraging success of marine mammals, the effects on marine mammals of individual prey that experience hearing damage, barotrauma, or mortality is less clear, though obviously population scale impacts that meaningfully reduce the amount of prey available could have more serious impacts.

Fishes, like other vertebrates, have a variety of different sensory systems to glean information from ocean around them (Astrup and Mohl, 1993; Astrup, 1999; Braun and Grande, 2008; Carroll *et al.,* 2017; Hawkins and Johnstone, 1978; Ladich and Popper, 2004; Ladich and Schulz-Mirbach, 2016; Mann, 2016; Nedwell *et al.,* 2004; Popper *et al.,* 2003; Popper *et al.,* 2005). 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) (terrestrial vertebrates generally only detect pressure). Most marine fishes primarily detect particle motion using the inner ear and lateral line system, while some fishes possess additional morphological

adaptations or specializations that can enhance their sensitivity to sound pressure, such as a gas-filled swim bladder (Braun and Grande, 2008; Popper and Fay, 2011).

Hearing capabilities vary considerably between different fish species with data only available for just over 100 species out of the 34,000 marine and freshwater fish species (Eschmeyer and Fong, 2016). In order to better understand acoustic impacts on fishes, fish hearing groups are defined by species that possess a similar continuum of anatomical features which result in varying degrees of hearing sensitivity (Popper and Hastings, 2009a). There are four hearing groups defined for all fish species (modified from Popper *et al.,* 2014) within this analysis and they include: Fishes without a swim bladder (*e.g.,* flatfish, sharks, rays, etc.); fishes with a swim bladder not involved in hearing (*e.g.,* salmon, cod, pollock, etc.); fishes with a swim bladder involved in hearing (*e.g.,* sardines, anchovy, herring, etc.); and fishes with a swim bladder involved in hearing and high-frequency hearing (*e.g.,* shad and menhaden). A fifth group was designated for fish eggs and larvae. Most marine mammal fish prey species would not be likely to perceive or hear mid- or high-frequency HRG equipment used by Empire Wind during HRG surveys, but would perceive the noise from pile driving.

In terms of behavioral responses, Juanes *et al.* (2017) discuss the potential for negative impacts from anthropogenic noise on fish, but the author's focus was on broader based sounds such as ship and boat noise sources. Watwood *et al.* (2016) also documented no behavioral responses by reef fish after exposure to mid-frequency active sonar. Doksaeter *et al.* (2009; 2012) reported no behavioral responses to mid-frequency sonar (such as naval sonar) by Atlantic herring; specifically, no escape reactions (vertically or horizontally) were observed in free swimming herring exposed to mid-frequency sonar transmissions. Based on these results (Doksaeter *et al.,* 2009; Doksaeter *et al.,* 2012; Sivle *et al.,* 2012), Sivle *et al.* (2014) created a model in order to report on the possible population-level effects on Atlantic herring from active sonar. The authors concluded that the use of sonar poses little risk to populations of herring regardless of season, even when the herring populations are aggregated and directly exposed to sonar. Finally, Bruintjes *et al.* (2016) commented that fish exposed to any short-term noise within their hearing range might initially startle, but would quickly return to normal behavior.

Pile-driving noise during construction is of particular concern as the very high sound pressure levels could potentially prevent fish from reaching breeding or spawning sites, finding food, and acoustically locating mates (Mueller-Blenkle *et al.,* 2010). A playback study in West Scotland revealed that there was a significant movement response to the pile-driving stimulus in both species at relatively low received sound pressure levels (sole: 144–156 dB re 1µPa Peak; cod: 140–161 dB re 1 µPaPeak, particle motion between 6.51 x 10–3 and 8.62 x1 0–4 m/s2 peak). Sole showed a significant increase in swimming speed during the playback period compared to before and after playback. Cod exhibited a similar reaction, yet results were not significant. Cod showed a significant freezing response at onset and cessation of playback. There were indications of directional movements away from the sound source in both species. The results further showed a high variability in behavioral reactions across individuals and a decrease of response with multiple exposures. During wind farm construction in Eastern Taiwan Strait in 2016, fish chorusing intensity and duration during construction were investigated. Two different types of fish chorusing were found to repeat over a diurnal pattern. In the 2 days after the pile driving, one type of chorusing showed lower intensity and longer duration, while the second type exhibited higher intensity and no changes in its duration. During the operational phases in 2017 and 2018, both choruses were longer in duration. Fish choruses have been associated with several behavioral functions. Deviation from regular fish vocalization patterns might affect fish reproductive success, cause migration, augmented predation, or physiological alterations (Siddagangaiah *et al*., 2021).

Occasional behavioral reactions to activities that produce underwater noise sources are unlikely to cause long-term consequences for individual fish or populations. The most likely impact to fish from impact and vibratory pile driving activities at the project areas would be temporary behavioral avoidance of the area. 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. The duration of fish avoidance of an area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution and behavior is anticipated. In general, any behavioral impacts are expected to be temporary and occur close to the activity given the relatively small areas being affected.

SPLs of sufficient strength have been known to cause fish auditory impairment, injury and mortality. Popper *et al.,* 2014 found that fish with or without air bladders could experience TTS at 186 dB SELcum. Mortality could occur for fish without swim bladders at >216 dB SELcum. Those with swim bladders or at the egg or larvae life stage, mortality was possible at >203 dB SELcum. Other studies found that 203 dB SELcum or above caused a physiological response in other fish species (Casper *et al.,* 2012, Halvorsen *et al.,* 2012a, Halvorsen *et al.,* 2012b, Casper *et al.,* 2013a; Casper *et al.,* 2013b). 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 4–6 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). As described in the Proposed Mitigation section below, Empire Wind would utilize a sound attenuation device which would reduce potential for injury to marine mammal prey. Other fish that experience hearing loss as a result of exposure to impulsive sound sources may have a reduced ability to detect relevant sounds such as predators, prey, or social vocalizations. However, PTS has not been known to occur in fishes and any hearing loss in fish may be as temporary as the timeframe required to repair or replace the sensory cells that were damaged or destroyed (Popper *et al.,* 2005; Popper *et al.,* 2014; Smith *et al.,* 2006). It is not known if damage to auditory nerve fibers could occur, and if so, whether fibers would recover during this process.

Required soft-starts would allow prey and marine mammals to move away from the source prior to any noise levels that may physically injure prey and the use of the noise attenuation devices would reduce noise levels to the degree any mortality or injury of prey is also minimized. Use of bubble curtains, in addition to reducing impacts to marine mammals, for example, is a key mitigation measure in reducing injury and mortality of marine mammal prey.

However, we recognize some mortality, physical injury and hearing impairment in marine mammal prey may occur but we anticipate the amount of prey impacted in this manner is minimal compared to overall availability. Any behavioral responses to pile driving by marine mammal prey are expected to be relatively brief. We expect that other impacts such as stress or masking would occur in fish that serve as marine mammals prey (Popper *et al.,* 2019); however, those impacts would be limited to the duration of impact pile driving if prey were to move out the area in response to noise, these impacts would be minimized.

In addition to fish, prey sources such as marine invertebrates could potentially be impacted by noise stressors as a result of the proposed activities. However, most marine invertebrates' ability to sense sounds is limited. Invertebrates appear to be able to detect sounds (Pumphrey, 1950; Frings and Frings, 1967) and are most sensitive to low-frequency sounds (Packard *et al.,* 1990; Budelmann and Williamson, 1994; Lovell *et al.,* 2005; Mooney *et al.,* 2010). Data on response of invertebrates such as squid, another marine mammal prey species, to anthropogenic sound is more limited (de Soto, 2016; Sole *et al.,* 2017b). Data suggest that cephalopods are capable of sensing the particle motion of sounds and detect low frequencies up to 1–1.5 kHz, depending on the species, and so are likely to detect air gun noise (Kaifu *et al.,* 2008; Hu *et al.,* 2009; Mooney *et al.,* 2010; Samson *et al.,* 2014). Sole *et al.* (2017) reported physiological injuries to cuttlefish in cages placed at-sea when exposed during a controlled exposure experiment to low-frequency sources (315 Hz, 139 to 142 dB *re 1* μPa^2 and 400 Hz, 139 to 141 dB *re 1* μPa^2). Fewtrell and McCauley (2012) reported squids maintained in cages displayed startle responses and behavioral changes when exposed to seismic air gun sonar (136–162 *re 1* $\mu Pa^2 \cdot s$). Jones *et al.* (2020) found that when squid (*Doryteuthis pealeii*) were exposed to impulse pile driving noise, body pattern changes, inking, jetting, and startle responses were observed and nearly all squid exhibited at least one response. However, these responses occurred primarily during the first eight impulses and diminished quickly, indicating potential rapid, short-term habituation. Packard *et al.* (1990) showed that cephalopods were sensitive to particle motion, not sound pressure, and Mooney *et al.* (2010) demonstrated that squid statocysts (specialized sensory organ inside the head called a statocyst that may help an animal determine its position in space (orientation) and maintain balance) act as an accelerometer through which particle motion of the sound field can be detected (Budelmann, 1992). Auditory injuries (lesions occurring on the statocyst sensory hair cells) have been reported upon controlled exposure to low-frequency sounds, suggesting that cephalopods are particularly sensitive to low-frequency sound (Andre *et al.,* 2011; Sole *et al.,* 2013). Behavioral responses, such as inking and jetting, have also been reported upon exposure to low-frequency sound (McCauley *et al.,* 2000b; Samson *et al.,* 2014). Squids, like most fish species, are likely more sensitive to low frequency sounds, and may not perceive mid- and high-frequency sonars.

With regard to potential impacts on zooplankton, McCauley *et al.* (2017) found that exposure to airgun noise resulted in significant depletion for more than half the taxa present and that there were two to three times more dead zooplankton after airgun exposure compared with controls for all taxa, within 1 km of the airguns. However, the authors also stated that in order to have significant impacts on *r*-selected species (*i.e.,* those with high growth rates and that produce many offspring) such as plankton, the spatial or temporal scale of impact must be large in comparison with the ecosystem concerned, and it is possible that the findings reflect avoidance by zooplankton rather than mortality (McCauley *et al.,* 2017). In addition, the results of this study are inconsistent with a large body of research that generally finds limited spatial and temporal impacts to zooplankton as a result of exposure to airgun noise (*e.g.,* Dalen and Knutsen, 1987; Payne, 2004; Stanley *et al.,* 2011). Most prior research on this topic, which has focused on relatively small spatial scales, has showed minimal effects (*e.g.,* Kostyuchenko, 1973; Booman *et al.,* 1996; Sætre and Ona, 1996; Pearson *et al.,* 1994; Bolle *et al.,* 2012).

A modeling exercise was conducted as a follow-up to the McCauley *et al.* (2017) study (as recommended by McCauley *et al.*), in order to assess the potential for impacts on ocean ecosystem dynamics and zooplankton population dynamics (Richardson *et al.,* 2017). Richardson *et al.* (2017) found that a full-scale airgun survey would impact copepod abundance within the survey area, but that effects at a regional scale were minimal (2 percent decline in abundance within 150 km of the survey area and effects not discernible over the full region). The authors also found that recovery within the survey area would be relatively quick (3 days following survey completion), and suggest that the quick recovery was due to the fast growth rates of zooplankton, and the dispersal and mixing of zooplankton from both inside and outside of the impacted region. The authors also suggest that surveys in areas with more dynamic ocean circulation in comparison with the study region and/or with deeper waters (*i.e.,* typical offshore wind locations) would have less net impact on zooplankton.

Notably, a recently described study produced results inconsistent with those of McCauley *et al.* (2017). Researchers conducted a field and laboratory study to assess if exposure to airgun noise affects mortality, predator escape response, or gene expression of the copepod *Calanus finmarchicus* (Fields *et al.,* 2019). Immediate mortality of copepods was significantly higher, relative to controls, at distances of 5 m or less from the airguns. Mortality one week after the airgun blast was significantly higher in the copepods placed 10 m from the airgun but was not significantly different from the controls at a distance of 20 m from the airgun. The increase in mortality, relative to controls, did not exceed 30 percent at any distance from the airgun. Moreover, the authors caution that even this higher mortality in the immediate vicinity of the airguns may be more pronounced than what would be observed in free-swimming animals due to increased flow speed of fluid inside bags containing the experimental animals. There were no sublethal effects on the escape performance or the sensory threshold needed to initiate an escape response at any of the distances from the airgun that were tested. Whereas McCauley *et al.* (2017) reported an SEL of 156 dB at a range of 509–658 m, with zooplankton mortality observed at that range, Fields *et al.* (2019) reported an SEL of 186 dB at a range of 25 m, with no reported mortality at that distance.

The presence of large numbers of turbines has been shown to impact meso- and sub-meso-scale water column circulation, which can affect the density, distribution, and energy content of zooplankton, and thereby their availability as marine mammal prey. The presence and operation of structures such as WTGs are, in general, likely to result in local and broader oceanographic effects in the marine environment, and may disrupt marine mammal prey such as dense aggregations and distribution of zooplankton through altering the strength of tidal currents and associated

fronts, changes in stratification, primary production, the degree of mixing, and stratification in the water column (Chen *et al.,* 2021, Johnson *et al.,* 2021, Christiansen *et al.,* 2022, Dorrell *et al.,* 2022). However, the scale of impacts is difficult to predict and may vary from meters to hundreds of meters for local individual turbine impacts (Schultze *et al.,* 2020) to large-scale dipoles of surface elevation changes stretching hundreds of kilometers (Christiansen *et al.,* 2022).

Empire Wind intends to install up to 147 operational turbines over the duration of the proposed LOA. As described above, there is scientific uncertainty around the scale of oceanographic impacts (meters to kilometers) associated with turbine operation. However, the project area does not include key foraging grounds for marine mammals with planktonic diets (*e.g,* North Atlantic right whale). Overall, any impact to plankton aggregation, and hence availability as marine mammal prey, from turbine presence and operation during the effective period of the proposed rule is likely to be limited.

In general, impacts to marine mammal prey species are primarily expected to be relatively minor and temporary due to the relatively small areas being affected compared to available habitat. Some mortality of prey inside the bubble curtain may occur; however, this would be very limited. NMFS does not expect HRG acoustic sources to impact fish and most sources are likely outside the hearing range of the primary prey species in the project area.

These potential impacts on prey could impact the distribution of marine mammals within the project area, potentially necessitating additional energy expenditure to find and capture prey, but at the temporal and spatial scales anticipated for this activity are not expected to impact the reproduction or survival of any individual marine mammals. Although studies assessing the impacts of offshore wind development on marine mammals are limited, the repopulation of wind energy areas by harbor porpoises (Brandt *et al.,* 2016; Lindeboom *et al.,* 2011) and harbor seals (Lindeboom *et al.,* 2011; Russell *et al.,* 2016) following the installation of WTGs are promising. Overall, any impacts to marine mammal foraging capabilities due to effects on prey aggregation from Empire Wind turbine presence and operation during the effective period of the proposed rule, if issued, is likely to be limited and nearby habitat that is known to support marine mammal foraging would be unaffected by turbine operation.

Overall, the combined impacts of sound exposure and oceanographic impacts on marine mammal habitat resulting from the proposed activities would not be expected to have measurable effects on populations of marine mammal prey species. Prey species exposed to sound might move away from the sound source, experience TTS, experience masking of biologically relevant sounds, or show no obvious direct effects.

Acoustic Habitat

Acoustic habitat is the soundscape, which encompasses all of the sound present in a particular location and time, as a whole when considered from the perspective of the animals experiencing it. Animals produce sound for, or listen for sounds produced by, conspecifics (communication during feeding, mating, and other social activities), other animals (finding prey or avoiding predators), and the physical environment (finding suitable habitats, navigating). Together, sounds made by animals and the geophysical environment (*e.g.,* produced by earthquakes, lightning, wind, rain, waves) make up the natural contributions to the total acoustics of a place. These acoustic conditions, termed acoustic habitat, are one attribute of an animal's total habitat.

Soundscapes are also defined by, and acoustic habitat influenced by, the total contribution of anthropogenic sound. This may include incidental emissions from sources such as vessel traffic or may be intentionally introduced to the marine environment for data acquisition purposes (as in the use of air gun arrays) or for Navy training and testing purposes (as in the use of sonar and explosives and other acoustic sources). Anthropogenic noise varies widely in its frequency, content, duration, and loudness and these characteristics greatly influence the potential habitat-mediated effects to marine mammals (please also see the previous discussion on Masking), which may range from local effects for brief periods of time to chronic effects over large areas and for long durations. Depending on the extent of effects to habitat, animals may alter their communications signals (thereby potentially expending additional energy) or miss acoustic cues (either conspecific or adventitious). Problems arising from a failure to detect cues are more likely to occur when noise stimuli are chronic and overlap with biologically relevant cues used for communication, orientation, and predator/prey detection (Francis and Barber, 2013). For more detail on these concepts, see Barber *et al.,* 2009; Pijanowski *et al.,* 2011; Francis and Barber, 2013; Lillis *et al.,* 2014.

The term ''listening area'' refers to the region of ocean over which sources of sound can be detected by an animal at the center of the space. Loss of communication space concerns the area over which a specific animal signal, used to communicate with conspecifics in biologically important contexts (*e.g.,* foraging, mating), can be heard, in noisier relative to quieter conditions (Clark *et al.,* 2009). Lost listening area concerns the more generalized contraction of the range over which animals would be able to detect a variety of signals of biological importance, including eavesdropping on predators and prey (Barber *et al.,* 2009). Such metrics do not, in and of themselves, document fitness consequences for the marine animals that live in chronically noisy environments. Long-term population-level consequences mediated through changes in the ultimate survival and reproductive success of individuals are difficult to study, and particularly so underwater. However, it is increasingly well documented that aquatic species rely on qualities of natural acoustic habitats, with researchers quantifying reduced detection of important ecological cues (*e.g.,* Francis and Barber, 2013; Slabbekoorn *et al.,* 2010) as well as survivorship consequences in several species (*e.g.,* Simpson *et al.,* 2014; Nedelec *et al.,* 2015).

Sound produced from construction activities in the Empire Wind project area may be widely dispersed or concentrated in small areas for varying periods. However, anthropogenic noise attributed to construction activities in the project area would not be interminable. There would be breaks between noise-generating activities on active pile driving days. Similarly, there would likely be periods of days or even weeks without construction-related underwater noise.

Although this proposed rulemaking primarily covers the noise produced from construction activities relevant to the Empire Wind offshore wind facility, operational noise was a consideration in NMFS' analysis of the project, as all turbines would become operational during the effective period of the proposed rule, if issued. Empire Wind anticipates that WTGs in EW 1 would become operational late in Q2 or early Q3 in 2026 while those in EW 2 would become operational in Q4 of 2027; the rule, if issued, would be effective until January 2029. Once operational, offshore wind turbines are known to produce continuous, non-impulsive underwater noise, primarily below 1

kHz (Tougaard *et al.,* 2020; Stöber and Thomsen, 2021).

In both newer, quieter, direct-drive systems (such as what has been proposed for Empire Wind) and older generation, geared turbine designs, recent scientific studies indicate that operational noise from turbines is on the order of 110 to 125 dB re 1 µPa root-mean-square sound pressure level (SPL_{rms}) at an approximate distance of 50 m (Tougaard *et al.,* 2020). Recent measurements of operational sound generated from wind turbines (direct drive, 6 MW, jacket piles) at Block Island wind farm (BIWF) indicate average broadband levels of 119 dB at 50 m from the turbine, with levels varying with wind speed (HDR, 2019). Interestingly, measurements from BIWF turbines showed operational sound had less tonal components compared to European measurements of turbines with gear boxes.

Tougaard *et al.* (2020) further stated that the operational noise produced by WTGs is static in nature and lower than noise produced by passing ships. This is a noise source in this region to which marine mammals are likely already habituated. Furthermore, operational noise levels are likely lower than those ambient levels already present in active shipping lanes, such that operational noise would likely only be detected in very close proximity to the WTG (Thomsen *et al.,* 2006; Tougaard *et al.,* 2020). Similarly, recent measurements from a wind farm (3 MW turbines) in China found at above 300 Hz, turbines produced sound that was similar to background levels (Zhang *et al.,* 2021). Other studies by Jansen and de Jong (2016) and Tougaard *et al.* (2009) determined that, while marine mammals would be able to detect operational noise from offshore wind farms (again, based on older 2 MW models) for several kilometers, they expected no significant impacts on individual survival, population viability, marine mammal distribution, or the behavior of the animals considered in their study (harbor porpoises and harbor seals).

More recently, Stöber and Thomsen (2021) used monitoring data and modeling to estimate noise generated by more recently developed, larger (10 MW) direct-drive WTGs. Their findings, similar to Tougaard *et al.* (2020), demonstrate that there is a trend that operational noise increases with turbine size. Their study predicts broadband source levels could exceed 170 dB SPL_{rms} for a 10 MW WTG; however, those noise levels were generated based on geared turbines; newer turbines operate with direct drive technology. The shift from using gear boxes to direct drive technology is expected to reduce the levels by 10 dB. The findings in the Stöber and Thomsen (2021) study have not been experimentally validated, though the modeling (using largely geared turbines) performed by Tougaard *et al.* (2020) yields similar results for a hypothetical 10 MW WTG. Overall, noise from operating turbines would raise ambient noise levels in the immediate vicinity of the turbines; however, the spatial extent of increased noise levels would be limited. NMFS proposes to require Empire Wind to measure operational noise levels.

Water Quality

Temporary and localized reduction in water quality will occur as a result of in-water construction activities. Most of this effect will occur during pile driving and installation of the cables, including auxiliary work such as dredging and scour placement. These activities will disturb bottom sediments and may cause a temporary increase in suspended sediment in the project area. Currents should quickly dissipate any raised total suspended sediment (TSS) levels, and levels should return to background levels once the project activities in that area cease. No direct impacts on marine mammals is anticipated due to increased TSS and turbidity; however, turbidity within the water column has the potential to reduce the level of oxygen in the water and irritate the gills of prey fish species in the proposed project area. However, turbidity plumes associated with the project would be temporary and localized, and fish in the proposed project area would be able to move away from and avoid the areas where plumes may occur. Therefore, it is expected that the impacts on prey fish species from turbidity, and therefore on marine mammals, would be minimal and temporary.

Equipment used by Empire Wind within the project area, including ships and other marine vessels, potentially aircrafts, and other equipment, are also potential sources of by-products (*e.g.,* hydrocarbons, particulate matter, heavy metals). All equipment is properly maintained in accordance with applicable legal requirements. All such operating equipment meets Federal water quality standards, where applicable. Given these requirements, impacts to water quality are expected to be minimal.

Reef Effects

The presence of monopile foundations, scour protection, and cable protection will result in a conversion of the existing sandy bottom habitat to a hard bottom habitat with areas of vertical structural relief. This could potentially alter the existing habitat by creating an ''artificial reef effect'' that results in colonization by assemblages of both sessile and mobile animals within the new hard-bottom habitat (Wilhelmsson *et al.,* 2006; Reubens *et al.,* 2013; Bergström *et al.,* 2014; Coates *et al.,* 2014). This colonization by marine species, especially hard-substrate preferring species, can result in changes to the diversity, composition, and/or biomass of the area thereby impacting the trophic composition of the site (Wilhelmsson *et al.,* 2010, Krone *et al.,* 2013; Bergström *et al.,* 2014, Hooper *et al.,* 2017; Raoux *et al.,* 2017; Harrison and Rousseau, 2020; Taormina *et al.,* 2020; Buyse *et al.,* 2022a; ter Hofstede *et al.,* 2022).

Artificial structures can create increased habitat heterogeneity important for species diversity and density (Langhamer, 2012). The WTG and OSS foundations will extend through the water column, which may serve to increase settlement of meroplankton or planktonic larvae on the structures in both the pelagic and benthic zones (Boehlert and Gill, 2010). Fish and invertebrate species are also likely to aggregate around the foundations and scour protection which could provide increased prey availability and structural habitat (Boehlert and Gill, 2010; Bonar *et al.,* 2015). Further, instances of species previously unknown, rare, or nonindigenous to an area have been documented at artificial structures, changing the composition of the food web and possibly the attractability of the area to new or existing predators (Adams *et al.,* 2014; de Mesel, 2015; Bishop *et al.,* 2017; Hooper *et al.,* 2017; Raoux *et al.,* 2017; van Hal *et al.,* 2017; Degraer *et al.,* 2020; Fernandez-Betelu *et al.,* 2022). Notably, there are examples of these sites becoming dominated by marine mammal prey species, such as filter-feeding species and suspension-feeding crustaceans (Andersson and Öhman, 2010; Slavik *et al.,* 2019; Hutchison *et al.,* 2020; Pezy *et al.,* 2020; Mavraki *et al.,* 2022).

Numerous studies have documented significantly higher fish concentrations including species like cod and pouting (*Trisopterus luscus*), flounder (*Platichthys flesus*), eelpout (*Zoarces viviparus*), and eel (*Anguilla anguilla*) near in-water structures than in surrounding soft bottom habitat (Langhamer and Wilhelmsson, 2009; Bergström *et al.,* 2013; Reubens *et al.,* 2013). In the German Bight portion of the North Sea, fish were most densely

congregated near the anchorages of jacket foundations, and the structures extending through the water column were thought to make it more likely that juvenile or larval fish encounter and settle on them (RI–CRMC, 2010; Krone *et al.,* 2013). In addition, fish can take advantage of the shelter provided by these structures while also being exposed to stronger currents created by the structures, which generate increased feeding opportunities and decreased potential for predation (Wilhelmsson *et al.,* 2006). The presence of the foundations and resulting fish aggregations around the foundations is expected to be a long-term habitat impact, but the increase in prey availability could potentially be beneficial for some marine mammals.

Estimated Take of Marine Mammals

This section provides an estimate of the number of incidental takes proposed for authorization through the regulations, which will inform both NMFS' consideration of ''small numbers'' and the negligible impact determination.

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 noise from impact and vibratory pile driving and HRG surveys could result in behavioral disturbance of marine mammals that qualifies as take. Impacts such as masking and TTS can contribute to the disruption of behavioral patterns and are accounted for within those requested takes. There is also some potential for auditory injury (Level A harassment) of fin whales and minke whales due to the increased likelihood that they would be present during foundation installation than other mysticetes. North Atlantic right whales, sei whales, and humpback whales occur in very low densities in the project area during foundation installation activities. For mid-frequency, high-frequency, and phocid hearing groups, when the associated PTS zone sizes are considered (*e.g.,* Table 13 to Table 20), the potential for PTS from the noise produced by the project is negligible. Hence, Empire Wind did not request, and NMFS is not proposing to authorize Level A harassment of these hearing groups. While NMFS is proposing to authorize Level A harassment and Level B harassment, the proposed mitigation and monitoring measures are expected to minimize the amount and severity of such taking to the extent practicable (see Proposed Mitigation).

As described previously, no serious injury or mortality is anticipated or proposed to be authorized incidental to Empire Wind's specified activities. With or without mitigation, neither pile driving nor HRG surveys have the potential to directly cause marine mammal mortality or serious injury. While, in general, mortality and serious injury of marine mammals could occur from vessel strikes, the mitigation and monitoring measures contained within this proposed rule would avoid vessel strikes. No other activities have the potential to result in mortality or serious injury.

For acoustic impacts, we estimate take by considering: (1) acoustic thresholds above which the best available science indicates marine mammals will 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.

In this case, as described below, there are multiple methods available to address density or occurrence and, for each species and activity, the largest value resulting from the three take estimation methods described below (*i.e.,* density-based, PSO-based, or mean group size) was carried forward as the amount of requested take, by Level B harassment. The amount of requested take, by Level A harassment, reflects the density-based exposure estimates and, for some species and activities, consideration of other data such as group size and the effectiveness of mitigation measures to avoid or minimize the potential for injury.

Below, we describe the acoustic thresholds NMFS uses, discuss the marine mammal density and occurrence information used, and then describe the modeling and methodologies applied to estimate take for each of Empire Wind's proposed construction activities. NMFS has carefully considered all information and analysis presented by Empire Wind as well as all other applicable information and, based on the best available science, concurs that Empire Wind's estimates of the types and amounts of take for each species and stock are reasonable, and is what NMFS is proposing to authorize. NMFS notes the take estimates described herein for foundation installation can be considered conservative as the estimates do not reflect the implementation of clearance and shutdown zones for any marine mammal species or stock.

Marine Mammal Acoustic Thresholds

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 PTS of some degree (equated to Level A harassment). A summary of all NMFS' thresholds can be found at (*https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance*).

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, ambient noise, and the receiving animal's hearing, motivation, experience, demography, behavior at time of exposure, 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 the received root-mean-square sound pressure levels (RMS SPL) of 120 dB for continuous (*e.g.,* vibratory pile-driving, drilling) and above the received RMS SPL 160 dB for non-explosive intermittent (*e.g.,* impact

pile driving, scientific sonar) sources (Table 6). 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 behavioral patterns that would not otherwise occur.

TABLE 6—UNDERWATER LEVEL B HARASSMENT ACOUSTIC THRESHOLDS

[NMFS, 2005]

Source type	Level B harassment threshold (RMS SPL)
Continuous	120 dB re 1 μPa.
Non-explosive impulsive or intermittent.	160 dB re 1 μPa.

Empire Wind's construction activities include the use of continuous (*e.g.,* vibratory pile driving), and intermittent (*e.g.,* impact pile driving, HRG acoustic sources) sources, and, therefore, the 120 and 160 dB *re 1 μPa* (rms) thresholds are applicable.

Level A Harassment

NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0; Technical Guidance) (NMFS, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). As dual metrics, NMFS considers onset of PTS (Level A harassment) to have occurred when either one of the two metrics is exceeded (*i.e.,* metric resulting in the largest isopleth). Empire Wind's proposed activities include the use of both impulsive and non-impulsive sources.

These thresholds are provided in Table 7 below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS' 2018 Technical Guidance, which may be accessed at: *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 7—ONSET OF PERMANENT THRESHOLD SHIFT (PTS)

[NMFS, 2018]

Hearing group	PTS onset thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{p,0\text{-}pk,flat}$: 219 dB; $L_{E,p,LF,24h}$: 183 dB	*Cell 2:* $L_{E,p,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	*Cell 3:* $L_{p,0\text{-}pk,flat}$: 230 dB; $L_{E,p,MF,24h}$: 185 dB	*Cell 4:* $L_{E,p,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	*Cell 5:* $L_{p,0\text{-}pk,flat}$: 202 dB; $L_{E,p,HF,24h}$: 155 dB	*Cell 6:* $L_{E,p,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	*Cell 7:* $L_{p,0\text{-}pk.flat}$: 218 dB; $L_{E,p,PW,24h}$: 185 dB	*Cell 8:* $L_{E,p,PW,24h}$: 201 dB.

* Dual metric thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds are recommended for consideration.

Note: Peak sound pressure level ($L_{p,0\text{-}pk}$) has a reference value of 1 μPa, and weighted cumulative sound exposure level ($L_{E,p}$) has a reference value of $1\mu Pa^2s$. In this Table, thresholds are abbreviated to be more reflective of International Organization for Standardization standards (ISO, 2017). The subscript ''flat'' is being included to indicate peak sound pressure are flat weighted or unweighted within the generalized hearing range of marine mammals (*i.e.,* 7 Hz to 160 kHz). The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW pinnipeds) and that the recommended accumulation period is 24 hours. The weighted cumulative sound exposure level thresholds 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 thresholds will be exceeded.

Below, we describe, in detail, the assumptions and methodologies used to estimate take, in consideration of acoustic thresholds and appropriate marine mammals density and occurrence information, for WTG and OSS foundation installation, cable landfall construction, marina activities, and HRG surveys. Resulting distances to thresholds, densities used, activity-specific exposure estimates (as relevant to the analysis), and activity-specific take estimates can be found in each activity subsection below. At the end of this section, we present the total annual and 5-year estimates that Empire Wind requested, and NMFS proposes to authorize, from all activities combined.

Acoustic and Exposure Modeling

As described above, predominant underwater noise associated with the construction of EW 1 and EW 2 results from installing monopile and jacket foundations using an impact hammer. Empire Wind employed JASCO to conduct acoustic and animal movement exposure modeling to better understand sound fields produced during these activities and to estimate exposures (Küsel *et al.,* 2022). The basic modeling approach is to characterize the sounds produced by the source, determine how the sounds propagate within the surrounding water column, and then estimate species-specific exposure probability by considering the range- and depth-dependent sound fields in relation to animal movement in simulated representative construction scenarios. Animal movement modeling was not conducted to estimate take for cable landfall construction, marina activities, and HRG surveys due to either their short duration or limited harassment zones.

JASCO's Pile Driving Source Model (PDSM), a physical model of pile vibration and near-field sound radiation (MacGillivray 2014), was used in conjunction with the GRLWEAP 2010 wave equation model (GRLWEAP, Pile Dynamics 2010) to predict source levels associated with impact pile driving activities (WTG and OSS foundation installation and casing pipe installation). The PDSM physical model computes the underwater vibration and sound radiation of a pile by solving the theoretical equations of motion for axial and radial vibrations of a cylindrical

shell. This model is used to estimate the energy distribution per frequency (source spectrum) at a close distance from the source (10 m). Piles are modeled as a vertical installation using a finite-difference structural model of pile vibration based on thin-shell theory. To model the sound emissions from the piles, the force of the pile driving hammers also had to be modeled. The force at the top of each monopile and jacket foundation pile was computed using the GRLWEAP 2010 wave equation model (GRLWEAP; Pile Dynamics, 2010), which includes a large database of simulated hammers. The forcing functions from GRLWEAP were used as inputs to the finite difference model to compute the resulting pile vibrations. The sound radiating from the pile itself was simulated using a vertical array of discrete point sources. These models account for several parameters that describe the operation—pile type, material, size, and length—the pile driving equipment, and approximate pile penetration depth. The model assumed direct contact between the representative hammers, helmets, and piles (*i.e.,* no cushioning material).

Empire Wind modeled three WTG monopile scenarios: 9.6-m typical; 9.6-m difficult-to-drive; and 11-m typical. For each scenario, Empire Wind assumed various hammer energy schedules, including the hammer energies and number of strikes predicted at various penetration depths during the pile driving process and different soil conditions. Typical monopile foundation locations are those where the standard hammer energy would be sufficient to complete installation of the foundation to the target penetration depth. Difficult-to-drive foundation locations would require higher hammer energies and/or additional hammer strikes to complete foundation installation to the target penetration depth. Difficult-to-drive scenarios would only utilize 9.6-m piles as the larger 11-m piles could not be driven to target penetration depth in the soil conditions associated with difficult-to-drive turbine positions. Empire Wind estimates that a maximum of 17 total foundations may be difficult-to-drive (including as many as 7 difficult-to-drive foundations for EW 1 and as many as 10 difficult-to-drive foundations for EW 2). The actual number of difficult-to-drive piles will be informed by additional analysis of geotechnical data and other studies that will occur prior to construction but would not be greater than 17 foundations.

The amount of sound generated during pile driving varies with the energy required to drive piles to a desired depth and depends on the sediment resistance encountered. Sediment types with greater resistance require hammers that deliver higher energy strikes and/or an increased number of strikes relative to installations in softer sediment. Maximum sound levels usually occur during the last stage of impact pile driving where the greatest resistance is encountered (Betke, 2008). Empire Wind developed hammer energy schedules typical and difficult-to-drive 9.6-m piles and for three different seabed penetration depths for the 11-m diameter piles to represent the various soil conditions that may be encountered in the Lease Area (*i.e.,* normal soil conditions (identified as ''T1''), harder soil conditions (identified as ''R3''), and outlier softer soil conditions (identified as ''U3''). The maximum penetration depths for typical and difficult-to-drive 9.6-m piles (38 m (125 ft)); typical 11-m piles (55 m (180 ft)) and pin piles (56 m (184 ft) at OSS 1) were all carried forward as part of the modeling analysis.

One OSS foundation scenario was modeled; however, this scenario was modeled at two locations (representing locations in EW 1 and EW 2) resulting in two hammer schedules. Empire Wind anticipates the different locations will require different hammer schedules depending on site-specific soil conditions.

Key modeling assumptions for the WTG monopiles and OSS foundation pin piles are listed in Table 8 (additional modeling details and input parameters can be found in Küsel *et al.* (2022)). Hammer energy schedules for WTG monopiles (9.6 m and 11 m) and OSS foundation pin piles are provided in Table 9, Table 10, and Table 11 respectively.

TABLE 8—KEY PILING ASSUMPTIONS USED IN THE SOURCE MODELING

Foundation type	Modeled maximum impact hammer energy (kJ)	Pile length (m)	Pile wall thickness (mm)	Seabed penetration (m)	Number of piles per day
9.6 m Monopile	[4] 2,300/5,500	78.5	73–101	38	1–2
11 m Monopile R3 [1]	2,000	75.3	8.5	35	1–2
11 m Monopile T1 [2]	2,500	84.1	8.5	40	1–2
11 m Monopile U3 [3]	1,300	97.5	85	55	1–2
Jacket (2.5 m pin pile)	3,200	57–66	50	47–56	2–3

[1] R3 = harder soil conditions.
[2] T1 = normal soil conditions.
[3] U3 = softer soil conditions.
[4] Typical 2.300; difficult to drive 5,500.

TABLE 9—HAMMER ENERGY SCHEDULES FOR MONOPILES UNDER THE TWO PILE DRIVING SCENARIOS

[9.6-m Diameter Pile; IHC S–5500 hammer]

''Typical'' pile driving scenario (9.6-m diameter pile)			''Difficult-to-drive'' pile driving scenario (9.6-m diameter pile)		
Energy level (kJ)	Strike count	Pile penetration depth (m)	Energy level (kJ)	Strike count	Pile penetration depth (m)
Initial sink depth	0	2	Initial sink depth	0	2
450	1,607	12	450	1,607	12

TABLE 9—HAMMER ENERGY SCHEDULES FOR MONOPILES UNDER THE TWO PILE DRIVING SCENARIOS—Continued

[9.6-m Diameter Pile; IHC S–5500 hammer]

"Typical" pile driving scenario (9.6-m diameter pile)			"Difficult-to-drive" pile driving scenario (9.6-m diameter pile)		
Energy level (kJ)	Strike count	Pile penetration depth (m)	Energy level (kJ)	Strike count	Pile penetration depth (m)
800	731	5	800	731	5
1,400	690	4	1,400	690	4
1,700	1,050	6	1,700	1,050	6
2,300	1,419	9	2,300	1,087	4
5,500	0	0	5,500	2,000	5
Total	5,497	38	Total	7,615	38
Strike rate (strikes/min)	30		Strike rate (strikes/min)	30	

TABLE 10—HAMMER ENERGY SCHEDULE AND NUMBER OF STRIKES PER MONOPILES UNDER THREE PILE DRIVING SCENARIOS

[11 m Diameter pile; IHC S–5500 hammer]

Energy level (kJ)	R3-harder soil conditions		T1-normal soil conditions		U3-softer soil conditions	
	Strike count	Penetration depth	Strike count	Penetration depth	Strike count	Penetration depth
Initial Sink Depth	.....	1	.....	3	.....	5
450	.....	.....	.....	.....	622	6
500	1168	14	1339	14	.....	.....
750	433	3	857	6	2781	20
1000	.....	.....	632	4	1913	12
1100	265	2	.....	.....	.....	.....
1300	.....	.....	.....	.....	2019	12
1500	.....	.....	1109	7	.....	.....
2000	2159	15	326	2	.....	.....
2500	.....	.....	656	4	.....	.....
Totals	4025	35	4919	40	7335	55

TABLE 11—HAMMER ENERGY SCHEDULES FOR PIN PILES SUPPORTING THE JACKET FOUNDATION LOCATED AT OSS 1 AND OSS 2, WITH AN IHC S–4000 HAMMER

OSS 1 location			OSS 2 location		
Energy level (kJ)	Strike count	Pile penetration depth (m)	Energy level (kJ)	Strike count	Pile penetration depth (m)
Initial sink depth	0	8	Initial sink depth	0	5
500	1,799	30	500	1,206	22
750	1,469	12	750	1,153	9
2,000	577	4	1,100	790	7
3,200	495	2	3,200	562	4
Total	4,340	56	Total	3,711	47
Strike rate (strikes/min)	30		Strike rate (strikes/min)	30	

Sounds produced by installation of the 9.6- and 11-m monopiles were modeled at nine representative locations as shown in Figure 2 in Küsel *et al.* (2022). Sound fields from pin piles were modeled at the two planned jacket foundation locations, OSS 1 and OSS 2. Modeling locations are shown in Figure 8 in Küsel *et al.* (2022). The modeling locations were selected as they represent the range of soil conditions and water depths in the lease area. The monopiles were assumed to be vertical and driven to a maximum expected penetration depth of 38 m (125 ft) for 9.6-m piles and 55 m (180 ft) for 11-m piles. Jacket pin piles were assumed to be vertical and driven to a maximum expected penetration depth of 56 m (184 ft).

Empire Wind would employ a noise attenuation system during all impact pile driving of monopile and jacket foundations. Noise attenuation systems, such as bubble curtains, are sometimes used to decrease the sound levels radiated from a source. Hence,

hypothetical broadband attenuation levels of 0 dB, 6 dB, 10 dB, 15 dB, and 20 dB were incorporated into the foundation source models to gauge effects on the ranges to thresholds given these levels of attenuation. Although five attenuation levels were evaluated, Empire Wind and NMFS anticipate that the noise attenuation system ultimately chosen will be capable of reliably reducing source levels by 10 dB; therefore, modeling results assuming 10-dB attenuation are carried forward in this analysis for monopile and jacket foundation installation. See the Proposed Mitigation section for more information regarding the justification for the 10-dB assumption.

To estimate sound propagation, JASCO's used the FWRAM (Küsel *et al.,* 2022, Appendix E.4) propagation model for foundation installation to combine the outputs of the source model with spatial and temporal environmental factors (*e.g.,* location, oceanographic conditions, and seabed type) to get time-domain representations of the sound signals in the environment and estimate sound field levels. FWRAM is based on the wide-angle parabolic equation (PE) algorithm (Collins 1993). Because the foundation pile is represented as a linear array and FWRAM employs the array starter method to accurately model sound propagation from a spatially distributed source (MacGillivray and Chapman, 2012), using FWRAM ensures accurate characterization of vertical directivity effects in the near-field zone (1 km). Due to seasonal changes in the water column, sound propagation is likely to differ at different times of the year. The speed of sound in seawater depends on the temperature T (degree celsius), salinity S (parts per thousand (ppt)), and depth D (m) and can be described using sound speed profiles. Oftentimes, a homogeneous or mixed layer of constant velocity is present in the first few meters. It corresponds to the mixing of surface water through surface agitation. There can also be other features, such as a surface channel, which corresponds to sound velocity increasing from the surface down. This channel is often due to a shallow isothermal layer appearing in winter conditions, but can also be caused by water that is very cold at the surface. In a negative sound gradient, the sound speed decreases with depth, which results in sound refracting downwards which may result in increased bottom losses with distance from the source. In a positive sound gradient, as is predominantly present in the winter season, sound speed increases with depth and the sound is, therefore, refracted upwards, which can aid in long distance sound propagation. To capture this variability, acoustic modeling was conducted using an average sound speed profile for a ''summer'' period including the months of May through November, and a ''winter'' period including December through April. FWRAM computes pressure waveforms via Fourier synthesis of the modeled acoustic transfer function in closely spaced frequency bands. Examples of decidecade spectral levels for each foundation pile type, hammer energy, and modeled location, using average summer sound speed profile are provided in Küsel *et al.* (2022).

To estimate the probability of exposure of animals to sound above NMFS' harassment thresholds during foundation installation, JASCO's Animal Simulation Model Including Noise Exposure (JASMINE) was used to integrate the sound fields generated from the source and propagation models described above with species-typical behavioral parameters (*e.g.,* dive patterns). Sound exposure models such as JASMINE use simulated animals (animats) to sample the predicted 3–D sound fields with movement rules derived from animal observations. Animats that exceed NMFS' acoustic thresholds are identified and the range for the exceedances determined. The output of the simulation is the exposure history for each animat within the simulation. An individual animat's sound exposure levels are summed over a specific duration, (24 hrs), to determine its total received acoustic energy (SEL) and maximum received PK and SPL. These received levels are then compared to the threshold criteria within each analysis period. The combined history of all animats gives a probability density function of exposure during the project. The number of animals expected to exceed the regulatory thresholds is determined by scaling the number of predicted animat exposures by the species-specific density of animals in the area. By programming animats to behave like marine species that may be present near the Empire Wind Lease Area, the sound fields are sampled in a manner similar to that expected for real animals. The parameters used for forecasting realistic behaviors (*e.g.,* diving, foraging, and surface times) were determined and interpreted from marine species studies (*e.g.,* tagging studies) where available, or reasonably extrapolated from related species (Küsel *et al.,* 2022).

As described in Section 2.6 of JASCO's acoustic modeling report for Empire Wind (Küsel *et al.,* 2022), for modeled animals that have received enough acoustic energy to exceed a given harassment threshold, the exposure range for each animal is defined as the closest point of approach (CPA) to the source made by that animal while it moved throughout the modeled sound field, accumulating received acoustic energy. The CPA for each of the species-specific animats during a simulation is recorded and then the CPA distance that accounts for 95 percent of the animats that exceed an acoustic impact threshold is determined. The $ER_{95\%}$ (95 percent exposure radial distance) is the horizontal distance that includes 95 percent of the CPAs of animats exceeding a given impact threshold. The $ER_{95\%}$ ranges are species-specific rather than categorized only by any functional hearing group, which allows for the incorporation of more species-specific biological parameters (*e.g.,* dive durations, swim speeds, etc.) for assessing the impact ranges into the model. Furthermore, because these $ER_{95\%}$ ranges are species-specific, they can be used to develop mitigation monitoring or shutdown zones.

Empire Wind also calculated acoustic ranges which represent the distance to a harassment threshold based on sound propagation through the environment (*i.e.,* independent of any receiver). As described above, applying animal movement and behavior within the modeled noise fields allows for a more realistic indication of the distances at which PTS acoustic thresholds are reached that considers the accumulation of sound over different durations. Acoustic ranges ($R_{95\%}$) to the Level A harassment SELcum metric thresholds are considered overly conservative as the accumulation of acoustic energy does not account for animal movement and behavior and therefore assumes that animals are essentially stationary at that distance for the entire duration of the pile installation, a scenario that does not reflect realistic animal behavior. The acoustic ranges to the SEL_{cum} Level A harassment thresholds for WTG and OSS foundation installation can be found in Tables 16–18 in Empire Wind's application but will not be discussed further in this analysis. Because NMFS Level B harassment threshold is an instantaneous exposure, acoustic ranges are more relevant to the analysis and are used to derive mitigation and monitoring measures. Acoustic ranges to the Level B harassment threshold for each activity are provided in the activity-specific subsections below. The differences between exposure ranges and acoustic ranges for Level B

harassment are minimal given it is an instantaneous method.

For vibratory pile driving of cofferdams, Empire Wind estimated source levels and frequency spectra assuming an 1,800 kilonewton (kN) vibratory force. Modeling was accomplished using adjusted one-third-octave band vibratory pile driving source levels cited for similar vibratory pile driving activities conducted during cofferdam installation for the Block Island Wind Farm (Tetra Tech, 2012; Schultz-von Glahn *et al.,* 2006). The assumed sound source level for vibratory pile driving corresponded to 195 dB SEL re 1 µPa. The frequency distribution of the vibratory pile driving sound source is displayed in Figure 5 in Küsel *et al.* (2022). The anticipated duration is 1 hour of active pile driving per day.

Underwater sound propagation modeling for cofferdam installation was completed using dBSea, a powerful software for the prediction of underwater noise in a variety of environments. The 3D model is built by importing bathymetry data and placing noise sources in the environment. Each source can consist of equipment chosen from either the standard or user defined databases. Noise mitigation methods may also be included. The user has control over the seabed and water properties including sound speed profile (SSP), temperature, salinity, and current.

The dBSeaPE solver makes use of the parabolic equation method, a versatile and robust method of marching the sound field out in range from the sound source. This method is one of the most widely used in the underwater acoustics community and offers excellent performance in terms of speed and accuracy in a range of challenging scenarios. For high frequencies, the dBSeaRay ray tracing solver is used, which forms a solution by tracing rays from the source to the receiver. Many rays leave the source covering a range of angles, and the sound level at each point in the receiving field is calculated by coherently summing the components from each ray. This is currently the only computationally efficient method at high frequencies. The underwater acoustic modeling analysis used a split solver, with dBSeaPE evaluating the 12.5 Hz to 800 Hz and dBSeaRay addressing 1,000 Hz to 20,000 Hz.

The acoustic modeling for impact hammering the casing pipe and goal posts and vibratory pile driving and removal associated with Onshore Substation C marina activities relied on NMFS' Multi-Species Calculator, available at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance,* which applies formulaic equations to predict distances to thresholds. Information on assumptions into the Multi-Species Calculator are provided in the activity specific sections below.

Marine Mammal Density and Occurrence

In this section we provide the information about marine mammal presence, density, or group dynamics that will inform the take calculations for all activities. Empire Wind applied the Duke University Marine Geospatial Ecology Laboratory 2022 marine mammal habitat-based density models (*https://seamap.env.duke.edu/models/Duke/EC/*) to estimate take from WTG and OSS foundation installation, cable landfall construction, and site characterization surveys (please see each activity subsection for these densities). For foundation installation, the width of the perimeter around the activity area used to select density data from the Duke models was based on the largest exposure range (typically the Level B harassment range) applicable to that activity and then rounded up to the nearest 5-km increment, (which reflects the spatial resolution of the Roberts and Halpin (2022) density models). All information provided by Empire Wind since submission of their adequate and complete application is contained within the final updated density and take addendum that they submitted to NMFS on January 25, 2023. The Updated Density and Take Estimation Memo is available at: *https://www.fisheries.noaa.gov/action/incidental-take-authorization-empire-offshore-wind-llc-construction-empire-wind-project-ew1?check_logged_in=1.*

The mean density for each month was determined by calculating the unweighted mean of all 5 x 5 km grid cells partially or fully within the analysis polygon (Roberts and Halpin, 2022). Densities were computed each month for an entire year to coincide with possible planned activities. In cases where monthly densities were unavailable (*i.e.,* long and short-finned pilot whales), annual mean densities were used instead. Additionally, Roberts and Halpin (2022) provide density for pilot whales as a guild that includes both species and, since it is very difficult to differentiate species at sea, take numbers for pilot whales are requested at the guild level. To obtain density estimates for long-finned and short-finned pilot whales to estimate exposures from foundation installation, the guild density from Roberts and Halpin (2022) was scaled by the relative stock sizes based on the best available abundance estimate from NOAA Fisheries SARs (Hayes *et al.,* 2021).

The equation below shows an example of how abundance scaling is applied to compute density for short-finned pilot whales.

$$D_{\text{short-finned}} = D_{\text{both}} \times N_{\text{coastal}} / (N_{\text{short-finned}} + N_{\text{long-finned}})$$

where:

D represents density and N represents abundance.

Similarly, densities are provided for seals as a guild consisting primarily of harbor and gray seals (Robert and Halpin 2022). Gray and harbor seal densities were scaled by relative NOAA Fisheries SARs (Hayes *et al.,* 2021) abundance to estimate exposures from foundation installation.

For some species and activities, observational data from Protected Species Observers (PSOs) aboard HRG and geotechnical survey vessels indicate that the density-based exposure estimates may be insufficient to account for the number of individuals of a species that may be encountered during the planned activities. A review of Empire Wind's PSO sightings data ranging from 2018–2021 for the Project Area indicated that exposure estimates based on the exposure modeling methodology for some species were likely underestimates for humpback whales, fin whales, and pilot whales. These findings are described in greater detail below.

For other less-common species, the predicted densities from Roberts and Halpin (2022) are very low and the resulting density-based exposure estimate is less than a single animal or a typical group size for the species. In such cases, the mean group size was considered as an alternative to the density-based or PSO data-based take estimates to account for potential impacts on a group during an activity. Mean group sizes for each species were calculated from recent aerial and/or vessel-based surveys, as shown in Table 12. Group size data were also used to estimate take from marina activities given there is no density data available for the area given its inshore location. Additional detail regarding the density and occurrence as well as the assumptions and methodology used to estimate take for specific activities is included in the activity-specific subsections below.

TABLE 12—AVERAGE MARINE MAMMAL GROUP SIZES

Marine mammal species	Average group size	Information source
North Atlantic right whale	1–2	Roberts and Halpin 2022.
Atlantic spotted dolphin	45	Kenney & Vigness-Raposa (2010).
Atlantic white-sided dolphin	52	Jefferson *et al.* (2015).
Bottlenose dolphin	15	Jefferson *et al.* (2015).
Common dolphin	30	Reeves *et al.* (2002).
Risso's dolphin	100	Jefferson *et al.* (2015).
Sperm whale	1	Barkaszi *et al.* 2019.

WTG and OSS Foundation Installation

Here we describe the results from the methodologies outlined above. We present exposure ranges to Level A harassment and Level B harassment thresholds, acoustic ranges to PTS peak and Level B harassment thresholds, densities, exposure estimates and take estimates from Empire Wind's WTG and OSS foundation installation following the aforementioned assumptions (*e.g.,* construction and hammer schedules).

Table 13 through Table 20 provide exposure ranges for the 9.5-m monopile (typical and difficult-to-drive), 11-m monopile, and OSS foundation pin piles, respectively, assuming 10 dB attenuation for summer and winter. Table 21 provides relevant acoustic ranges (PTS peak and Level B harassment). Of note, in some cases (*e.g.,* 9.6 m difficult-to-drive piles), distances to PTS peak thresholds exceed SELcum thresholds. However, those distances are small (less than 1 km) and only applicable to harbor porpoise. Please see tables 34–37 in Küsel *et al.* (2022) for more peak threshold modeling results.

TABLE 13—MAXIMUM EXPOSURE RANGES ($ER_{95\%}$) TO LEVEL A HARASSMENT PTS (SEL_{CUM}) AND LEVEL B HARASSMENT THRESHOLDS FROM IMPACT PILE DRIVING OF 9.6-m DIAMETER "TYPICAL" AND "DIFFICULT-TO-DRIVE" MONOPILE FOUNDATIONS (SUMMER), ASSUMING 10 dB ATTENUATION [b]

Species	"Typical" (in km)				"Difficult-to-drive" (in km)			
	One pile per day		Two piles per day		One pile per day		Two piles per day	
	Level A harassment (SEL; dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)	Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)	Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)	Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)
LF:								
Fin Whale	0.86	3.18	0.94	3.09	1.35	4.74	1.84	4.51
Minke Whale [a]	0.22	3.13	0.54	3.02	0.89	4.46	0.90	4.45
Humpback Whale [a]	0.24	3.15	0.33	3.01	0.74	4.47	0.69	4.53
North Atlantic Right Whale [a]	0.33	2.89	0.47	2.87	1.09	4.33	1.13	4.30
Sei Whale [a]	0.43	3.09	0.54	3.07	1.04	4.47	1.21	4.52
MF:								
Atlantic White-sided Dolphin	0	2.98	0	2.94	0	4.24	0	4.30
Atlantic Spotted dolphin	0	0	0	0	0	0	0	0
Common Dolphin	0	3.07	0	2.92	0	4.48	0	4.42
Bottlenose Dolphin	0	2.46	0	2.41	0	3.77	0	3.83
Risso's Dolphin	0	3.07	0	2.93	0	4.73	0	4.41
Long-finned Pilot Whale	0	0	0	0	0	0	0	0
Short-Finned Pilot Whale	0	0	0	0	0	0	0	0
Sperm Whale	0	3.25	0	2.96	0	4.59	0	4.47
HF:								
Harbor Porpoise	0	3.07	0	3.05	0	4.52	0	4.37
PW:								
Gray Seal	0	3.33	<0.01	3.26	<0.01	4.91	<0.01	4.87
Harbor Seal	0	3.02	0	2.97	0	4.68	0	4.38

Note: LF = low-frequency cetaceans; MF = mid-frequency cetaceans; HF = high-frequency cetaceans; PW = pinnipeds in water.
[a] Species was considered as "migrating" in the analysis.
[b] The values here were found in Tables I–19, I–20, I–23, and I–24 in Küsel et al. (2022) (Appendix I).

TABLE 14—MAXIMUM EXPOSURE RANGES ($ER_{95\%}$) TO LEVEL A HARASSMENT PTS (SEL_{CUM}) AND LEVEL B HARASSMENT THRESHOLDS FROM IMPACT PILE DRIVING OF 9.6-m DIAMETER "TYPICAL" AND "DIFFICULT-TO-DRIVE" MONOPILE FOUNDATIONS (WINTER), ASSUMING 10 dB ATTENUATION [c]

Species	"Typical" (in km)				"Difficult-to-drive" (in km)			
	One pile per day		Two piles per day		One pile per day		Two piles per day	
	Level A harassment (SEL; dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)	Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)	Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)	Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)
LF:								
Fin Whale	0.88	3.40	1.01	3.46	1.80	5.24	1.95	4.87
Minke Whale [a]	0.26	3.31	0.48	3.29	0.89	4.88	1.05	4.66
Humpback Whale [a]	0.24	3.38	0.36	3.31	0.74	5.10	0.83	5.07
North Atlantic Right Whale [a]	0.43	3.04	0.47	3.11	1.13	4.73	1.19	4.62
Sei Whale [a]	0.43	3.28	0.58	3.43	1.24	4.95	1.29	4.85
MF:								
Atlantic White-sided Dolphin	0	3.30	0	3.19	0	4.73	0	4.72
Atlantic Spotted dolphin	0	0	0	0	0	0	0	0
Common Dolphin	0	3.28	0	3.08	0	4.89	0	4.73
Bottlenose Dolphin	0	2.73	0	2.77	0	4.23	0	4.12
Risso's Dolphin	0	3.39	0	3.32	0	5.14	0	4.92
Long-finned Pilot Whale	0	0	0	0	0	0	0	0
Short-Finned Pilot Whale	0	0	0	0	0	0	0	0
Sperm Whale	0	3.40	0	3.19	0	4.96	0	4.92
HF:								
Harbor Porpoise	0	3.15	0	3.22	0	5.04	0	4.75
PW:								
Gray Seal	0	3.54	<0.01	3.50	<0.01	[b] 5.35	<0.01	5.19
Harbor Seal	0	3.28	0	3.29	0	4.93	0	4.71

Note: LF = low-frequency cetaceans; MF = mid-frequency cetaceans; HF = high-frequency cetaceans; PW = pinnipeds in water.
[a] Species was considered as "migrating" in the analysis.
[b] These values represent the maximum Level B.
[c] The values here were found in Tables I–21, I–22, I–25, and I–26 in Küsel et al. (2022) (Appendix I).

TABLE 15—EXPOSURE RANGES ($ER_{95\%}$) TO LEVEL A HARASSMENT (PTS (SEL_{CUM})) AND LEVEL B HARASSMENT THRESHOLDS FROM IMPACT PILE DRIVING 11-m DIAMETER MONOPILE FOUNDATIONS (SUMMER) IN NORMAL (T1) SOIL CONDITIONS, ASSUMING 10 dB ATTENUATION [b]

Species	Normal (T1) soil conditions (in km)			
	One pile per day		Two piles per day	
	Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)	Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)
LF:				
Fin Whale	0.87	3.32	0.83	3.16
Minke Whale [a]	0.17	3.10	0.35	2.98
Humpback Whale [a]	0.25	3.01	0.16	3.10
North Atlantic Right Whale [a]	0.20	3.09	0.44	2.93
Sei Whale [a]	0.44	3.19	0.27	3.26
MF:				
Atlantic White-sided Dolphin	0	2.97	0	2.98
Atlantic Spotted dolphin	0	0	0	0
Common Dolphin	0	3.08	0	2.94
Bottlenose Dolphin	0	2.60	0	2.62
Risso's Dolphin	0	3.21	0	3.11
Long-finned Pilot Whale	0	0	0	0
Short-Finned Pilot Whale	0	0	0	0
Sperm Whale	0	3.40	0	3.19
HF:				
Harbor Porpoise	0	3.06	0	3.04
PW:				
Gray Seal	0	3.39	0	3.40
Harbor Seal	0	3.25	0	3.09

Note: LF = low-frequency cetaceans; MF = mid-frequency cetaceans; HF = high-frequency cetaceans; PW = pinnipeds in water.
[a] Species was considered as "migrating" in the analysis.
[b] The values here were found in Tables I–31 and I–32 in Küsel et al. (2022) (Appendix I).

TABLE 16—EXPOSURE RANGES ($ER_{95\%}$) TO LEVEL A HARASSMENT (PTS (SEL_{CUM})) AND LEVEL B HARASSMENT THRESHOLDS FROM IMPACT PILE DRIVING OF 11-M DIAMETER MONOPILE FOUNDATIONS (WINTER) IN NORMAL (T1) SOIL CONDITIONS, ASSUMING 10 dB ATTENUATION [b]

Species	Normal (T1) soil conditions (in km)			
	One pile per day		Two piles per day	
	Level A harassment (dB re 1 μPa2·s)	Level B harassment Behavior (dB re 1 μPa)	Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)
LF:				
Fin Whale	0.87	3.56	0.82	3.53
Minke Whale [a]	0.27	3.29	0.35	3.31
Humpback Whale [a]	0.25	3.24	0.16	3.40
North Atlantic Right Whale [a]	0.20	3.17	0.44	3.28
Sei Whale [a]	0.44	3.33	0.41	3.53
MF:				
Atlantic White-sided Dolphin	0	3.28	0	3.31
Atlantic Spotted dolphin	0	0	0	0
Common Dolphin	0	3.26	0	3.16
Bottlenose Dolphin	0	2.73	0	2.93
Risso's Dolphin	0	3.48	0	3.44
Long-finned Pilot Whale	0	0	0	0
Short-Finned Pilot Whale	0	0	0	0
Sperm Whale	0	3.48	0	3.35
HF:				
Harbor Porpoise	0	3.41	0	3.35
PW:				
Gray Seal	0	3.66	0	3.66
Harbor Seal	0	3.36	0	3.36

Note: LF = low-frequency cetaceans; MF = mid-frequency cetaceans; HF = high-frequency cetaceans; PW = pinnipeds in water.
[a] Species was considered as ''migrating'' in the analysis.
[b] The values here were found in Tables I–33 and I–34 in Küsel et al. (2022) (Appendix I).

TABLE 17—EXPOSURE RANGES ($ER_{95\%}$) TO PTS (SEL_{CUM}) AND LEVEL B HARASSMENT THRESHOLDS FROM IMPACT PILE DRIVING OF 11-M WTG MONOPILE FOUNDATIONS (SUMMER) IN SOFT (R3) AND SOFTER (U3) SOIL CONDITIONS, ASSUMING 10 dB ATTENUATION [b]

Species	Soft (R3) soil conditions (in km)					Softer (U3) soil conditions (in km)		
	One pile per day	Two piles per day				One pile per day	Two piles per day	
		Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)	Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)		Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)
LF:								
Fin Whale	0.87	3.02	0.43	2.89	0.90	2.65	0.58	2.48
Minke Whale [a]	0.16	2.78	0.26	2.82	0.02	2.32	0.16	2.27
Humpback Whale [a]	0.14	2.68	0.15	2.79	<0.01	2.26	0.11	2.31
North Atlantic Right Whale [a]	0.20	2.72	0.37	2.67	0.37	2.21	0.28	2.20
Sei Whale [a]	0.31	2.96	0.27	2.91	0.13	2.33	0.23	2.47
MF:								
Atlantic White-sided Dolphin	0	2.75	0	2.73	0	2.24	0	2.23
Atlantic Spotted dolphin	0	0	0	0	0	0	0	0
Common Dolphin	0	2.86	0	2.76	0	2.38	0	2.41
Bottlenose Dolphin	0	2.29	0	2.32	0	1.92	0	1.95
Risso's Dolphin	0	2.86	0	2.79	0	2.41	0	2.40
Long-finned Pilot Whale	0	0	0	0	0	0	0	0
Short-Finned Pilot Whale	0	0	0	0	0	0	0	0
Sperm Whale	0	2.77	0	2.86	0	2.36	0	2.26
HF:								
Harbor Porpoise	0	2.76	0	2.73	0	2.19	0	2.28
PW:								
Gray Seal	0	2.87	0	3.01	0	2.60	<0.01	2.58
Harbor Seal	0	2.91	0	2.75	0	2.50	0	2.36

Note: LF = low-frequency cetaceans; MF = mid-frequency cetaceans; HF = high-frequency cetaceans; PW = pinnipeds in water.
[a] *Species was considered as ''migrating'' in the analysis.*
[b] *The values for U3 were found in Tables I–27 and I–28 in Küsel et al. (2022) (Appendix I). The values for R3 were found in Tables I–35 and I–36 in Küsel et al. (2022) (Appendix I).*

TABLE 18—EXPOSURE RANGES (ER**95%**) TO PTS (SEL**CUM**) AND LEVEL B HARASSMENT THRESHOLDS FROM IMPACT PILE DRIVING OF 11-M WTG MONOPILE FOUNDATIONS (WINTER) IN SOFT (R3) AND SOFTER (U3) SOIL CONDITIONS, ASSUMING 10 dB ATTENUATION [b]

Species	Soft (R3) soil conditions (in km)					Softer (U3) soil conditions (in km)		
	One pile per day	Two piles per day				One pile per day	Two piles per day	
		Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)	Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)		Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)
LF:								
Fin Whale	0.87	3.17	0.48	3.14	0.89	2.71	0.82	2.54
Minke Whale [a]	0.19	3.12	0.28	3.02	0.20	2.50	0.23	2.59
Humpback Whale [a]	0.14	3.04	0.19	2.96	<0.01	2.46	0.11	2.54
North Atlantic Right Whale [a]	0.20	2.93	0.37	2.89	0.49	2.37	0.32	2.38
Sei Whale [a]	0.46	3.09	0.27	3.11	0.13	2.60	0.28	2.56
MF:								
Atlantic White-sided Dolphin	0	2.90	0	2.98	0	2.43	0	2.40
Atlantic Spotted dolphin	0	0	0	0	0	0	0	0
Common Dolphin	0	3.08	0	3.08	0	2.50	0	2.53
Bottlenose Dolphin	0	2.63	0	2.41	0	2.07	0	2.11
Risso's Dolphin	0	3.04	0	3.08	0	2.63	0	2.53
Long-finned Pilot Whale	0	0	0	0	0	0	0	0
Short-Finned Pilot Whale	0	0	0	0	0	0	0	0
Sperm Whale	0	3.10	0	3.04	0	2.60	0	2.38
HF:								
Harbor Porpoise	0	3.07	0	3.09	0	2.53	0	2.51
PW:								
Gray Seal	0	3.25	0	3.25	0	2.70	<0.01	2.67
Harbor Seal	0	3.09	0	3.03	0	2.58	0	2.54

Note: LF = low-frequency cetaceans; MF = mid-frequency cetaceans; HF = high-frequency cetaceans; PW = pinnipeds in water.
[a] Species was considered as ''migrating'' in the analysis.
[b] The values for U3 were found in Tables I–29 and I–30 in Küsel et al. (2022) (Appendix I). The values for R3 were found in Tables I–37 and I–38 in Küsel et al. (2022) (Appendix I).

As shown in the tables above, modeling results indicated that exposure ranges associated with the 9.6-m diameter typical monopile scenario were predominantly greater than for the 11-m diameter monopile scenarios. While larger diameter monopiles can be associated with greater resulting sound fields than smaller diameter piles, in this case, the 11-m diameter monopile scenarios resulted in smaller modeled acoustic ranges than the 9.6-m diameter monopile scenarios likely because the 11-m monopile would only be installed in softer sediments which would require less hammer energy and/or number of hammer strikes for installation than the 9.6-m diameter pile in harder sediments. Hence, the 9.6-m diameter monopile scenario was carried forward to the exposure analysis to be conservative, for all ''typical'' monopiles.

TABLE 19—EXPOSURE RANGES ($ER_{95\%}$) TO LEVEL A HARASSMENT (PTS (SEL_{CUM})) AND LEVEL B HARASSMENT THRESHOLDS FROM IMPACT PILE DRIVING OF 2.5-M DIAMETER OSS FOUNDATIONS (SUMMER), ASSUMING 10 dB ATTENUATION [b]

Species	OSS 1 foundation (in km)					OSS 2 foundation (in km)		
	Two pin piles per day	Three pin piles per day				Two pin piles per day	Three pin piles per day	
		Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)	Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)		Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)
LF:								
Fin Whale	0	1.04	0	1.10	0	1.10	0	0.99
Minke Whale [a]	0	1.00	0	0.99	0	1.01	0	1.01
Humpback Whale [a]	0	1.02	0	1.02	0	0.94	0	0.93
North Atlantic Right Whale [a]	0	0.85	0	0.89	0	1.06	0	1.01
Sei Whale [a]	<0.01	1.08	<0.01	1.04	0	0.94	0	0.91
MF								
Atlantic White-sided Dolphin	0	0.98	0	0.98	0	0.82	0	0.84
Atlantic Spotted dolphin	0	0	0	0	0	0	0	0
Common Dolphin	0	1.03	0	1.03	0	0.96	0	0.96
Bottlenose Dolphin	0	0.82	0	0.81	0	0.72	0	0.74
Risso's Dolphin	0	1.08	0	1.05	0	0.87	0	0.86

TABLE 19—EXPOSURE RANGES ($ER_{95\%}$) TO LEVEL A HARASSMENT (PTS (SEL_{CUM})) AND LEVEL B HARASSMENT THRESHOLDS FROM IMPACT PILE DRIVING OF 2.5-M DIAMETER OSS FOUNDATIONS (SUMMER), ASSUMING 10 dB ATTENUATION [b]—Continued

Species	OSS 1 foundation (in km)					OSS 2 foundation (in km)		
	Two pin piles per day	Three pin piles per day				Two pin piles per day	Three pin piles per day	
		Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)	Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)		Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)
Long-finned Pilot Whale	0	0	0	0	0	0	0	0
Short-Finned Pilot Whale	0	0	0	0	0	0	0	0
Sperm Whale	0	0.88	0	0.95	0	1.03	0	1.02
HF:								
Harbor Porpoise	0	0.95	0	1.02	0	0.94	0	0.92
PW:								
Gray Seal	0	1.15	0	1.14	0	0.78	0	0.77
Harbor Seal	0	1.12	0	0.99	0	1.05	0	1.04

Note: LF = low-frequency cetaceans; MF = mid-frequency cetaceans; HF = high-frequency cetaceans; PW = pinnipeds in water.
[a] Species was considered as ''migrating'' in the analysis.
[b] The values here were found in Tables I–39, I–40, I–43, and I–44 in Küsel et al. (2022) (Appendix I).

TABLE 20—EXPOSURE RANGES ($ER_{95\%}$) TO LEVEL A HARASSMENT (PTS (SEL_{CUM})) AND LEVEL B HARASSMENT THRESHOLDS FROM IMPACT PILE DRIVING OF 2.5-M DIAMETER OSS FOUNDATIONS (WINTER), ASSUMING 10 dB ATTENUATION [b]

Species	OSS 1 foundation (in km)					OSS 2 foundation (in km)		
	Two pin piles per day	Three pin piles per day				Two pin piles per day	Three pin piles per day	
		Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)	Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)		Level A harassment (dB re 1 μPa2·s)	Level B harassment (dB re 1 μPa)
LF:								
Fin Whale	0	1.08	0.18	1.04	0	1.10	0	0.99
Minke Whale [a]	0	1.01	0	1.01	0	1.06	0	1.03
Humpback Whale [a]	0	1.02	0	1.02	0	0.94	0	0.92
North Atlantic Right Whale [a]	0	0.79	0	0.88	0	1.06	0	1.04
Sei Whale [a]	0	1.08	<0.01	1.05	0	0.94	0	0.90
MF:								
Atlantic White-sided Dolphin	0	0.93	0	0.96	0	0.86	0	0.86
Atlantic Spotted dolphin	0	0	0	0	0	0	0	0
Common Dolphin	0	0.96	0	0.86	0	0.96	0	0.96
Bottlenose Dolphin	0	0.85	0	0.84	0	0.80	0	0.74
Risso's Dolphin	0	0.92	0	0.89	0	0.87	0	0.86
Long-finned Pilot Whale	0	0	0	0	0	0	0	0
Short-Finned Pilot Whale	0	0	0	0	0	0	0	0
Sperm Whale	0	0.91	0	0.89	0	1.03	0	1.02
HF:								
Harbor Porpoise	0	0.95	0	0.95	0	0.94	0	0.92
PW:								
Gray Seal	0	1.08	0	1.10	0	0.78	0	0.77
Harbor Seal	0	1.08	0	0.95	0	1.04	0	1.04

Note: LF = low-frequency cetaceans; MF = mid-frequency cetaceans; HF = high-frequency cetaceans; PW = pinnipeds in water.
[a] Species was considered as ''migrating'' in the analysis.
[b] The values here were found in Tables I–41, I–42, I–45, and I–46 in Küsel et al. (2022) (Appendix I).

TABLE 21—MAXIMUM ACOUSTIC RANGES ($R_{95\%}$) TO LEVEL A HARASSMENT (PTS (PEAK)) AND LEVEL B HARASSMENT THRESHOLDS (160 dB SPL) FOR 9.6-M WTG MONOPILE (TYPICAL AND DIFFICULT TO DRIVE SCENARIOS), 11-M WTG MONOPILE, AND 2.5-M OSS PIN PILES (SUMMER AND WINTER), ASSUMING 10-dB ATTENUATION

Foundation type	Modeled maximum impact hammer energy (kJ)	Marine mammal group	Level A harassment Pk (in km)		Level B harassment 160 dB SPL (in km)	
			$R_{95\%}$ (summer)	$R_{95\%}$ (winter)	$R_{95\%}$ (summer)	$R_{95\%}$ (winter)
WTG—9.6-m monopile	2,300 kJ (5,500 kJ)	LF: MF: HF:	–[b] (–[b]) –[b] (–[b]) 0.10[c] (0.15[d])	–[b] (–[b]) –[b] (–[b]) 0.11[c] (0.17[d])	3.51[g] (5.05[j])	3.77[g] (5.49[j])

TABLE 21—MAXIMUM ACOUSTIC RANGES ($R_{95\%}$) TO LEVEL A HARASSMENT (PTS (PEAK)) AND LEVEL B HARASSMENT THRESHOLDS (160 dB SPL) FOR 9.6-M WTG MONOPILE (TYPICAL AND DIFFICULT TO DRIVE SCENARIOS), 11-M WTG MONOPILE, AND 2.5-M OSS PIN PILES (SUMMER AND WINTER), ASSUMING 10-dB ATTENUATION—Continued

Foundation type	Modeled maximum impact hammer energy (kJ)	Marine mammal group	Level A harassment Pk (in km)		Level B harassment 160 dB SPL (in km)	
			$R_{95\%}$ (summer)	$R_{95\%}$ (winter)	$R_{95\%}$ (summer)	$R_{95\%}$ (winter)
WTG—11-m monopiles	2,500 kJ	PW:	– [b] (– [b])	– [b] (– [b])	[h] 3.64	[h] 3.92
		LF:	– [b]	– [b]		
		MF:	– [b]	– [b]		
		HF:	[e] 0.11	0.12 [e]		
OSS—2.5-m pin pile [a]	3,200 kJ	PW:	– [b]	– [b]		
		LF:	– [b]	– [b]	[i] 1.19	[i] 1.17
		MF:	– [b]	– [b]		
		HF:	[f] 0.01	[f] 0.01		
		PW:	– [b]	– [b]		

LF = low-frequency cetaceans; MF = mid-frequency cetaceans; HF = high-frequency cetaceans; PW = pinnipeds in water.
[a] Assumes a 2dB post-piling shift.
[b] A dash (–) indicates that the threshold was not exceeded.
[c] Found in Table H–11 in Küsel et al. (2022) (Appendix H).
[d] Found in Table H–47 in Küsel et al. (2022) (Appendix H).
[e] Found in Table H–31 in Küsel et al. (2022) (Appendix H).
[f] Found in Table H–51 in Küsel et al. (2022) (Appendix H).
[g] Found in Table H–343 in Küsel et al. (2022) (Appendix H).
[h] Found in Table H–439 in Küsel et al. (2022) (Appendix H).
[i] Found in Table H–495 in Küsel et al. (2022) (Appendix H).
[j] Found in Table H–479 in Küsel et al. (2022) (Appendix H).

Exposure estimates were calculated for marine mammals based on proposed construction schedules and resulting density calculations. As described above, Empire Wind applied densities within grid cells within the lease area and extending 10 km beyond the lease area. The resulting monthly densities used are provided in Table 22.

TABLE 22—MEAN MONTHLY MARINE MAMMAL DENSITY ESTIMATES WITHIN A 10 KM BUFFER AROUND OCS–A 0512 LEASE AREA

Species	Monthly densities (animals/100 km^2) [1]	Annual mean											
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Fin whale	0.172	0.139	0.113	0.137	0.174	0.171	0.157	0.1	0.055	0.04	0.038	0.13	0.119
Minke whale	0.071	0.06	0.072	0.936	1.485	0.803	0.198	0.107	0.066	0.111	0.026	0.059	0.333
Humpback whale	0.091	0.061	0.076	0.119	0.133	0.113	0.03	0.022	0.054	0.101	0.13	0.113	0.087
North Atlantic right whale	0.1	0.116	0.115	0.088	0.025	0.006	0.003	0.003	0.004	0.008	0.016	0.05	0.045
Sei whale	0.029	0.016	0.033	0.071	0.055	0.011	0.002	0.002	0.005	0.013	0.037	0.049	0.027
Atlantic white-sided dolphin	0.642	0.399	0.356	0.846	1.373	1.237	0.117	0.049	0.279	0.892	0.863	0.99	0.67
Atlantic spotted dolphin	0.001	0	0.001	0.003	0.01	0.019	0.033	0.072	0.177	0.26	0.133	0.013	0.06
Short-beaked common dolphin	5.664	1.852	1.246	2.457	3.474	2.835	1.566	1.917	1.623	3.495	7.244	9.177	3.546
Bottlenose dolphin	0.851	0.247	0.205	0.629	2.005	3.232	3.534	2.953	2.552	2.898	2.772	2.52	2.033
Risso's dolphin	0.042	0.005	0.003	0.021	0.034	0.014	0.014	0.007	0.008	0.01	0.056	0.186	0.033
Long-finned pilot whale	0.028	0.028	0.028	0.028	0.028	0.028	0.028	0.028	0.028	0.028	0.028	0.028	0.028
Short-finned pilot whale	0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021	0.021
Sperm whale	0.007	0.002	0.002	0.004	0.005	0.011	0.011	0.015	0.003	0	0.008	0.005	0.006
Harbor porpoise	5.469	5.73	5.916	7.066	2.421	0.347	0.435	0.215	0.13	0.144	0.342	3.757	2.664
Gray seals	4.762	4.505	3.689	4.337	5.968	1.093	0.071	0.049	0.104	0.684	1.625	4.407	2.608
Harbor seals	10.698	10.121	8.289	9.745	13.40	2.456	0.16	0.11	0.233	1.537	3.651	9.902	5.859

[1] Density estimates are from habitat-based density modeling of the entire Atlantic Exclusive Economic Zone (Roberts and Halpin, 2022).

Construction schedules (piles per day and number of days of pile driving per month) are an input into exposure calculations. However, they are difficult to predict because of factors like first year weather and installation variation related to drivability. Because it is hard to anticipate the installation schedule, a conservative approach was used to generate potential installation schedules for animal exposure calculation. Empire Wind assumed that a maximum of 24 monopiles could be installed per month, with a maximum of 96 WTG monopiles and two OSS foundations installed in the first year and the remaining 51 WTG monopile foundations installed in year 2. In Year 1, Empire Wind assumed that 24 monopiles would be installed in the four highest density months for each species during the May to December period and the two OSSs would be installed in the highest and second highest density months. Empire Wind also assumed that all 17 difficult-to-drive piles would be installed in the first year but the distribution would be spread relatively evenly among the four highest months (*i.e.,* four piles per month except the highest density month which assumed 5 difficult-to-drive piles for a total of 17 piles). In the second year, 24 monopiles would be installed in the two highest density months and the remaining 3 monopiles would be installed in the third highest density month. This approach is reflected in Table 23. Thus, each species was presumed to be exposed to the

maximum amount of pile driving based on their monthly densities.

TABLE 23—MOST CONSERVATIVE CONSTRUCTION SCHEDULE FOR ESTIMATING LEVEL B HARASSMENT

[One monopile per day/two pin piles per day] [1]

Foundation type	Year 1				Year 2			
	Monthly density				Monthly density			
	Highest	Second	Third	Fourth	Highest	Second	Third	Fourth
WTG monopile—typical ...	19	20	20	20	24	24	3	0
WTG monopile—difficult ..	5	4	4	4	0	0	0	0
OSS 1 pin pile	0	6	0	0	0	0	0	0
OSS 2 pin pile	6	0	0	0	0	0	0	0
Total # of piles	30	30	24	24	24	24	3	0

[1] Maximum number of piles to be driven per month for each foundation type in each of the four highest density months for each species during May To December Period.

As described above, Empire Wind conducted exposure modeling to estimate potential exposures by Level A harassment and Level B harassment incidental to installation of WTG and OSS foundations. Tables 24 and 25 show calculated exposures for 2025 and 2026 respectively based on the methodologies and assumptions described above.

TABLE 24—CALCULATED EXPOSURES BY LEVEL A HARASSMENT AND LEVEL B HARASSMENT RESULTING FROM MONOPILE AND OSS FOUNDATION INSTALLATION IMPACT PILE DRIVING

[Year 1]

Hearing group	Species	Calculated take		Calculated take	Requested take	Requested take
		Level A harassment		Level B harassment	Level A harassment	Level B harassment
		LE	LpK	Lp[a]		
LF	Fin [b]	1.15	0	8.78	1	[c] 133
	Minke	3.72	0	65.05	4	65
	Humpback	0.36	<0.01	8.12	0	[c] 60
	North Atlantic Right Whale [b]	0.01	0	2.36	0	[f] 11
	Sei [b]	0.27	<0.01	2.78	0	3
MF	Atlantic white-sided dolphin	0	0	116.00	0	[f] 416
	Atlantic spotted dolphin	0	0	0	0	[d] 45
	Short-beaked common dolphin	0	0	902.19	0	[d] 3,600
	Bottlenose dolphin	0	0	226.02	0	[d] 1,800
	Risso's dolphin	0	0	5.96	0	[d] 100
	Pilot whales	0	0	0	0	[c] 161
	Sperm whale [b]	0	0	0.56	0	[d] 3
HF	Harbor porpoise	0	0.09	133.77	0	134
PW	Gray seal	0.17	0	162.46	0	162
	Harbor seal	0	0	356.44	0	356

Note: LF = low-frequency cetaceans; MF = mid-frequency cetaceans; HF = high-frequency cetaceans; PW = pinnipeds in water.

[a] NOAA Fisheries (2005).

[b] Listed as Endangered under the ESA.

[c] Requested take adjusted based on PSO sighting data from 2018–2021 (A.I.S., 2019; Alpine Ocean Seismic Survey, 2018; Gardline, 2021a,b; Geoquip Marine, 2021; Marine Ventures International, 2021; RPS, 2021; Smultea Environmental Sciences, 2019, 2020, 2021); 0.5 humpback whales per day, 1.11 fin whales per day, 1.34 pilot whales per day.

[d] Requested take adjusted based on 1 group size per year as follows: 3 sperm whales (Barkaszi *et al.,* 2019), 45 Atlantic spotted dolphins (Kenney and Vigness-Raposa, 2010), and 100 Risso's dolphins (Jefferson *et al.,* 2015).

[e] Requested take adjusted by 1 group size per day as follows: 30 short-beaked common dolphins (Reeves *et al.,* 2002), 15 bottlenose dolphins (Jefferson *et al.,* 2015).

[f] Requested take adjusted by 1 group size per month of 52 Atlantic white-sided dolphins (Jefferson *et al.,* 2015) and 1 (monthly density < 0.01) or 2 (monthly density > 0.01) of North Atlantic right whales (Roberts and Halpin, 2022).

TABLE 25—CALCULATED EXPOSURES BY LEVEL A AND LEVEL B HARASSMENT RESULTING FROM MONOPILE AND OSS FOUNDATION INSTALLATION IMPACT PILE DRIVING

[Year 2]

Hearing group	Species	Calculated take		Calculated take	Requested take	Requested take
		Level A harassment		Level B harassment	Level A harassment	Level B harassment
		LE	LpK	Lp [a]		
LF	Fin [b]	0.52	0	4.00	1	[c] 57
	Minke	2.18	0	47.73	2	48
	Humpback	0.14	0	3.82	0	[c] 26
	North Atlantic Right Whale [b]	0.05	0	1.57	[g] 0	[f] 11
	Sei [b]	0.16	0	1.66	0	2
MF	Atlantic white-sided dolphin	0	0	59.23	0	[f] 416
	Atlantic spotted dolphin	0	0	0	0	[d] 45
	Short-beaked common dolphin	0	0	560.75	0	[e] 1,530
	Bottlenose dolphin	0	0	110.28	0	[e] 765
	Risso's dolphin	0	0	4.09	0	[d] 100
	pilot whales	0	0	0	0	[c] 68
	Sperm whale [b]	0	0	0.29	0	[d] 3
HF	Harbor porpoise	0	0	98.43	0	98
PW	Gray seal	0	0	111.95	0	112
	Harbor seal	0	0	229.89	0	230

Note: LF = low-frequency cetaceans; MF = mid-frequency cetaceans; HF = high-frequency cetaceans; PW = pinnipeds in water.

[a] NOAA Fisheries (2005).

[b] Listed as Endangered under the ESA.

[c] Requested take adjusted based on PSO sighting data from 2018–2021 (A.I.S., 2019; Alpine Ocean Seismic Survey, 2018; Gardline, 2021a,b; Geoquip Marine, 2021; Marine Ventures International, 2021; RPS, 2021; Smultea Environmental Sciences, 2019, 2020, 2021); 0.5 humpback whales per day, 1.11 fin whales per day, 1.34 pilot whales per day.

[d] Requested take adjusted based on 1 group size per year as follows: 3 sperm whales (Barkaszi *et al.,* 2019), 45 Atlantic spotted dolphins (Kenney and Vigness-Raposa, 2010), and 100 Risso's dolphins (Jefferson *et al.,* 2015).

[e] Requested take adjusted by 1 group size per day as follows: 30 short-beaked common dolphins (Reeves *et al.,* 2002), 15 bottlenose dolphins (Jefferson *et al.,* 2015).

[f] Requested take adjusted by 1 group size per month of 52 Atlantic white-sided dolphins (Jefferson *et al.,* 2015) and 1 (when monthly density < 0.01) or 2 (when monthly density > 0.01) of North Atlantic right whales (Roberts and Halpin, 2022).

[g] Enhanced mitigation measures for NARWs would avoid take by Level A harassment.

A review of Empire Wind's PSO sightings data ranging from 2018–2021 for the Project Area indicated that exposure estimates based on the exposure modeling methodology above were likely an underestimate for humpback whales, fin whales, and pilot whales (A.I.S. 2019; Alpine Ocean Seismic Survey 2018; Gardline 2021a,b; Geoquip Marine 2021; Marine Ventures International 2021; RPS 2021; Smultea Environmental Sciences 2019, 2020, 2021). PSO sightings data were analyzed to determine the average number of each species sighted per day during high-resolution geophysical (HRG) surveys in the Project Area. Results indicated that the highest average sightings-per-day rate among PSO reports from 2018–2021 was 0.5 humpback whales (Smultea Environmental Sciences 2019), 1.11 fin whales (Alpine Ocean Seismic Survey 2018), and 1.34 pilot whales (Geoquip Marine 2021) sighted per day. These highest daily averages per day were then multiplied by the maximum potential number of days of pile driving associated with wind turbine and offshore substation foundation installation for these species. In the event that one monopile or one pin pile is installed per day, up to 120 days of pile driving (*i.e.,* 96 days of monopile installation and 24 days of pin pile installation) could occur in 2025 and up to 51 days of pile driving (*i.e.,* 51 days of monopile installation) could occur in 2026.

At a rate of 0.5 humpback whales per day, 120 days of pile driving in 2025 resulted in an estimated 60 takes by level B harassment in that year, and 51 days of pile driving in 2026 resulted in an estimated 25.5 (rounded to 26) takes by level B harassment in that year. Since these alternate estimates of take by Level B harassment for humpback whales are higher than numbers calculated based on the exposure analysis method described above. To be conservative, Empire Wind requested, and NMFS is proposing to authorize, take by Level B harassment of 60 humpback whales in 2025 and 26 whales in 2026 based on this alternate take calculation method.

At a rate of 1.11 fin whales per day, 120 days of pile driving in 2025 resulted in an estimated 133 takes by level B harassment in that year, and 51 days of pile driving in 2026 resulted in an estimated 56.6 (rounded to 57) takes by level B harassment in that year. Since these alternate estimates of take by Level B harassment for fin whales are higher than numbers calculated based on the exposure analysis method described above, Empire Wind has requested, and NMFS is proposing to authorize, take by Level B harassment for fin whales (133 in 2025; 57 in 2026) based on this alternate take calculation method.

At a rate of 1.34 pilot whales per day, 120 days of pile driving in 2025 resulted in an estimated 160.7 (rounded to 161) takes by level B harassment in that year, and 51 days of pile driving in 2026 resulted in an estimated 68 takes by level B harassment in that year. Since these alternate estimates of take by Level B harassment for pilot whales are higher than numbers calculated based on the exposure analysis method. Empire Wind has requested take by Level B harassment for pilot whales based on this alternate take calculation method. NMFS concurs with this assessment and is proposing to authorize the same number of takes by Level B harassment for 2025 (161) and 2026 (68).

For certain species for which the exposure modeling methodology described previously above may result in potential underestimates of take and Empire Wind's PSO sightings data were relatively low, adjustments to the take request were made based on the best available information on marine mammal group sizes to ensure conservatism. For species considered rare but still have the potential for occurrence in the Project Area, requested take by Level B harassment was adjusted to one group size per year. NMFS concurs with this assessment and is proposing to authorize take by Level B harassment of 3 sperm whales per year in 2025 and 2026 (Barkaszi *et al.* 2019); 45 Atlantic spotted dolphins per year in 2025 and 2026 (Kenney and Vigness-Raposa 2010); and 100 Risso's dolphins per year in 2025 and 2026 (100 individuals; Jefferson *et al.* 2015).

For species considered relatively common in the Project Area, requested take by Level B harassment was adjusted to one group size per month. These include Atlantic white-sided dolphins (52 individuals, Jefferson *et al.* 2015) and North Atlantic right whales. The group size determination for North Atlantic right whales was derived based on consultation with NOAA Fisheries. A group size of 1 animal was used for months with mean monthly densities less than 0.01, while a group size of 2 animals, reflective of the potential for a mother and calf, was used for months with mean monthly densities greater than 0.01 based on the Roberts and Halpin 2022 predictive densities. For the months when pile driving activities may occur (May through December), those criteria result in a group size of 1 animal for the months of June through October and 2 animals for the months of May, November, and December. This group size determination is intended to account for the potential presence of mother-calf pairs. Therefore, Empire Wind requested and NMFS is proposing to authorize 11 takes of North Atlantic right whale by Level B harassment per year in 2025 and 2026 and 416 takes of Atlantic white-sided dolphin by Level B harassment per year in 2025 and 2026.

For species considered common in the Project Area, requested takes by Level B harassment was adjusted to one group size per day. These include short-beaked common dolphins (30 individuals, Reeves *et al.* 2002), and bottlenose dolphins (15 individuals, Jefferson *et al.* 2015). Empire Wind has requested, and NMFS is proposing to authorize, 3,600 and 1,530 takes of short-beaked common dolphins by Level B harassment per year in 2025 and 2026. Empire Wind has also requested, and NMFS is proposing to authorize, 1,800 and 765 takes of bottlenose dolphins by Level B harassment per year in 2025 and 2026 respectively.

Cable Landfall Construction

As described in the Description of the Specified Activities section above, Empire Wind is considering two options to facilitate the transition of the offshore export cable to the onshore cable: (1) a cofferdam or (2) a casing pipe with goal posts. The general methodologies used to estimate take of marine mammals incidental to cable landfall construction activities is described above. Here we present details regarding those methodologies specific to these activities followed by the take NMFS proposes to authorize incidental to cable landfall construction.

Cofferdam Vibratory Driving—As many as two temporary cofferdams may be installed for EW 1 and as many as three temporary cofferdams may be installed for EW 2. Empire Wind assumed a source level of 195 dB SEL and 195 dB rms at 10 m (Schultz-von Glahn *et al.* 2006). As described above, propagation modeling was conducted using dBSea. Resulting distances to NMFS harassment isopleths for cofferdam installation are provided in Table 26 (note that very shallow water depths (3–4 m) at the cofferdam pile driving site is responsible for the limited acoustic propagation of vibratory driving noise.

TABLE 26—DISTANCES (METERS) TO THE LEVEL A AND LEVEL B HARASSMENT THRESHOLD ISOPLETHS FOR COFFERDAM VIBRATORY PILE DRIVING AND ESTIMATED AREA OF LEVEL B HARASSMENT ZONE

Location	PTS onset by hearing group (m)				Behavioral harassment	Area within estimated Level B harassment zone (km^2)
	LF (199 $L_{E, 24\ hr}$)	MF (198 $L_{E, 24\ hr}$)	HF (173 $L_{E, 24\ hr}$)	PW (201 $L_{E, 24\ hr}$)	ALL (120 SPL RMS)	
EW 1	122	0	44	62	1,985	2.679
EW 2	13	0	12	11	1,535	1.672

Note: LF = low-frequency cetaceans; MF = mid-frequency cetaceans; HF = high-frequency cetaceans; PW = pinnipeds in water.

To estimate take, Empire Wind averaged the maximum monthly densities by season as reported by Roberts and Halpin (2002): spring (March through May), summer (June through August), fall (September through November), and winter (December through February). To be conservative, the maximum average seasonal density for each species was then carried forward in the take calculations.

Empire Wind considered the ensonified areas and density estimates to calculate potential exposures (Table 27). However, for some species, group size data demonstrate that the density-based exposure calculations underestimate the potential for take. Hence, the amount of requested take varies from exposure estimates (Table 27). Given the noise from cofferdam installation would not extend beyond the 20-m isobath, where the coastal stock predominates, it is expected that only the coastal stock of bottlenose dolphins is likely to be taken by this activity. As the density models do not account for group size and the resulting calculated exposures were very small, the predicted take was increased to account for the exposure of one average-sized group per day each of bottlenose and common dolphins.

Due to the presence of several seal haul outs, Empire Wind determined the Roberts and Halpin (2022) density data likely underestimated potential seal occurrence; therefore, 10 Level B harassment seal takes per day were estimated, based on pinniped observations in New York City between 2011 and 2017 (Woo and Biolsi, 2018). For pinnipeds, because the seasonality of and habitat use by gray seals roughly overlaps with harbor seals, and the density data as presented by Roberts and Halpin (2022) do not differentiate between pinniped species, the estimated takes were split evenly between harbor and gray seals (Table 27). Note that any

species in Table 27 where the calculated take was less than 0.5 animals, the proposed take was reduced to zero.

TABLE 27—AVERAGE MARINE MAMMAL DENSITIES, EXPOSURE ESTIMATES AND AMOUNT OF PROPOSED TAKE (IN PARENTHESES), BY LEVEL B HARASSMENT, FROM COFFERDAM VIBRATORY PILE DRIVING [f]

Species	EW 1 cofferdams (2024)		EW 2 cofferdams (2024–2025) totals		Total proposed take by Level B harassment
	Average seasonal density [a] (No./100 km^2)	Calculated take (proposed take) by Level B harassment	Average seasonal density [a] (No/.100 km^2)	Calculated take (proposed take) by Level B harassment	
North Atlantic Right Whale	0.073	0.020 (0)	0.073	0.020 (0)	0
Humpback Whale	0.099	0.030 (0)	0.099	0.030 (0)	0
Fin Whale	0.097	0.030 (0)	0.097	0.030 (0)	0
Sei Whale	0.030	0.010 (0)	0.030	0.010 (0)	0
Sperm Whale	0.006	0.000 (0)	0.006	0.000 (0)	.....
Minke Whale	0.526	0.170 (0)	0.526	0.160 (0)	0
Bottlenose dolphin (Western N.A. Northern Migratory Coastal Stock) [b]	6.299	2.030 (180)	6.299	1.900 (270)	450
Atlantic Spotted Dolphin	0.058	0.020 (0)	0.058	0.020 (0)	0
Short-beaked common dolphin [c]	2.837	0.910 (360)	2.837	0.850 (540)	900
Atlantic White-sided Dolphin	0.469	0.150 (0)	0.469	0.140 (0)	0
Risso's dolphin	0.034	0.010 (0)	0.034	0.010 (0)	0
Pilot whales spp. [d]	0.019	0.010 (0)	0.019	0.010 (0)	0
Harbor porpoise	3.177	1.020 (1)	3.177	0.960 (1)	2
Harbor seal [e]	13.673	2.200 (60)	13.673	2.060 (90)	150
Gray seal [e]	13.673	2.200 (60)	13.673	2.060 (90)	150

[a] Cetacean density values from Duke University (Roberts and Halpin, 2022).
[b] Bottlenose dolphin density values from Duke University (Roberts and Halpin, 2022) reported as ''bottlenose'' and not identified to stock. Given the noise from cofferdam installation would not extend beyond the 20 m isobath, where the coastal stock predominates, it is expected that all estimated takes by Level B harassment of bottlenose dolphins from cofferdam installation will accrue to the coastal stock. As Roberts and Halpin does not account for group size, the requested and proposed take was adjusted to account for one group size, 15 individuals (Jefferson *et al.,* 2015) per day (18 days) of bottlenose.
[c] As Roberts *et al.* does not account for group size, the estimated take was adjusted to account for one group size, 30 individuals (Reeves *et al.,* 2002) per day of each common dolphins.
[d] Pilot whale density values from Duke University (Roberts and Halpin, 2022) reported as ''*Globicephala spp.*'' and not species-specific.
[e] Pinniped density values from Duke University (Roberts and Halpin, 2022) are reported as ''seals'' and are not species-specific, therefore, 50 percent of expected takes by Level B harassment are expected to accrue to harbor seals and 50 percent to gray seals. Due to the presence of several seal haul outs in the area, requested and proposed level B harassment seal takes were calculated by estimating 10 individuals per day (9 days) (Woo and Biolsi, 2018), divided evenly between harbor seals and gray seals.
[f] Data not available for harp seals for which take was requested and is being proposed.

Casing Pipe and Goal Post Impact Pile Driving—Empire Wind estimated distances to NMFS thresholds using the optional User Spreadsheet tool. The casing pipe may be installed using a pneumatic hammer, hence the number of strikes considered is high. The goal posts would be installed with a traditional impact hammer. Parameters input into the user spreadsheet for casing pipe and goal post installation and removal are provided in Table 28.

TABLE 28—ESTIMATED SOURCE LEVELS (AT 10 m) AND INSTALLATION RATES FOR CASING PIPE AND GOAL POST INSTALLATION

Structure	dB SEL	dB rms	#strikes per pile	Piles per day	Transmission loss
Casing pipe	166	182	43,200	1	15 log.
Goal Posts	174	184	2,000	2	

Using NMFS' Multi-Species Calculator Tool and the assumptions provided above, Empire Wind calculated distances to PTS and Level B harassment thresholds from casing pipe and goal post installation. The resulting distances to NMFS thresholds are provided in Table 29.

TABLE 29—DISTANCES (METERS) TO THE LEVEL A AND LEVEL B HARASSMENT THRESHOLD ISOPLETH DISTANCES FOR CASING PIPE AND GOAL POST IMPACT PILE DRIVING

Scenario	PTS onset by hearing group (m)								Behavioral harassment SPL (m)
	LF		MF		HF		PW		
	peak	SEL	peak	SEL	peak	SEL	peak	SEL	
Pile	219	183	230	185	202	155	218	185	160
42" casing pipe	0.3	904.5	0.1	32.2	4.6	1,077.4	0.4	484	293
12-inch steel goal post	0	632.1	0	22.5	7.4	752.9	0	338.3	398.1

Note: LF = low-frequency cetaceans; MF = mid-frequency cetaceans; HF = high-frequency cetaceans; PW = pinnipeds in water.

As described above, either cofferdams or goal post and casing pipe installation may occur as part of cable landfall activities, but not both. For goal post installation, two hours per goal post (two piles), for 3 goal posts (6 piles) per HDD, for a total of 18 piles and 36 total hours of pile driving are anticipated. For cofferdams, there is 1 hour per day for 6 days (installation and removal) per cofferdam for a total of 18 hours pile driving anticipated. While modeled distances to the Level A harassment threshold for goal post pile driving were larger than for cofferdam vibratory driving based on the SEL_{cum} metric, it should be noted that modeled distances based on the SEL_{cum} metric are based on the assumption that an individual animal remains at that distance for the entire duration of pile driving in order to incur PTS. This is not considered realistic as marine mammals are highly mobile. As modeled distances to the Level B harassment threshold and zones of influence for Level B harassment were orders of magnitude larger for cofferdam vibratory driving compared to goal post pile driving (compare Table 26 to Table 29), the amount of take resulting from cofferdam vibratory driving activities were determined to be greater than that of the alternative goal post and casing pipe scenario. Therefore, to be conservative the cofferdam scenario was carried forward for the analysis of potential takes by harassment from cable landfall activities. As such, goal post pile driving is not analyzed further in this application.

Since the acoustic impact of the marina work was minimal and densities are not available for the specific inshore region where the activity will occur, potential take by harassment for marine mammals could not be calculated. Instead, to be conservative, 10 takes by Level B harassment of seals per day were estimated (Woo and Biolsi 2018), which were split evenly between harbor and gray seals.

Estimates of take are computed according to the following formula as provided by NOAA Fisheries (Personal Communication, November 24, 2015):

$$\text{Estimated Take} = D \times ZOI \times (d)$$

Where:

D = average highest species density (number per km2)

ZOI = maximum ensonified area to MMPA threshold for impulsive noise (160 dB RMS 90 percent re 1 µPa)

d = number of days

The area ensonified to the Level B harassment threshold, as well as the projected duration of cofferdam installation and removal at each respective vibratory pile driving location, was then used to produce the results of take calculations provided in Table 27. It is expected to take three days to install and three days to remove each cofferdam. Therefore six days of vibratory pile driving/removal at each location were included. It should be noted that calculations do not take into account whether a single animal is harassed multiple times or whether each exposure is a different animal. Therefore, the numbers in Table 28 are the maximum number of animals that may be exposed to sound above relevant thresholds during vibratory pile driving (*i.e.,* Empire Wind assumes that each exposure event is a different animal).

For cofferdam exposure estimates, the Robert and Halpin (2022) densities were overlaid on the modeled Level B harassment zones to estimate exposures. The maximum monthly densities as reported by Roberts and Halpin (2022) were averaged by season over the duration of cofferdam installation/removal (spring (March through May), summer (June through August), fall (September through November), and winter (December through February)). To be conservative, the maximum average seasonal density for each species was then carried forward in the take calculations. Bottlenose dolphin density values from Duke University (Roberts and Halpin, 2022) are reported as ''bottlenose'' and not identified to stock. Given the noise from cofferdam installation would not extend beyond the 20-m isobath, where the coastal stock predominates, it is expected that all estimated takes by Level B harassment of bottlenose dolphins harassment from cofferdam installation will accrue to the coastal stock. As the density models do not account for group size, the estimated take was adjusted to account for one group size per day of each of bottlenose (group size of 15) and common dolphins (group size of 30) as shown in Table 27.

Marina Activities

Pile driving at the onshore substation C constitutes a small amount of work. Empire Wind assumed source levels during pile driving sheet piles at onshore substation C would be similar to that during installation of the cofferdams for cable landfall construction. Since densities are not available for the specific inshore region where the activity will occur, potential take by harassment for marine mammals using density could not be calculated. Instead, to be conservative, 10 takes by Level B harassment of seals per day (49 days) were estimated based on pinniped observations in New York City between 2011 and 2017 (Woo and Biolsi, 2018), which were split evenly between harbor and gray seals (Table 31). Similarly, the requested and proposed take of bottlenose dolphins was adjusted to account for one group size, 15 individuals (Jefferson *et al.,* 2015) per day for 49 days.

TABLE 30—DISTANCES (METERS) TO THE LEVEL A AND LEVEL B HARASSMENT THRESHOLD ISOPLETH DISTANCES FOR VIBRATORY DRIVING AT ONSHORE SUBSTATION C LOCATION MARINA

Location	PTS onset by hearing group				Behavioral response
	LF ($199\ L_{E,\ 24hr}$)	MF ($199\ L_{E,\ 24hr}$)	HF ($199\ L_{E,\ 24hr}$)	PHOCID ($199\ L_{E,\ 24hr}$)	All (120 SPL RMS)
Marina Bulkhead Work (Sheetpile installation)	43.2	3.8	63.8	26.2	1,000
Marina Berthing Pile Removal	43.5	3.9	64.3	26.5	1,600

TABLE 31—AVERAGE MARINE MAMMAL DENSITIES USED IN EXPOSURE ESTIMATES AND ESTIMATES OF POTENTIAL TAKES BY LEVEL B HARASSMENT FROM MARINA PILE DRIVING

Species	Marina work (2024)	
	Average seasonal density[a] (No./100 km^2)	Proposed take by level B harassment
Bottlenose dolphin (Western N.A. Northern Migratory Coastal Stock)[b]	6.299	735
Harbor seal[c]	13.673	245
Gray seal[c]	13.673	245

[a] Cetacean density values from Duke University (Roberts and Halpin, 2022).
[b] Bottlenose dolphin density values from Duke University (Roberts and Halpin, 2022) reported as ''bottlenose'' and not identified to stock. Given the noise from cofferdam installation would not extend beyond the 20 m isobath, where the coastal stock predominates, it is expected that all estimated takes by Level B harassment of bottlenose dolphins from cofferdam installation will accrue to the coastal stock. As Roberts and Halpin (2022) does not account for group size, the requested take was adjusted to account for one group size, 15 individuals (Jefferson *et al.,* 2015) per day of bottlenose.
[c] Pinniped density values from Duke University (Roberts and Halpin, 2022) are reported as ''seals'' and are not species-specific, therefore, 50 percent of expected takes by Level B harassment are expected to accrue to harbor seals and 50 percent to gray seals.

HRG Survey Activities

Empire Wind's proposed HRG survey activity includes the use of non-impulsive sources (*i.e.,* CHIRP SBPs) that have the potential to harass marine mammals. Of the list of equipment proposed in Table 2 (see Detailed Description of Specified Activities), USBL, MBES, SSS, and the Innomar SBP were removed from further analysis due to either the extremely low likelihood of the equipment resulting in marine mammal harassment (*i.e.,* USBL, MBES, select SSS) or due to negligible calculated isopleth distances corresponding to the Level B harassment threshold (<2 m) (*i.e.,* select SSS and Innomar SBP). No boomers or sparkers would be used.

Authorized takes would be by Level B harassment only in the form of disruption of behavioral patterns for individual marine mammals resulting from exposure to noise from certain HRG acoustic sources. Based primarily on the characteristics of the signals produced by the acoustic sources planned for use, Level A harassment is neither anticipated, even absent mitigation, nor proposed to be authorized. Therefore, the potential for Level A harassment is not evaluated further in this document. Empire Wind did not request, and NMFS is not proposing to authorize, take by Level A harassment incidental to HRG surveys. No serious injury or mortality is anticipated to result from HRG survey activities.

Specific to HRG surveys, in order to better consider the narrower and directional beams of the sources, NMFS has developed a tool for determining the sound pressure level (SPLrms) at the 160 dB isopleth for the purposes of estimating the extent of Level B harassment isopleths associated with HRG survey equipment (NMFS, 2020). This methodology incorporates frequency-dependent absorption and some directionality to refine estimated ensonified zones. Empire Wind used NMFS' methodology with additional modifications to incorporate a seawater absorption formula and account for energy emitted outside of the primary beam of the source. For sources that operate with different beam widths, the maximum beam width was used, and the lowest frequency of the source was used when calculating the frequency-dependent absorption coefficient.

The isopleth distances corresponding to the Level B harassment threshold for each type of HRG equipment with the potential to result in harassment of marine mammals were calculated per NOAA Fisheries' Interim Recommendation for Sound Source Level and Propagation Analysis for High Resolution Geophysical Sources. The distances to the 160 dB RMS re 1 µPa isopleth for Level B harassment are presented in Table 31. Please refer to Section 6.3.2 of the LOA application for a full description of the methodology and formulas used to calculate distances to the Level B harassment threshold.

TABLE 31—ISOPLETH DISTANCES CORRESPONDING TO THE LEVEL B HARASSMENT THRESHOLD FOR HRG EQUIPMENT

HRG survey equipment	Source level (SL_{RMS}) (dB re 1µPa)	Lateral distance (m) to Level B harassment threshold
Edgetech DW106	194	50.00

TABLE 31—ISOPLETH DISTANCES CORRESPONDING TO THE LEVEL B HARASSMENT THRESHOLD FOR HRG EQUIPMENT—Continued

HRG survey equipment	Source level (SL_{RMS}) (dB re 1μPa)	Lateral distance (m) to Level B harassment threshold
Edgetech 424	180	8.75
Teledyne Benthos Chirp III—TTV 170	219	50.05

The survey activities that have the potential to result in Level B harassment (160 $dB_{RMS90\ percent}$ re 1 μPa) include the noise produced by EdgeTech DW106, EdgeTech 424, or Teledyne Benthos Chirp III (see Table 31), of which the Teledyne Benthos Chirp III results in the greatest calculated distance to the Level B harassment criteria at 50.05 m (164 ft). Therefore, to be conservative, Empire Wind has applied the estimated distance of 50.05 m (164 ft) to the 160 $dB_{RMS90\ percent}$ re 1 μPa Level B harassment criteria as the basis for determining potential take from all HRG sources.

The basis for the take estimate is the number of marine mammals that would be exposed to sound levels in excess of the Level B harassment threshold (160 dB). Typically, this is determined by estimating an ensonified area for the activity, by calculating the area associated with the isopleth distance corresponding to the Level B harassment threshold. This area is then multiplied by marine mammal density estimates in the project area and then corrected for seasonal use by marine mammals, seasonal duration of Project-specific noise-generating activities, and estimated duration of individual activities when the maximum noise-generating activities are intermittent or occasional.

The estimated distance of the daily vessel track line was determined using the estimated average speed of the vessel and the 24-hour operational period within each of the corresponding survey segments. All noise-producing survey equipment is assumed to be operated concurrently. Using the distance of 50.05 m (164 ft) to the 160 $dB_{RMS90\ percent}$ re 1 μPa Level B harassment isopleth (Table 31), the estimated daily vessel track of approximately 177.792 km (110.475 mi) for 24-hour operations, inclusive of an additional circular area to account for radial distance at the start and end of a 24-hour cycle, estimates of the total area ensonified to the Level B harassment threshold per day of HRG surveys were calculated (Table 32).

TABLE 32—ESTIMATED NUMBER OF SURVEY DAYS, ESTIMATED SURVEY DISTANCE PER DAY, AND ESTIMATED DAILY ENSONIFIED AREA FOR HRG SURVEYS, FROM 2024 THROUGH 2029

Survey segment	Number of active survey vessel days	Estimated distance per day (km)	Calculated daily ensonfied area (km^2)
2024 Survey Effort	41	177.792	17.805
2025 Survey Effort	191		
2026 Survey Effort	150		
2027 Survey Effort	100		
2028–January 2029 Survey Effort	100		

As described in the LOA application, density data were mapped within the boundary of the Project Area (Figure 1 in the LOA application) using geographic information systems; these data were updated based on the revised data from Roberts and Halpin (2022) (Table 33). Maximum monthly densities as reported by Roberts and Halpin (2022) were averaged by season over the survey duration (for winter (December through February)), spring (March through May), summer (June through August), and fall (September through November)) for the entire HRG Project Area. To be conservative, the maximum average seasonal density within the HRG survey schedule, for each species, was then carried forward in the take calculations (Table 33).

TABLE 33—MARINE MAMMAL DENSITIES USED IN EXPOSURE ESTIMATES AND ESTIMATED TAKES BY LEVEL B HARASSMENT FROM HRG SURVEYS

Species	Average seasonal density[a] (No./100 km^2)	HRG survey 2024—calculated take (No.)	HRG survey 2025—calculated take (No.)	HRG survey 2026—calculated take (No.)	HRG survey 2027—calculated take (No.)	HRG survey 2028–January 2029—calculated take (No.)	Total requested take (No.)
North Atlantic Right Whale	0.073	0.532	2.480	1.948	1.298	0.605	7
Humpback	0.099	0.722	3.363	2.641	1.761	1.192	11
Fin	0.097	0.707	3.295	2.588	1.725	1.227	11
Sei	0.030	0.219	1.019	0.800	0.534	0.320	4
Sperm	0.006	0.044	0.204	0.160	0.107	0.071	0
Minke	0.526	3.836	17.870	14.034	9.356	3.468	54
Pilot whales *spp.*[d]	0.019	0.139	0.645	0.507	0.338	0.338	[b]780
Bottlenose dolphin (Western N.A. Northern Migratory Coastal Stock)[b]	6.299	45.937	213.997	168.060	112.040	66.932	[c]8,730

TABLE 33—MARINE MAMMAL DENSITIES USED IN EXPOSURE ESTIMATES AND ESTIMATED TAKES BY LEVEL B HARASSMENT FROM HRG SURVEYS—Continued

Species	Average seasonal density[a] (No./100 km^2)	HRG survey 2024—calculated take (No.)	HRG survey 2025—calculated take (No.)	HRG survey 2026—calculated take (No.)	HRG survey 2027—calculated take (No.)	HRG survey 2028–January 2029—calculated take (No.)	Total requested take (No.)
Atlantic White-sided Dolphin[d]	0.469	3.420	15.933	12.513	8.342	6.297	1,008
Short-beaked common dolphin[c]	2.837	20.689	96.382	75.693	50.462	31.501	17,460
Atlantic Spotted Dolphin[e]	0.058	0.423	1.970	1.547	1.032	0.338	225
Risso's dolphin	0.035	0.255	1.189	0.934	0.623	0.249	500
Harbor porpoise	3.177	23.169	107.933	84.764	56.509	28.762	330
Harbor seal[f]	13.673	48.859	232.258	182.401	121.601	85.102	708
Gray seal[f]	13.673	48.859	232.258	182.401	121.601	85.102	708

[a] Cetacean density values from Duke University (Roberts and Halpin, 2022).
[b] Requested take adjusted based on PSO sighting data from 2018–2021 (A.I.S., 2019; Alpine Ocean Seismic Survey, 2018; Gardline, 2021a, b; Geoquip Marine, 2021; Marine Ventures International, 2021; RPS, 2021; Smultea Environmental Sciences, 2019, 2020, 2021).
[c] Bottlenose dolphin density values from Duke University (Roberts and Halpin, 2022) reported as ''bottlenose dolphin'' and not identified to stock. HRG survey activities were not differentiated by region relative to the 20-m isopleth and therefore bottlenose takes are not identified to stock. As Roberts and Halpin does not account for group size, the estimated take was adjusted to account for one group size, 15 individuals (Jefferson *et al.,* 2015) per day of bottlenose dolphins and 30 individuals (Reeves *et al.,* 2002), per day of common dolphins.
[d] As Roberts and Halpin does not account for group size, the estimated take was adjusted to account for one group size, 52 individuals (Jefferson *et al.,* 2015) per month of Atlantic white-sided dolphins.
[e] As Roberts and Halpin does not account for group size, the estimated take was adjusted to account for one group size, 100 individuals (Jefferson *et al.,* 2015), per year of Risso's dolphins and 45 individuals (Kenney and Vigness-Raposa, 2010) per year of Atlantic spotted dolphins.
[f] Pinniped density values from Duke University (Roberts and Halpin, 2022) reported as ''seals,'' so take allocated by 50 percent accrued to harbor seals and 50 percent accrued to gray seals.

The calculated exposure estimates based on the exposure modeling methodology described above were compared with the best available information on marine mammal group sizes, and with Empire Wind's PSO sightings data ranging from 2018–2021 for the Project Area, to ensure requested take numbers associated with HRG survey activities were conservative and based on best available information. As a result of this comparison, it was determined that the calculated number of potential takes by Level B harassment based on the exposure modeling methodology above may be underestimates for some species and therefore warranted adjustment to ensure conservatism in requested take numbers. Despite the relatively small modeled Level B harassment zone (50 m) for HRG survey activities, it was determined that adjustments to the requested numbers of take by Level B harassment for some dolphin species was warranted in some cases to be conservative, based on the expectation that dolphins may approach or bow ride near the survey vessel. No adjustments were made to take requests for large whale species as a result of HRG survey activities due to the relatively small Level B harassment zone (50 m) and the low likelihood that large whales would be encountered within such a short distance of the vessel except in rare circumstances.

For certain species for which the density-based methodology described above may result in potential underestimates of take and Empire Wind's PSO sightings data were relatively low, adjustments to the exposure estimates were made based on the best available information on marine mammal group sizes to ensure conservatism. For species considered common in the Project Area, requested takes by Level B harassment was adjusted to one group size per day of HRG surveys; these include bottlenose dolphins (15 individuals; Jefferson *et al.,* 2015) and common dolphins (30 individuals; Reeves *et al.,* 2002) (note that these adjustments to take estimates were made previously and are included in the LOA application). For species considered relatively common in the Project Area, requested takes by Level B harassment were adjusted to one group size per month of HRG surveys; these include Atlantic white-sided dolphins (52 individuals; Jefferson *et al.,* 2015). For species considered rare but that still have the potential for occurrence in the Project Area, requested takes by Level B harassment were adjusted to one group size per year of HRG surveys; these include Atlantic spotted dolphin (45 individuals; Kenney & Vigness-Raposa, 2010) and Risso's dolphin (100 individuals; Jefferson *et al.,* 2015). The requested take for pilot whales was adjusted based on PSO data by multiplying the maximum reported daily density (1.34 individuals; Geoquip Marine, 2021) by the annual days of operation.

Total Proposed Take Across All Activities

Level A harassment and Level B harassment proposed take numbers for the combined activities of impact pile driving (assuming 10-dB of sound attenuation) during the impact installation of monopile and OSS foundations, cable landfall and marina activities and removal and HRG surveys are shown in Table 34. NMFS also presents the 5-year total amount of take for each species in Table 35. The mitigation and monitoring measures provided in the Proposed Mitigation and Proposed Monitoring and Reporting sections are activity-specific and are designed to minimize acoustic exposures to marine mammal species.

The take numbers NMFS proposes for authorization (Table 34) are considered conservative (*i.e.,* somewhat higher than is most likely to occur) for the following key reasons:

- Proposed take numbers assume that up to one WTG monopile foundation and two pin piles for OSS foundations would be installed per day, by impact pile driving, to estimate the maximum potential for both Level A and Level B harassment. However, Empire Wind may install more than one monopile and more than two pin piles per day, completing the project more quickly. These proposed numbers also assumed that all foundations would be installed during the highest density months.
- The maximum number of sheet piles (n=300) for all temporary cofferdams (n=5) would be installed;
- The casing pipe and the maximum number of piles (n=18) necessary for all goal posts (n=3) would be installed;
- Proposed take numbers for the vibratory pile driving associated with temporary cofferdams assume the maximum number of sheet piles (n=300) would be installed;
- Proposed Level A harassment takes do not fully account for the likelihood that marine mammals would avoid a stimulus when possible before the individual accumulates enough acoustic

energy to potentially cause auditory injury, or the effectiveness of the proposed monitoring and mitigation measures (with exception of North Atlantic right whales, given the extensive mitigation measures proposed for this species).

Table 34 below depicts the proposed annual take for authorization over the length of the proposed authorization, given that specific activities are expected to occur within specific years. Empire Wind plans that all construction activities related to permanent structures (*i.e.,* monopile foundations and OSS foundations installation, cofferdams) would occur within the first two years of the project (2024–2025). HRG surveys are expected to occur, with varying effort, across all 5-years of the proposed rulemaking's effective duration. In addition to HRG surveys occurring during parts of Year 1 (2024) and Year 2 (2025), the entire durations of Year 3 (2026), Year 4 (2027), and Year 5 (2028–2029) are only expected to consist of HRG surveys as all construction-specific activities are expected to be completed by the start of Year 3. NMFS notes that while HRG surveys are expected to occur across all five years (2024–2029) of the effective period of the rulemaking (a total of 582 days across all 5 years), survey effort will vary. All activities are expected to be completed by 2029, equating to the five years of activities, as described in this preamble.

Table 34 shows the estimated take of each species for each year based on the planned distribution of activities. Tables 35 and 36 show the total take over five years and the maximum take proposed for authorization in any one year, respectively.

TABLE 34—PROPOSED LEVEL A HARASSMENT AND LEVEL B HARASSMENT TAKES FOR ALL ACTIVITIES PROPOSED TO BE CONDUCTED DURING THE CONSTRUCTION OF EMPIRE WIND PROJECT OVER 5 YEARS

Marine mammal species	NMFS stock abundance	Year 1		Year 2		Year 3		Year 4		Year 5	
		Level A harassment	Level B harassment	Level A harassment	Level B harassment	Level A harassment	Level B harassment	Level A harassment	Level B harassment	Level A harassment	Level B harassment
Mysticetes											
Fin Whale *	6,802	0	1	1	136	1	60	0	2	0	2
Humpback Whale	1,396	0	1	0	63	0	29	0	2	0	2
Minke Whale	21,968	0	4	4	83	0	62	2	9	0	3
North Atlantic Right Whale *	338	0	1	0	13	0	13	0	1	0	1
Sei Whale *	6,292	0	0	0	4	0	3	0	1	0	1
Odontocetes											
Atlantic Spotted Dolphin	39,921	0	45	0	90	0	90	0	1	0	1
Atlantic White-sided Dolphin	93,233	0	71	0	747	0	676	0	178	0	173
Bottlenose Dolphin [a]											
Western North Atlantic, Offshore	62,851	0	0	0	1,800	0	765	0	0	0	0
Western North Atlantic, Coastal	6,639	0	1,185	0	270	0	0	0	0	0	0
Western North Atlantic, Offshore and Coastal	.....	0	615	0	2,865	0	2,250	0	1,500	0	1,500
Common Dolphin	172,974	0	2,130	0	9,870	0	6,030	0	3,000	0	3,000
Harbor Porpoise	95,543	0	25	0	243	0	183	0	57	0	57
Pilot Whales [b]	68,139	0	55	0	417	0	269	0	25	0	25
Risso's Dolphin	35,215	0	100	0	200	0	200	0	25	0	25
Sperm Whale *	1,180	0	0	0	3	0	3	0	0	0	0
Phocid (pinnipeds)											
Gray Seal [c]	27,300	0	445	0	484	0	294	0	122	0	122
Harbor Seal [c]	61,336	0	445	0	678	0	412	0	122	0	122
Harp Seal [d]	7.6 M	0	4	0	4	0	4	0	4	0	4

* Denotes species listed under the Endangered Species Act.

[a] Bottlenose dolphin density values from Duke University (Roberts and Halpin 2022) reported as ''bottlenose dolphin'' and not identified to stock. Given the noise from cofferdam installation would not extend beyond the 20-meter isobath, where the coastal stock predominates, all estimated takes by Level B harassment of bottlenose dolphins from cofferdam installation were attributed to the coastal stock. Takes from impact pile driving were attributed to each stock (coastal and offshore) according to delineation along the 20-meter isobath during the animat modeling process. Takes from HRG survey activities were not differentiated.

[b] Pilot whale density values from Duke University (Roberts and Halpin 2022) reported as ''Globicephala spp.'' and not species-specific.

[c] Pinniped density values from Duke University (Roberts and Halpin 2022) reported as ''seals'' and not species-specific, so take allocated by 50% accrued to harbor seals and 50% accrued to gray seals for cable landfall construction, marina construction, and HRG surveys. Scaling based on abundance was used for WTG and OSS foundation installation.

[d] Harp seal occurrence is anticipated to be rare. Anecdotal stranding data indicate only a few harp seals are sighted within the vicinity of the Project each year. Therefore, 4 harp seal Level B takes have been requested per year of the Project.

TABLE 35—TOTAL 5-YEAR PROPOSED TAKES OF MARINE MAMMALS (BY LEVEL A HARASSMENT AND LEVEL B HARASSMENT) FOR ALL ACTIVITIES PROPOSED TO BE CONDUCTED DURING THE CONSTRUCTION OF EMPIRE WIND PROJECT

Marine mammal species	NMFS stock abundance	5-Year totals		
		Proposed Level A harassment	Proposed Level B harassment	5-year sum (Level A harassment + Level B harassment)
Mysticetes				
Fin Whale *	6,802	2	201	203
Humpback Whale	1,396	0	97	97
Minke Whale	21,968	6	167	173

TABLE 35—TOTAL 5-YEAR PROPOSED TAKES OF MARINE MAMMALS (BY LEVEL A HARASSMENT AND LEVEL B HARASSMENT) FOR ALL ACTIVITIES PROPOSED TO BE CONDUCTED DURING THE CONSTRUCTION OF EMPIRE WIND PROJECT—Continued

Marine mammal species	NMFS stock abundance	5-Year totals		
		Proposed Level A harassment	Proposed Level B harassment	5-year sum (Level A harassment + Level B harassment)
North Atlantic Right Whale *	336	0	29	29
Sei Whale *	6,292	0	9	9
Odontocetes				
Atlantic Spotted Dolphin	39,921	0	227	227
Atlantic White-sided Dolphin	93,221	0	1,840	1,840
Bottlenose Dolphin (WNA Offshore)	62,851	0	2,565	2,563
Bottlenose Dolphin (Northern Migratory Coastal)	6,639	0	1,455	1,455
Bottlenose Dolphin (WNA Offshore and Northern Migratory Coastal)	69,490	0	8,730	8,730
Common Dolphin	172,974	0	24,030	24,030
Harbor Porpoise	95,543	0	565	565
Pilot Whales	68,139	0	552	552
Risso's Dolphin	35,215	0	700	700
Sperm Whale *	4,349	0	6	6
Phocid (pinnipeds)				
Gray Seal	27,300	0	1,467	1,467
Harbor Seal	61,336	0	1,779	1,779
Harp Seal [a]	UNK	0	20	20

* Denotes species listed under the Endangered Species Act.
[a] Harp seal occurrence is anticipated to be rare. Anecdotal stranding data indicate only a few harp seals are sighted within the vicinity of the Project each year. Therefore, 4 harp seal Level B harassment takes have been requested per year of the Project.

To inform both the negligible impact analysis and the small numbers determination, NMFS assesses the greatest amount of proposed take of marine mammals that could occur within any given year (which in the case of this rule is based on the predicted Year 1 for all species). In this calculation, the maximum estimated number of Level A harassment takes in any one year is summed with the maximum estimated number of Level B harassment takes in any one year for each species to yield the highest number of estimated take that could occur in any year (Table 36). Table 36 also depicts the amount of take proposed relative to each stock assuming that each individual is taken only once, which specifically informs the small numbers determination.

TABLE 36—MAXIMUM NUMBER OF PROPOSED TAKES (LEVEL A HARASSMENT AND LEVEL B HARASSMENT) THAT COULD OCCUR IN ANY ONE YEAR OF THE PROJECT RELATIVE TO STOCK POPULATION SIZE ASSUMING EACH TAKE IS OF A DIFFERENT INDIVIDUAL

Marine mammal species	NMFS stock abundance	Maximum annual take proposed for authorization			
		Maximum Level A harassment	Maximum Level B harassment	Maximum annual take [a]	Total percent stock taken based on maximum annual take [b]
Mysticetes					
Fin Whale *	6,802	1	136	137	2.01
Humpback Whale	1,396	0	63	63	4.51
Minke Whale	21,968	4	83	87	0.40
North Atlantic Right Whale *	336	0	13	13	3.87
Sei Whale *	6,292	0	4	4	0.06
Odontocetes					
Atlantic Spotted Dolphin	39,921	0	90	90	0.23
Atlantic White-sided Dolphin	93,221	0	747	747	0.80
Bottlenose Dolphin (WNA Offshore)	62,851	0	1,800	1,800	2.86
Bottlenose Dolphin (Northern Migratory Coastal)	6,639	0	1,185	1,185	17.84
Bottlenose Dolphin (WNA Offshore and Northern Migratory Coastal) [e]	69,490	0	2,865	2,865	4.12
Common Dolphin	172,974	0	9,870	9,870	5.71

TABLE 36—MAXIMUM NUMBER OF PROPOSED TAKES (LEVEL A HARASSMENT AND LEVEL B HARASSMENT) THAT COULD OCCUR IN ANY ONE YEAR OF THE PROJECT RELATIVE TO STOCK POPULATION SIZE ASSUMING EACH TAKE IS OF A DIFFERENT INDIVIDUAL—Continued

Marine mammal species	NMFS stock abundance	Maximum annual take proposed for authorization			
		Maximum Level A harassment	Maximum Level B harassment	Maximum annual take [a]	Total percent stock taken based on maximum annual take [b]
Harbor Porpoise	95,543	0	243	243	0.25
Pilot Whale *spp.*	68,139	0	58	58	0.09
Risso's Dolphin	35,215	0	200	200	0.57
Sperm Whale *	4,349	0	3	3	0.07
Phocid (pinnipeds)					
Gray Seal	27,300	0	484	484	1.78
Harbor Seal	61,336	0	678	678	1.10
Harp Seal	UNK	0	4	4	UNK

* Denotes species listed under the Endangered Species Act.

[a] Calculations of the maximum annual take are based on the maximum requested Level A harassment take in any one year + the total requested Level B harassment take in any one year.

[b] Calculations of percentage of stock taken are based on the maximum requested Level A harassment take in any one year + the total requested Level B harassment take in any one year and then compared against the best available abundance estimate. For this proposed action, the best available abundance estimates are derived from the NMFS Stock Assessment Reports (Hayes *et al.,* 2022).

[c] Bottlenose dolphin density values from Duke University (Roberts and Halpin, 2022) reported as ''bottlenose dolphin'' and not identified to stock. Given the noise from cofferdam installation would not extend beyond the 20-meter isobath, where the coastal stock predominates, all estimated takes by Level B harassment of bottlenose dolphins from cofferdam installation were attributed to the coastal stock. Takes from impact pile driving were attributed to each stock (coastal and offshore) according to delineation along the 20-meter isobath during the animat modeling process. Takes from HRG survey activities were not differentiated.

Proposed Mitigation

In order to promulgate a rulemaking under section 101(a)(5)(A) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable 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, we carefully consider 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, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

The mitigation strategies described below are consistent with those required and successfully implemented under previous incidental take authorizations issued in association with in-water construction activities (*e.g.,* soft-start, establishing shutdown zones). Additional measures have also been incorporated to account for the fact that the proposed construction activities would occur offshore. Modeling was performed to estimate harassment zones, which were used to inform mitigation measures for pile driving activities to minimize Level A harassment and Level B harassment to the extent practicable, while providing estimates of the areas within which Level B harassment might occur.

Generally speaking, the mitigation measures considered and proposed here fall into three categories: temporal (seasonal and daily) work restrictions, real-time measures (shutdown, clearance, and vessel strike avoidance), and noise attenuation/reduction measures. Seasonal work restrictions are designed to avoid or minimize operations when marine mammals are concentrated or engaged in behaviors that make them more susceptible, or make impacts more likely) in order to reduce both the number and severity of potential takes, and are effective in reducing both chronic (longer-term) and acute effects. Real-time measures, such as implementation of shutdown and pre-clearance zones and vessel strike avoidance measures, are intended to reduce the probability or severity of harassment by taking steps in real time once a higher-risk scenario is identified (*e.g.,* once animals are detected within an impact zone). Noise attenuation measures, such as bubble curtains, are intended to reduce the noise at the source, which reduces both acute impacts, as well as the contribution to aggregate and cumulative noise that may result in longer term chronic impacts.

Below, we describe training, coordination, and vessel strike avoidance measures that apply to all activity types, and then in the following

subsections we describe the measures that apply specifically to monopile foundation and OSS foundation installation, cable landfall and marina activities, and HRG surveys.

Training and Coordination

Empire Wind would be required to ensure that a copy of any issued LOA must be in the possession of its designees, all vessel operators, visual protected species observers (PSOs), passive acoustic monitoring (PAM) operator, pile driver operators, and any other relevant designees operating under the authority of the issued IHA.

Empire Wind would also be required to instruct all project personnel regarding the authority of the marine mammal monitoring team(s) (*i.e.,* PSOs and PAM operators). For example, the HRG acoustic equipment operator, pile driving personnel, etc., would be required to immediately comply with any call for a delay or shutdown by the Lead PSO. Any disagreement between the Lead PSO and the project personnel would only be discussed after delay or shutdown has occurred. Prior to initiation of pile driving or survey work (depending on activity), all crew members will undergo environmental training, a component of which will focus on the procedures for sighting and protection of marine mammals. All relevant personnel and the marine mammal monitoring team would be required to participate in joint, onboard briefings that would be led by Empire Wind project personnel and the Lead PSO prior to the beginning of project activities. This would serve to ensure that all relevant responsibilities, communication procedures, marine mammal monitoring and mitigation protocols, reporting protocols, safety, operational procedures, and ITA requirements are clearly understood by all involved parties. The briefing would be repeated whenever new relevant personnel (*e.g.,* new PSOs, acoustic source operators, relevant crew) join the operation before work commences.

Empire Wind would ensure that any visual observations of an ESA-listed marine mammal are communicated to PSOs and vessel captains during the concurrent use of multiple project-associated vessels (of any size; *e.g.,* construction surveys, crew/supply transfers, *etc.*). Any large whale sighted by a PSO or acoustically detected by a PAM operator as if it were a North Atlantic right whale, unless a PSO or PAM operator confirms it is another species of whale. If an individual from a species for which authorization has not been granted, or a species for which authorization has been granted but the authorized take number has been met, is observed entering or within the relevant Level B harassment zone for each specified activity, pile driving and HRG acoustic sources would be required to shut down immediately, unless shutdown would result in imminent risk of injury or loss of life to an individual or risk of damage to a vessel that creates risk of injury or loss of life for individuals or be delayed if the activity has not commenced. Impact and vibratory pile driving and initiation of HRG acoustic sources must not commence or resume until the animal(s) has been confirmed to have left the relevant clearance zone or the observation time has elapsed with no further sightings. Any marine mammals observed within a clearance or shutdown zone must be allowed to remain in the area (*i.e.,* must leave of their own volition) prior to commencing pile driving activities or HRG surveys.

Before and when conducting any in-water construction activities and vessel operations, Empire Wind personnel would be required to use all available sources of information on North Atlantic right whale presence in or near the project area including daily monitoring of the Right Whale Sightings Advisory System, and monitoring of Coast Guard VHF Channel 16 throughout the day to receive notification of any sightings and/or information associated with any Slow Zones (*i.e.,* Dynamic Management Areas (DMAs) and/or acoustically-triggered slow zones) to provide situational awareness for both vessel operators and PSOs.

More information on vessel crew training requirements can be found in the *Vessel Strike Avoidance Measures* section below.

North Atlantic Right Whale Awareness Monitoring

Empire Wind must use available sources of information on North Atlantic right whale presence, including daily monitoring of the Right Whale Sightings Advisory System, WhaleAlert app, monitoring of Coast Guard VHF Channel 16 throughout each day to receive notifications of any sightings, and information associated with any regulatory management actions (*e.g.,* establishment of a zone identifying the need to reduce vessel speeds). Maintaining daily awareness and coordination affords increased protection of North Atlantic right whales by understanding North Atlantic right whale presence in the area through ongoing visual and passive acoustic monitoring efforts and opportunities (outside of Empire Wind's efforts), and allows for planning of construction activities, when practicable, to minimize potential impacts on North Atlantic right whales.

Protected Species Observers and PAM Operator Training

Empire Wind would employ NMFS-approved PSOs and PAM operators. PSOs would be required during all foundation installations, cable landfall and marina pile driving activities, and HRG surveys. PAM operators would be required during foundation installation. The PSO field team and PAM team would have a lead member (designated as the ''Lead PSO'' or ''PAM Lead'') who would have prior experience observing or detecting mysticetes, odontocetes and pinnipeds in the Northwestern Atlantic Ocean on other offshore projects requiring PSOs. Any remaining PSOs and PAM operators must have previous experience observing marine mammals during projects and must have the ability to work with all required and relevant software and equipment. New and/or inexperienced PSOs would be paired with an experienced PSO to ensure that the quality of marine mammal observations and data recording is kept consistent.

All PSOs and PAM operators would be required to complete a training program described under which will be provided to NOAA Fisheries for review and approval prior to the start of surveys. Confirmation of the training and understanding of the requirements will be documented on a training course log sheet. Signing the log sheet will certify that PSOs and PAM operators understand and will comply with the necessary mitigation and monitoring requirements.

More information on PSO and PAM operator requirements during each activity can be found in the Proposed Monitoring and Reporting section.

Vessel Strike Avoidance Measures

This proposed rule contains numerous vessel strike avoidance measures. Empire Wind will be required to comply with these measures, except under circumstances when doing so would create an imminent and serious threat to a person or vessel, or to the extent that a vessel is unable to maneuver and, because of the inability to maneuver, the vessel cannot comply (*e.g.,* due to towing, etc.). As part of vessel strike avoidance, the training program described above will be implemented. This training must occur prior to the start of construction activities. The training will include protected species identification training prior to the start of in-water

construction activities. This training will cover information about marine mammals and other protected species known to occur or which have the potential to occur in the project area. It will include training on making observations in both good weather conditions (*i.e.,* clear visibility, low wind, and low sea state) and bad weather conditions (*i.e.,* fog, high winds and high sea states, in glare). Training will not only include identification skills, but will also include information and resources available regarding applicable Federal laws and regulations for protected species.

Empire Wind will abide by the following vessel strike avoidance measures:

- All Empire Wind vessels must comply with existing NMFS vessel speed restrictions, as applicable, for North Atlantic right whales;
- All vessel operators and crews must maintain a vigilant watch for all marine mammals and slow down, stop their vessel, or alter course (as appropriate) to avoid striking any marine mammal;
- During any vessel transits within or to/from the Empire Wind project area, such as for crew transfers, an observer must be stationed at the best vantage point of the vessel(s) to ensure that the vessel(s) are maintaining the appropriate separation distance from marine mammals. Visual observers may be PSO or crew members, but crew members responsible for these duties must be provided sufficient training by Empire Wind to distinguish marine mammals from other types of animals or objects and must be able to identify a marine mammal as a North Atlantic right whale, other whale (defined in this context as sperm whales or baleen whales other than North Atlantic right whales), or other marine mammal. Crew members serving as visual observers must not have duties other than observing for marine mammals while the vessel is operating over 10 knots (kts);
- Year-round and when a vessel is in transit, all vessel operators will continuously monitor U.S. Coast Guard VHF Channel 16 over which North Atlantic right whale sightings are broadcasted;
- At the onset of transiting and at least once every four hours, vessel operators and/or trained crew members will monitor WhaleAlert and the Right Whale Sighting Advisory System (RWSAS) for the presence of North Atlantic right whales. Any notification of a whale in the project area from these systems or observations of any large whale by any Empire Wind staff or contractors, including vessel crew, must be communicated immediately to PSOs, PAM operator, and all vessel captains to increase situational awareness. Conversely, any large whale observation or detection via a sighting network (*e.g.,* Mysticetus) by PSOs or PAM operators will be conveyed to vessel operators and crew.
- All vessels, regardless of size, would operate at 10 knots (18.5 km/hr) or less in any SMA, DMA or visually triggered Slow Zone;
- Between November 1st and April 30th, all vessels, regardless of size, would operate port to port at 10 knots or less, specifically from ports in New Jersey, New York, Maryland, Delaware, and Virginia to the lease area;
- All vessels, regardless of size, would immediately reduce speed to 10 knots or less when a North Atlantic right whale is sighted, at any distance, by an observer or anyone else on the vessel.
- All vessels, regardless of size, would immediately reduce speed to 10 knots or less when any large whale, mother/calf pairs, or large assemblages of non-delphinid cetaceans are observed near (within 500 m) an underway vessel.
- All vessels must maintain a minimum separation distance of 500 m (1,640 ft) from North Atlantic right whales. If a whale is observed but cannot be confirmed as a species other than a North Atlantic right whale, the vessel operator must assume that it is a North Atlantic right whale and take appropriate action. If underway, vessels must steer a course away from any sighted North Atlantic right whale at 10 knots (18.5 km/hr) or less until the 500 m minimum separation distance has been established. If a North Atlantic right whale is sighted in a vessel's path, or within 100 m (330 ft) of an underway vessel, the underway vessel must reduce speed and shift the engine to neutral. Engines will not be engaged until the North Atlantic right whale has moved outside of the vessel's path and beyond 500 m. If stationary, the vessel must not engage engines until the North Atlantic right whale has moved beyond 500 m;
- All vessels must maintain a separation distance of 100 m or greater from any sighted whales. If sighted, the vessel underway must reduce speed and shift the engine to neutral, and must not engage the engines until the whale has moved outside of the vessel's path and beyond 100 m. If a vessel is stationary, the vessel will not engage engines until the whale has moved out of the vessel's path and beyond 100 m;
- All vessels must maintain a separation distance of 50 m (164 ft) or greater from any sighted small cetaceans and pinnipeds. Any vessel underway remain parallel to a sighted small cetacean or pinnipeds 's course whenever possible, and avoid excessive speed or abrupt changes in direction. Vessels may not adjust course and speed until the small cetaceans have moved beyond 50 m and/or the abeam of the underway vessel;
- All vessels underway must not divert or alter course in order to approach any whale, small cetacean, or pinniped. Any vessel underway must avoid excessive speed or abrupt changes in direction to avoid injury to the sighted cetacean or pinniped;
- For in-water construction heavy machinery activities other than impact or vibratory pile driving, if a marine mammal is on a path towards or comes within 10 m of equipment, Empire Wind must cease operations until the marine mammal has moved more than 10 m on a path away from the activity to avoid direct interaction with equipment;
- All underway vessels (*e.g.,* transiting, surveying) must have a dedicated visual observer on duty at all times to monitor for marine mammals within a 180 degree direction of the forward path of the vessel (90 degree port to 90 degree starboard). Visual observers must be equipped with alternative monitoring technology for periods of low visibility (*e.g.,* darkness, rain, fog, *etc.*). The dedicated visual observer must receive prior training on protected species detection and identification, vessel strike minimization procedures, how and when to communicate with the vessel captain, and reporting requirements in this proposed action. Visual observers may be third-party observers (*i.e.,* NMFS-approved PSOs) or crew members and must not have any other duties other than observing for marine mammals. Observer training related to these vessel strike avoidance measures must be conducted for all vessel operators and crew prior to the start of in-water construction activities to distinguish marine mammals from other phenomena and broadly to identify a marine mammal as a North Atlantic right whale, other whale (defined in this context as sperm whales or baleen whales other than North Atlantic right whales), or other marine mammal. Confirmation of the observers' training and understanding of the ITA requirements must be documented on a training course log sheet and reported to NMFS.

Monopile Foundation and OSS Foundation Installation

For monopile and OSS foundation installation, NMFS is proposing to include the following mitigation requirements, which are described in detail below: seasonal and daily restrictions; the use of noise abatement systems; the use of PSOs and PAM operators; the implementation of clearance and shutdown zones, and the use of soft-start.

Seasonal and Daily Restrictions

No foundation impact pile driving activities would occur January 1 through April 30. In addition, pile driving will not occur from December 1 through December 31, unless unanticipated delays due to weather or technical issues arise that necessitate extending pile driving into December in which case Empire Wind notify NMFS and BOEM in writing by September 1 that circumstances are expected to necessitate pile driving in December. Based on the best available information (Roberts and Halpin, 2022), the highest densities of North Atlantic right whales in the project area are expected during the months of January through April. NMFS is requiring this seasonal work restriction to minimize the potential for North Atlantic right whales to be exposed to noise incidental to impact pile driving of monopiles, which is expected to greatly reduce the number of takes of North Atlantic right whales.

No more than two monopiles or three pin piles would be installed per day. Monopiles would be no larger than 11-m in diameter and pin piles would be no larger than 2.5-m in diameter. During all pile installation, the minimum amount of hammer energy necessary to effectively and safely install and maintain the integrity of the piles must be used. Hammer energies must not exceed 5,500 kJ for monopile installation and 3,200 kJ for pin pile installation.

Impact pile driving will commence only during daylight hours no earlier than 1 hour after (civil) sunrise. Impact pile driving will not be initiated later than 1.5 hours before (civil) sunset. The exception to this would be if Empire Wind submits, and NMFS approves, an Alternative Monitoring Plan as part of the Pile Driving and Marine Mammal Monitoring Plan that reliably demonstrates the efficacy of their night time devices. Generally, pile driving may continue after dark when the installation of the same pile began during daylight (1.5 hours before (civil) sunset), when clearance zones were fully visible for at least 30 minutes and must proceed for human safety or installation feasibility reasons. Impact pile driving will not be initiated in times of low visibility when the visual clearance zones cannot be visually monitored, as determined by the lead Protected Species Observer (PSO) on duty.

Noise Attenuation Systems

Empire Wind would employ noise attenuation systems (NAS), during all impact pile driving of monopiles and pin piles to reduce the sound pressure levels that are transmitted through the water in an effort to reduce ranges to acoustic thresholds and minimize any acoustic impacts resulting from impact pile driving. Empire Wind would be required to employ a big double bubble curtain or may use a single bubble curtain paired with another noise abatement device. In either case, the NAS used would be required to attenuate pile driving noise such that measured ranges to isopleth distances corresponding to relevant marine mammal harassment thresholds are consistent with those modeled based on 10 dB attenuation, determined via sound field verification.

Noise attenuation systems, such as bubble curtains, are used to decrease the sound levels radiated from a source. Bubbles create a local impedance change that acts as a barrier to sound transmission. The size of the bubbles determines their effective frequency band, with larger bubbles needed for lower frequencies. There are a variety of bubble curtain systems, confined or unconfined bubbles, and some with encapsulated bubbles or panels. Attenuation levels also vary by type of system, frequency band, and location. Small bubble curtains have been measured to reduce sound levels but effective attenuation is highly dependent on depth of water, current, and configuration and operation of the curtain (Austin *et al.,* 2016; Koschinski and Lüdemann, 2013). Bubble curtains vary in terms of the sizes of the bubbles and those with larger bubbles tend to perform a bit better and more reliably, particularly when deployed with two separate rings (Bellmann, 2014; Koschinski and Lüdemann, 2013; Nehls *et al.,* 2016). Encapsulated bubble systems (*e.g.,* Hydro Sound Dampers (HSDs)), can be effective within their targeted frequency ranges (*e.g.,* 100–800 Hz), and when used in conjunction with a bubble curtain appear to create the greatest attenuation. The literature presents a wide array of observed attenuation results for bubble curtains. The variability in attenuation levels is the result of variation in design, as well as differences in site conditions and difficulty in properly installing and operating in-water attenuation devices.

If a bubble curtain is used (single or double), Empire Wind would be required to maintain the following operational parameters: The bubble curtain(s) must distribute air bubbles using a target air flow rate of at least 0.5 m^3/(min*m), and must distribute bubbles around 100 percent of the piling perimeter for the full depth of the water column. The lowest bubble ring must be in contact with the seafloor for the full circumference of the ring, and the weights attached to the bottom ring must ensure 100-percent seafloor contact; no parts of the ring or other objects should prevent full seafloor contact. Empire Wind must require that construction contractors train personnel in the proper balancing of airflow to the bubble ring, and must require that construction contractors submit an inspection/performance report for approval by Empire Wind within 72 hours following the performance test. Corrections to the attenuation device to meet the performance standards must occur prior to impact driving of monopiles. If Empire Wind uses a noise mitigation device in addition to a bubble curtain, similar quality control measures would be required.

The literature presents a wide array of observed attenuation results for bubble curtains. The variability in attenuation levels is the result of variation in design, as well as differences in site conditions and difficulty in properly installing and operating in-water attenuation devices. Dähne *et al.* (2017) found that single bubble curtains that reduce sound levels by 7 to 10 dB reduced the overall sound level by approximately 12 dB when combined as a double bubble curtain for 6-m steel monopiles in the North Sea. During installation of monopiles (~8 m) for more than 150 WTGs in comparable water depths (≤ 25 m) and conditions in Europe indicate that attenuation of 10 dB is readily achieved (Bellmann, 2019; Bellmann *et al.,* 2020) using single bubble curtains for noise attenuation. Designed to gather additional data regarding the efficacy of bubble curtains, the Coastal Virginia Offshore Wind (CVOW) pilot project systematically measured noise resulting from the impact driven installation of two 7.8-m monopiles, one installation using a double bubble curtain and the other installation using no noise abatement system (CVOW, unpublished data). Although many factors contributed to variability in received levels throughout the installation of the piles (*e.g.* hammer energy, technical challenges during operation of the

double bubble curtain), reduction in broadband SEL using the double bubble curtain (comparing measurements derived from the mitigated and the unmitigated monopiles) ranged from approximately 9–15 dB. Again, NMFS would require Empire Wind to apply a double bubble curtain, or a single bubble curtain coupled with an additional noise mitigation device, to ensure sound generated from the project does not exceed that modeled (assuming 10-dB reduction) at given ranges to harassment isopleths, and to minimize noise levels to the lowest level practicable. Double BBCs are successfully and widely applied across European wind development efforts, and are known to reduce noise levels more than single BBC alone (*e.g.,* Bellman *et al.,* 2020). Empire Wind anticipates, and NMFS agrees, that the use of a noise abatement system would likely produce field measurements of the isopleth distances to the Level A harassment and Level B harassment thresholds that accord with those modeled assuming 10-dB of attenuation for impact pile driving of monopiles (refer back to the Estimated Take, Proposed Mitigation, and Proposed Monitoring and Reporting sections).

Use of PSOs and PAM Operators

As described above, Empire Wind would be required to use PSOs and PAM operators during all foundation installation activities. At minimum, four PSOs would be actively observing marine mammals before, during, and after pile driving. At least two PSOs would be stationed on the pile driving vessel. Concurrently, at least one PAM operator would be actively monitoring for marine mammals before, during, and after pile driving. At least one active PSO on each platform must have a minimum of 90 days at-sea experience working in those roles in offshore environments with no more than eighteen months elapsed since the conclusion of the at-sea experience. Concurrently, at least one acoustic PSO (*i.e.,* passive acoustic monitoring (PAM) operator) must be actively monitoring for marine mammals before, during and after impact pile driving with PAM. More details on PSO and PAM operator requirements can be found in the Proposed Monitoring and Reporting section.

Furthermore, all crew and personnel working on the Empire Wind Project would be required to maintain situational awareness of marine mammal presence (discussed above) and would be required to report any sightings to the PSOs.

Clearance and Shutdown Zones

NMFS is proposing to require the establishment of both clearance and shutdown zones during all impact pile driving of monopile and pin pile, which would be monitored by visual PSOs and PAM operators before, during and after pile driving. PSOs must visually monitor clearance zones for marine mammals for a minimum of 60 minutes prior to commencing pile driving. At least one PAM operator must review data from at least 24 hours prior to pile driving and actively monitor hydrophones for 60 minutes prior to pile driving. Prior to initiating soft-start procedures, all clearance zones must be confirmed to be free of marine mammals for 30 minutes immediately prior to starting a soft-start of pile driving.

The purpose of ''clearance'' of a particular zone is to prevent or minimize potential instances of auditory injury and more severe behavioral disturbances by delaying the commencement of impact pile driving if marine mammals are near the activity. Prior to the start of impact pile driving activities, Empire Wind would ensure the area is clear of marine mammals, per the clearance zones in Table 37, to minimize the potential for and degree of harassment. Once pile driving activity begins, any marine mammal entering the shutdown zone would trigger pile driving to cease (unless shutdown is not practicable due to imminent risk of injury or loss of life to an individual or risk of damage to a vessel that creates risk of injury or loss of life for individuals).

In addition to the clearance and shutdown zones that would be monitored both visually and acoustically, NMFS is proposing to establish a minimum visibility zone to ensure both visual and acoustic methods are used in tandem to detect marine mammals resulting in maximum detection capability. The minimum visibility zone would extend from the location of the pile being driven out to 1.2 km. This value corresponds to just greater than the modeled maximum $ER_{95\ percent}$ distances to the Level A harassment isopleth for North Atlantic right whales assuming two difficult-to-drive monopiles are driven in a day, rounded up to the nearest hundred. This distance also corresponds to approximately the Level B harassment isopleth for OSS foundation installation. The entire minimum visibility zone must be visible (*i.e.,* not obscured by dark, rain, fog, *etc.*) for a full 30 minutes immediately prior to commencing impact pile driving. For North Atlantic right whales, there is an additional requirement that the clearance zone may only be declared clear if no confirmed North Atlantic right whale acoustic detections (in addition to visual) have occurred during the 60-minute monitoring period. Any large whale sighted by a PSO or acoustically detected by a PAM operator that cannot be identified as a non-North Atlantic right whale must be treated as if it were a North Atlantic right whale.

TABLE 37—WTG AND OSS CLEARANCE AND SHUTDOWN ZONES

[Impact]

Species	Impact pile	
	Clearance zone [1]	Shutdown zone [1]
North Atlantic right whale—PAM	5,000	1,500
North Atlantic right whale—visual detection	Any distance	1,500
All other Mysticetes and sperm whales	2 km	1,500
Harbor porpoise	400	400
Dolphins and Pilot Whales	200	200
Seals	200	200

[1] The minimum visibility zone, an area in which marine mammals must be able to be visually detected, extends 1.2 km.

Proposed clearance and shutdown zones have been developed in consideration of modeled distances to relevant PTS thresholds with respect to minimizing the potential for take by Level A harassment. All proposed

clearance and shutdown zones for large whales are larger than the largest modeled exposure range ($ER_{95\ percent}$) distances to thresholds corresponding to Level A harassment (SEL and peak). Recall that Empire Wind is seeking to avoid any pile driving during winter (December 1–December 31) and will only do so in cases of unanticipated delays due to weather or technical problems. The purpose of a shutdown is to prevent a specific acute impact, such as auditory injury or severe behavioral disturbance of sensitive species, by halting the activity. If a marine mammal is observed entering or within the respective shutdown zone (Table 37) after impact pile driving has begun, the PSO will request a temporary cessation of impact pile driving. If feasible, Empire Wind will stop pile driving immediately. In situations when shutdown is called for but Empire Wind determines shutdown is not practicable due to imminent risk of injury or loss of life to an individual or pile instability, reduced hammer energy must be implemented when the lead engineer determines it is practicable. Specifically, pile refusal or pile instability could result in not being able to shut down pile driving immediately. Pile refusal occurs when the pile driving sensors indicate the pile is approaching refusal, and a shut-down would lead to a stuck pile. Pile instability occurs when the pile is unstable and unable to stay standing if the piling vessel were to ''let go.'' During these periods of instability, the lead engineer may determine a shutdown is not feasible because the shutdown combined with impending weather conditions may require the piling vessel to ''let go'', which then poses an imminent risk of injury or loss of life to an individual or risk of damage to a vessel that creates risk for individuals. In these situations, Empire Wind must reduce hammer energy to the lowest level practicable.

The lead engineer must evaluate the following to determine if a shutdown is safe and practicable:

a. Use of site-specific soil data and real-time hammer log information to judge whether a stoppage would risk causing piling refusal at re-start of piling;

b. Confirmation that pile penetration is deep enough to secure pile stability in the interim situation, taking into account weather statistics for the relevant season and the current weather forecast; and

c. Determination by the lead engineer on duty will be made for each pile as the installation progresses and not for the site as a whole.

If it is determined that shutdown is not feasible, the reason must be documented and reported (see Proposed Monitoring and Reporting section).

Subsequent restart of the equipment can be initiated if the animal has been observed exiting its respective shutdown zone within 30 minutes of the shutdown, or, after an additional time period has elapsed with no further sighting (*i.e.,* 15 minutes for small odontocetes and 30 minutes for all other species).

For impact pile driving, Empire Wind will implement a 60-minute pre-start clearance period of the Clearance zones prior to the initiation of soft-start (described below)) to ensure no marine mammals are in the vicinity of the pile. During this period the Clearance zones will be monitored by both PSOs and passive acoustic monitoring (PAM). Pile driving will not be initiated if any marine mammal is observed within its respective Clearance zone. If a marine mammal is observed within a Clearance zone during the pre-start clearance period, impact pile driving would be delayed and may not begin until the animal(s) has been observed exiting its respective zone, or, until an additional time period has elapsed with no further sightings (*i.e.,* 15 minutes for small odontocetes and pinnipeds and 30 minutes for all other species). In addition, impact pile driving will be delayed upon a confirmed PAM detection of a North Atlantic right whale, if the PAM detection is confirmed to have been located within the 5 km North Atlantic right whale PAM Clearance zone. Any large whale sighted by a PSO within 1,000 m of the pile that cannot be identified to species must be treated as if it were a North Atlantic right whale.

Impact pile driving will not be initiated if the clearance zones cannot be adequately monitored (*i.e.,* if they are obscured by fog, inclement weather, poor lighting conditions) for a 30 minute period prior to the commencement of soft-start, as determined by the Lead PSO. If light is insufficient, the lead PSO will call for a delay until the Clearance zone is visible in all directions. If a soft-start has been initiated before the onset of inclement weather, pile driving activities may continue through these periods if deemed necessary to ensure human safety and/or the integrity of the Project. PAM operators would review data from at least 24 hours prior to pile driving and actively monitor hydrophones for 60 minutes immediately prior to pile driving. odontocetes and 30 minutes for all other marine mammal species).

Soft-Start

The use of a soft-start procedure is believed to provide additional protection to marine mammals by warning them, or providing them with a chance to leave the area prior to the hammer operating at full capacity. Soft-start typically involves initiating hammer operation at a reduced energy level (relative to full operating capacity) followed by a waiting period. Empire Wind must utilize a soft-start protocol for impact pile driving of monopiles by performing 4–6 strikes per minute at 10 to 20 percent of the maximum hammer energy, for a minimum of 20 minutes. NMFS notes that it is difficult to specify a reduction in energy for any given hammer because of variation across drivers. For impact hammers, the actual number of strikes at reduced energy will vary because operating the hammer at less than full power results in ''bouncing'' of the hammer as it strikes the pile, resulting in multiple ''strikes''; however, as mentioned previously, Empire Wind will target less than 20 percent of the total hammer energy for the initial hammer strikes during soft-start. Soft-start will be required at the beginning of each day's monopile installation, and at any time following a cessation of impact pile driving of 30 minutes or longer. If a marine mammal is detected within or about to enter the applicable clearance zones prior to the beginning of soft-start procedures, impact pile driving would be delayed until the animal has been visually observed exiting the clearance zone or until a specific time period has elapsed with no further sightings (*i.e.,* 15 minutes for small odontocetes and 30 minutes for all other species).

Cable Landfall and Marina Activities

For sheet pile or casing pipe installation and removal, NMFS is proposing to include the following mitigation requirements, which are described in detail below: daily restrictions; the use of PSOs; the implementation of clearance and shutdown zones; and the use of soft-start if a pneumatic impact hammer is used. Given the short duration of work, relatively small harassment zones if a pneumatic hammer is used, and lower noise levels during vibratory driving, NMFS is not proposing to require PAM or noise abatement system use during these activities.

Seasonal and Daily Restrictions

Empire Wind has proposed to install and remove the sheet piles or casing pipe and goal posts within 2025. NMFS is not requiring any seasonal work

restrictions for landfall construction in this proposed rule due to the relatively short duration of work (*i.e.,* low associated impacts). Empire Wind would be required, however, to conduct vibratory pile driving associated with sheet pile installation and pneumatic hammering of casing pipes during daylight hours only.

Use of PSOs

Prior to the start of vibratory pile driving or impact/pneumatic hammering activities, at least two PSOs located at the best vantage points would monitor the clearance zone for 30 minutes, continue monitoring during pile driving or pneumatic hammering, and for 30 minutes following cessation of either activity. The clearance zones must be fully visible for at least 30 minutes and must be confirmed to be clear of marine mammals for at least 30 minutes immediately prior to initiation of either activity.

Clearance and Shutdown Zones

Empire Wind would establish clearance and shutdown zones for vibratory pile driving activities associated with sheet pile installation and impact/pneumatic hammering for casing pipe installation (Table 38). PSOs would monitor the clearance zone for 30 minutes before the start of cable landfall activities, during pile driving associated with cable landfall, and for 30 minutes after pile driving of cable landfall. If a marine mammal is observed entering or is observed within the respective zones, activities will not commence until the animal has exited the zone or a specific amount of time has elapsed since the last sighting (*i.e.,* 30 minutes for large whales and 15 minutes for dolphins, porpoises, and pinnipeds). If a marine mammal is observed entering or within the respective shutdown zone after vibratory pile driving or pneumatic hammering has begun, the PSO will call for a temporary cessation of the activity. Pile driving or hammering must not be restarted until either the marine mammal(s) has voluntarily left the specific clearance zones and has been visually confirmed beyond that clearance zone or when specific time periods have elapsed with no further sightings or acoustic detections have occurred (*i.e.,* 15 minutes for small odontocetes and 30 minutes for all other marine mammal species). Because a vibratory hammer can grip a pile without operating, pile instability should not be a concern and no caveat for re-starting pile driving due to pile instability is proposed.

TABLE 38—CLEARANCE AND SHUTDOWN ZONES FOR SHEET PILE VIBRATORY DRIVING AND IMPACT/PNEUMATIC HAMMERING FOR CASING PIPES (m)

Hearing group (species)	Clearance zone (m)	Shutdown zone (m)
Low-Frequency (North Atlantic right whale, all other mysticetes)	1,600	1,600
High-Frequency (harbor porpoise)	100	100
Mid-Frequency (dolphins and pilot whales)	50	50
Phocid Pinniped (seals)	50	50

HRG Surveys

For HRG surveys, NMFS is proposing to include the following mitigation requirements, which are described in detail below, for all HRG survey activities employing SBPs: the use of PSOs; the implementation of clearance, shutdown, and vessel separation zones; and ramp-up of survey equipment.

There are no mitigation measures prescribed for sound sources operating at frequencies greater than 180 kHz, as these would be expected to fall outside of marine mammal hearing ranges and not result in harassment; however, all HRG survey vessels would be subject to the aforementioned vessel strike avoidance measures described earlier in this section. Furthermore, due to the frequency range and characteristics of some of the sound sources, shutdown, clearance, and ramp-up procedures are not proposed to be conducted during HRG surveys utilizing only non-impulsive sources (*e.g.,* Ultra-Short BaseLine (USBL) and other parametric sub-bottom profilers), with exception to usage of SBPs and other non-parametric sub-bottom profilers. PAM would not be required during HRG surveys. While NMFS agrees that PAM can be an important tool for augmenting detection capabilities in certain circumstances, its utility in further reducing impacts during HRG survey activities is limited. We have provided a thorough description of our reasoning for not requiring PAM during HRG surveys in several **Federal Register** notices (*e.g.,* 87 FR 40796, July 8, 2022; 87 FR 52913, August 3, 2022; 87 FR 51356, August 22, 2022).

Seasonal and Daily Restrictions

Given the potential impacts to marine mammals from exposure to HRG survey noise sources are relatively minor (*e.g.,* limited to Level B harassment) and that the distances to the Level B harassment isopleth is very small (maximum distance is 50.05 m), NMFS is not proposing to implement any seasonal or time-of-day restrictions for HRG surveys.

Although no temporal restrictions are proposed, NMFS would require Empire Wind to deactivate SBPs that result in take during periods where no data are being collected, except as determined necessary for testing. Any unnecessary use of the acoustic source would be avoided.

Use of PSOs

Prior to the start of HRG surveys, all personnel with responsibilities for marine mammal monitoring would participate in joint, onboard briefings that would be led by both the vessel operator and the Lead PSO.These briefings would be repeated whenever new relevant personnel (*e.g.,* new PSOs, acoustic source operators, relevant crew) join the survey operation before work begins.

During all HRG survey activities using SBPs, at least one PSO would be required to monitor during daylight hours and at least two would be required to monitor during nighttime hours, per vessel. PSOs would begin visually monitoring 30 minutes prior to the initiation of the specified acoustic source (*i.e.,* ramp-up, if applicable), during the HRG activities, and through 30 minutes after the use of the specified acoustic source has ceased. PSOs would be required to monitor the appropriate clearance and shutdown zones. These zones would be based around the radial distance from the acoustic source and not from the vessel.

Ramp-Up

At the start or restart of the use of SBPs, a ramp-up procedure would be required unless the equipment operates on a binary on/off switch. A ramp-up procedure, involving a gradual increase in source level output, is required at all times as part of the activation of the acoustic source when technically feasible. Operators would ramp up sources to half power for 5 minutes and then proceed to full power. Prior to a ramp-up procedure starting, the operator would have to notify the Lead PSO of the planned start of the ramp-up. This notification time would not be less than 60 minutes prior to the planned ramp-up activities as all relevant PSOs would need the appropriate 30 minute period to monitor prior to the initiation of ramp-up. The ramp-up procedure will not be initiated during periods of inclement conditions if the clearance zones cannot be adequately monitored by the PSOs using the appropriate visual technology (*e.g.,* reticulated binoculars, night vision equipment) for a 30-minute period. Prior to ramp-up beginning, the operator must receive confirmation from the PSO that the clearance zone is clear of any marine mammals. All ramp-ups would be scheduled to minimize the overall time spent with the source being activated. The ramp-up procedure must be used at the beginning of HRG survey activities or after more than a 30-minute break in survey activities using the specified HRG equipment to provide additional protection to marine mammals in or near the survey area by allowing them to vacate the area prior to operation of survey equipment at full power.

Empire Wind would not initiate ramp-up until the clearance process has been completed (see Clearance and Shutdown Zones section below). Ramp-up activities would be delayed if a marine mammal(s) enters its respective clearance zone. Ramp-up would only be reinitiated if the animal(s) has been observed exiting its respective shutdown zone or until additional time has elapsed with no further sighting (*i.e.,* 15 minutes for small odontocetes and seals, and 30 minutes for all other species).

Clearance and Shutdown Zones

Empire Wind would be required to implement a 30-minute clearance period of the clearance zones (Table 39) immediately prior to the commencing of the survey, or when there is more than a 30-minute break in survey activities and PSOs have not been actively monitoring. The clearance zones would be monitored by PSOs, using the appropriate visual technology. If a marine mammal is observed within a clearance zone during the clearance period, ramp-up (described below) may not begin until the animal(s) has been observed voluntarily exiting its respective clearance zone or until an additional time period has elapsed with no further sighting (*i.e.,* 15 minutes for small odontocetes and seals, and 30 minutes for all other species). In any case when the clearance process has begun in conditions with good visibility, including via the use of night vision equipment (IR/thermal camera), and the Lead PSO has determined that the clearance zones are clear of marine mammals, survey operations would be allowed to commence (*i.e.,* no delay is required) despite periods of inclement weather and/or loss of daylight.

Once the survey has commenced, Empire Wind would be required to shut down SBPs if a marine mammal enters a respective shutdown zone (Table 39). In cases when the shutdown zones become obscured for brief periods due to inclement weather, survey operations would be allowed to continue (*i.e.,* no shutdown is required) so long as no marine mammals have been detected. The use SBPs will not be allowed to commence or resume until the animal(s) has been confirmed to have left the shutdown zone or until a full 15 minutes (for small odontocetes and seals) or 30 minutes (for all other marine mammals) have elapsed with no further sighting. Any large whale sighted by a PSO within 1,000 m of the SBPs that cannot be identified as a non-North Atlantic right whale would be treated as if it were a North Atlantic right whale.

The shutdown requirement would be waived for small delphinids of the following genera: *Delphinus, Stenella, Lagenorhynchus,* and *Tursiops.* Specifically, if a delphinid from the specified genera is visually detected approaching the vessel (*i.e.,* to bow-ride) or towed equipment, shutdown would not be required. Furthermore, if there is uncertainty regarding identification of a marine mammal species (*i.e.,* whether the observed marine mammal(s) belongs to one of the delphinid genera for which shutdown is waived), the PSOs would use their best professional judgment in making the decision to call for a shutdown. Shutdown would be required if a delphinid that belongs to a genus other than those specified is detected in the shutdown zone.

If a SBP is shut down for reasons other than mitigation (*e.g.,* mechanical difficulty) for less than 30 minutes, it would be allowed to be activated again without ramp-up only if (1) PSOs have maintained constant observation, and (2) no additional detections of any marine mammal occurred within the respective shutdown zones. If a SBP was shut down for a period longer than 30 minutes, then all clearance and ramp-up procedures would be required, as previously described.

TABLE 39—HARASSMENT THRESHOLD RANGES AND MITIGATION ZONES DURING HRG SURVEYS

Species	Clearance zone (m)	Shutdown zone (m)
North Atlantic right whale	500	500
All other ESA-listed marine mammals (*e.g.,* fin, sei, sperm whale)	500	100
All other marine mammal species [1]	100	100

[1] With the exception of seals and delphinid(s) from the genera *Delphinus, Lagenorhynchus, Stenella* or *Tursiops,* as described below.

Fishery Monitoring Surveys

Training

All crew undertaking the fishery monitoring survey activities would be required to receive protected species identification training prior to activities occurring. Marine mammal monitoring must occur prior to, during, and after haul-back and gear must not be deployed if a marine mammal is observed in the area. Trawl operations must only start after 15 minutes of no marine mammal sightings within 1 nm of the sampling station.

Gear-Specific Best Management Practices (BMPs)

Empire Wind would be required to undertake BMPs to reduce risks to marine mammals during trawl surveys. These include:

• All captains and crew conducting trawl surveys will be trained in marine mammal detection and identification;
• Survey vessels will adhere to all vessel mitigation measures (see Proposed Mitigation section);
• Marine mammal monitoring will be conducted by the captain and/or a member of the scientific crew before (15 minutes prior to within 1 nm), during, and after haul back;
• Trawl operations will commence as soon as possible once the vessel arrives on station;
• If a marine mammal (other than dolphins and porpoises) is sighted within 1 nm of the planned location in the 15 minutes before gear deployment, Empire Wind will delay setting the trawl until marine mammals have not been resighted for 15 minutes or Empire Wind may move the vessel away from the marine mammal to a different section of the sampling area. If, after moving on, marine mammals are still visible from the vessel, Empire Wind may decide to move again or to skip the station;
• Gear will not be deployed if marine mammals are observed within the area and if a marine mammal is deemed to be at risk of interaction, all gear will be immediately removed;
• Empire Wind will maintain visual monitoring effort during the entire period of time that trawl gear is in the water (*i.e.,* throughout gear deployment, fishing, and retrieval). If marine mammals are sighted before the gear is fully removed from the water, Empire Wind will take the most appropriate action to avoid marine mammal interaction;
• Limit tow time to 20 minutes and monitoring for marine mammals throughout gear deployment, fishing, and retrieval;
• Empire Wind will open the codend of the net close to the deck/sorting area to avoid damage to animals that may be caught in gear;
• Trawl nets will be fully cleaned and repaired (if damaged) before setting again; and
• Any lost gear associated with the fishery surveys must be reported to the NOAA Greater Atlantic Regional Fisheries Office Protected Resources Division within 48 hours

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, NMFS has preliminarily determined that the proposed mitigation measures would provide the means of affecting 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 promulgate a rulemaking for an activity, section 101(a)(5)(A) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. 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 action; 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/or
• Mitigation and monitoring effectiveness.

Separately, monitoring is also regularly used to support mitigation implementation, which is referred to as mitigation monitoring, and monitoring plans typically include measures that both support mitigation implementation and increase our understanding of the impacts of the activity on marine mammals.

During Empire Wind's construction activities, visual monitoring by NMFS-approved PSOs would be conducted before, during, and after impact pile driving, vibratory pile driving, and HRG surveys. PAM would also be conducted during all impact pile driving. Observations and acoustic detections by PSOs would be used to support the activity-specific mitigation measures described above. Also, to increase understanding of the impacts of the activity on marine mammals, observers would record all incidents of marine mammal occurrence at any distance from the piling locations and during active HRG acoustic sources, and monitors would document all behaviors and behavioral changes, in concert with distance from an acoustic source. The required monitoring is described below, beginning with PSO measures that are applicable to all activities or monitoring, followed by activity-specific monitoring requirements.

Protected Species Observer Requirements

Empire Wind would be required to collect marine mammal sighting and behavioral response data during pile driving and HRG surveys using NMFS-approved visual and acoustic PSOs (see Proposed Mitigation section). All observers must be trained in marine mammal identification and behaviors, and are required to have no other construction-related tasks while conducting monitoring. PSOs would monitor all clearance and shutdown zones prior to, during, and following impact pile driving, vibratory pile driving, and during HRG surveys using SBPs (with monitoring durations specified further below). Any PSO would have the authority to call for a delay or shutdown of survey activities. PSOs will also monitor the Level B harassment zones and will document any marine mammals observed within these zones, to the extent practicable (noting that some zones are too large to fully observe). Observers would be located at the best practicable vantage points on the pile driving vessel. Full details regarding all marine mammal monitoring must be included in relevant Plans (*e.g.,* Pile Driving and Marine Mammal Monitoring Plan) that, under this proposed rule, Empire Wind would be required to submit to NMFS for approval at least 180 days in advance of the commencement of any construction activities.

The following measures apply to all visual monitoring efforts:

1. Monitoring must be conducted by NMFS-approved, trained PSOs who would be placed at the primary location relevant to the activity (*i.e.,* pile driving vessel, HRG survey vessel) and located in positions that allow for the best vantage point to monitor for marine mammals and implement the relevant clearance and shutdown procedures, when determined to be applicable;

2. PSO must be independent third-party observers and must have no tasks other than to conduct observational effort, collect data, and communicate with and instruct the relevant vessel crew with regard to the presence of protected species and mitigation requirements;

3. During all observation periods related to pile driving (impact and vibratory), and HRG surveys, PSOs would be located at the best vantage point(s) in order to ensure 360° visual coverage of the entire clearance and shutdown zones around the source and as much of the Level B harassment zone as possible, while still maintaining a safe work environment;

4. PSOs may not exceed 4 consecutive watch hours, must have a minimum 2-hour break between watches, and may not exceed a combined watch schedule of more than 12 hours in a single 24-hour period;

5. PSOs would be required to use appropriate equipment (specified below) to monitor for marine mammals. During periods of low visibility (*e.g.,* darkness, rain, fog, poor weather conditions, etc.), PSOs would be required to use alternative technologies (*i.e.,* infrared or thermal cameras) to monitor the shutdown and clearance zones.

6. PSOs must have the following minimum qualifications:

a. Visual acuity in both eyes (corrected is permissible) sufficient for discernment of moving targets at the water's surface with the ability to estimate the target size and distance. The use of binoculars is permitted and may be necessary to correctly identify the target(s);

b. Ability to conduct field observations and collect data according to the assigned protocols;

c. Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;

d. Writing skills sufficient to document observations, including but not limited to: the number and species of marine mammals observed, the dates and times of when in-water construction activities were conducted, the dates and time when in-water construction activities were suspended to avoid potential incidental injury of marine mammals from construction noise within a defined shutdown zone, and marine mammal behavior.

e. 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.

f. PSOs must successfully complete relevant training, including completion of all required coursework and passing a written and/or oral examination developed for the training;

g. PSOs must have successfully attained a bachelor's degree from an accredited college or university with a major in one of the natural sciences, a minimum of 30 semester hours or equivalent in the biological sciences, and at least one undergraduate course in math or statistics. The educational requirements may be waived if the PSO has acquired the relevant skills through alternate experience. Requests for such a waiver shall be submitted to NMFS and must include written justification. Alternate experience that may be considered includes, but is not limited to: Secondary education and/or experience comparable to PSO duties; Previous work experience conducting academic, commercial, or government sponsored marine mammal surveys; or previous work experience as a PSO; the PSO should demonstrate good standing and consistently good performance of PSO duties.

7. One observer on each platform will be designated as lead observer or monitoring coordinator (''Lead PSO''). This Lead PSO would be required to have a minimum of 90 days of at-sea experience working in this role in an offshore environment, and would be required to have no more than eighteen months elapsed since the conclusion of their last at-sea experience;

8. All PSOs must be approved by NMFS. Empire Wind would be required to submit resumes of the initial set of PSOs necessary to commence the project to NMFS OPR for approval at least 60 days prior to the first day of in-water construction activities requiring PSOs. Resumes would need to include the dates of training and any prior NMFS approval, as well as the dates and description of their last PSO experience, and must be accompanied by information documenting their successful completion of an acceptable training course. NMFS would allow three weeks to approve PSOs from the time that the necessary information is received by NMFS, after which any PSOs that meet the minimum requirements would automatically be considered approved.

Some activities planned to be undertaken by Empire Wind may require the use of Passive Acoustic Monitoring (PAM) systems, which would necessitate the employment of at least one acoustic PSO (aka PAM operator) on duty at any given time. PAM operators would be required to meet several of the specified requirements described above for PSOs. Furthermore, PAM operators would be required to complete a specialized training for operating PAM systems and must demonstrate familiarity with the PAM system on which they would be working.

PSOs would be able to act as both acoustic and visual observers for the project if the individual(s) demonstrates that they have had the required level and appropriate training and experience to perform each task. However, a single individual would not be allowed to concurrently act in both roles or exceed work hours specified in #4 above.

Empire Wind's personnel and PSOs would also be required to use available sources of information on North Atlantic right whale presence to aid in monitoring efforts. This includes:

1. Daily monitoring of the Right Whale Sightings Advisory System;

2. Consulting of the WhaleAlert app; and,

3. Monitoring of the Coast Guard's VHF Channel 16 throughout the day to receive notifications of any sightings and information associated with any Dynamic Management Areas, to plan construction activities and vessel routes, if practicable, to minimize the potential for co-occurrence with North Atlantic right whales.

Additionally, whenever multiple project-associated vessels (of any size; *e.g.,* construction survey, crew transfer) are operating concurrently, any visual observations of ESA-listed marine mammals must be communicated to PSOs and vessel captains associated with other vessels to increase situational awareness.

The following are proposed monitoring and reporting measures that NMFS would require specific to each construction activity:

Monopile and OSS Foundation Installation

Empire Wind would be required to implement the following monitoring procedures during all impact pile driving of monopile and OSS foundations.

During all observations associated with impact pile driving, PSOs would use high magnification (25x) binoculars, standard handheld (7x) binoculars, and the naked eye to search continuously for

marine mammals. At least one PSO on the foundation pile driving vessel and secondary dedicated-PSO vessel must be equipped with Big Eye binoculars (*e.g.,* 25 x 150; 2.7 view angle; individual ocular focus; height control) of appropriate quality. These would be pedestal-mounted on the deck at the best vantage point that provides optimal sea surface observation and PSO safety.

Empire Wind would be required to have a minimum of four PSOs actively observing marine mammals before, during, and after (specific times described below) the installation of foundation piles (monopiles). At least two PSOs must be actively observing on the pile driving vessel. Concurrently, at least one acoustic PSO (*i.e.,* passive acoustic monitoring (PAM) operator) must be actively monitoring for marine mammals before, during and after impact pile driving.

As described in the Proposed Mitigation section, if the minimum visibility zone cannot be visually monitored at all times, pile driving operations may not commence or, if active, must shutdown, unless Empire Wind determines shutdown is not practicable due to imminent risk of injury or loss of life to an individual, or risk of damage to a vessel that creates risk of injury or loss of life for individuals.

To supplement visual observation efforts, Empire Wind would utilize at least one PAM operator before, during, and after pile installation. PAM monitoring must occur for at least 24 hours immediately prior to foundation installation pile driving. The PAM operator would assist the PSOs in ensuring full coverage of the clearance and shutdown zones. All on-duty visual PSOs would remain in contact with the on-duty PAM operator, who would monitor the PAM systems for acoustic detections of marine mammals in the area. In some cases, the PAM operator and workstation may be located onshore or they may be located on a vessel. In either situation, PAM operators would maintain constant and clear communication with visual PSOs on duty regarding detections of marine mammals that are approaching or within the applicable zones related to impact pile driving. Empire Wind would utilize PAM to acoustically monitor the clearance and shutdown zones (and beyond for situational awareness), and would record all detections of marine mammals and estimated distance, when possible, to the activity (noting whether they are in the Level A harassment or Level B harassment zones). To effectively utilize PAM, Empire Wind would implement the following protocols:

- PAM operators would be stationed on at least one of the dedicated monitoring vessels in addition to the PSOs, or located remotely/onshore.
- PAM operators would have completed specialized training for operating PAM systems prior to the start of monitoring activities, including identification of species-specific mysticete vocalizations (*e.g.,* North Atlantic right whales).
- The PAM operator(s) on-duty would monitor the PAM systems for acoustic detections of marine mammals that are vocalizing in the area.
- Any detections would be conveyed to the PSO team and any PSO sightings would be conveyed to the PAM operator for awareness purposes, and to identify if mitigation is to be triggered.
- For real-time PAM systems, at least one PAM operator would be designated to monitor each system by viewing data or data products that are streamed in real-time or near real-time to a computer workstation and monitor located on a project vessel or onshore.
- The PAM operator would inform the Lead PSO on duty of marine mammal detections approaching or within applicable ranges of interest to the pile driving activity via the data collection software system (*i.e.,* Mysticetus or similar system), who would be responsible for requesting that the designated crewmember implement the necessary mitigation procedures (*i.e.,* delay or shutdown).
- Acoustic monitoring during nighttime and low visibility conditions during the day would complement visual monitoring (*e.g.,* PSOs and thermal cameras) and would cover an area of at least the Level B harassment zone around each foundation.

All PSOs and PAM operators would be required to begin monitoring 60 minutes prior to any impact pile driving, during, and after for 30 minutes. However, PAM operators must review acoustic data from the previous 24 hours as well. As described in the Proposed Mitigation section, impact pile driving of monopiles would only commence when the 1.2 km minimum visibility zone can be visually monitored and the clearance zones are clear of marine mammals for at least 30 minutes, as determined by the Lead PSO, immediately prior to the initiation of impact pile driving.

For North Atlantic right whales, any visual (regardless of distance) or acoustic detection would trigger a delay to the commencement of pile driving. In the event that a large whale is sighted or acoustically detected that cannot be confirmed as a non-North Atlantic right whale species, it must be treated as if it were a North Atlantic right whale. Following a shutdown, monopile installation may not recommence until the minimum visibility zone is fully visible and the clearance zone is clear of marine mammals for 30 minutes and no marine mammals have been detected acoustically within the PAM clearance zone for 30 minutes.

Empire Wind must prepare and submit a Pile Driving and Marine Mammal Monitoring Plan to NMFS for review and approval at least 180 days before the start of any pile driving. The plans must include final pile driving project design (*e.g.,* number and type of piles, hammer type, noise attenuation systems, anticipated start date, etc.) and all information related to PAM PSO monitoring protocols for pile-driving and visual PSO protocols for all activities.

When pile driving is not occurring, Empire Wind would ensure that visual PSOs conduct, as rotation schedules allow, observations for comparison of sighting rates and behavior during and in absence of pile driving. As described above, PAM data must be collected for 24-hours immediately prior to commencement of daily pile driving. Non-pile driving PSO monitoring data must be reflected in the monthly, annual, and final PSO monitoring reports.

As described previously, Empire Wind would be required to utilize a PAM system to supplement visual monitoring for all monopile installations. PAM operators may be on watch for a maximum of four consecutive hours followed by a break of at least two hours between watches. Again, PSOs can act as PAM operators or visual PSOs (but not simultaneously) as long as they demonstrate that their training and experience are sufficient to perform each task.

The PAM system must be monitored by a minimum of one PAM operator beginning at least 60 minutes prior to soft-start of impact pile driving of monopiles, at all times during monopile installation, and 30 minutes post-completion of both activities. PAM operators must immediately communicate all detections of marine mammals at any distance (*i.e.,* not limited to the Level B harassment zones) to visual PSOs, including any determination regarding species identification, distance, and bearing and the degree of confidence in the determination.

PAM systems may be used for real-time mitigation monitoring. The requirement for real-time detection and

localization limits the types of PAM technologies that can be used to those systems that are either cabled, satellite, or radio-linked. It is most likely that Empire Wind would deploy autonomous or moored-remote PAM devices, including sonobuoy arrays or similar retrievable buoy systems. The system chosen will dictate the design and protocols of the PAM operations. Empire Wind is not considering seafloor cabled PAM systems, in part due to high installation and maintenance costs, environmental issues related to cable laying, and the associated permitting complexities. For a review of the PAM systems Empire Wind is considering, please see Appendix 4 of the Protected Species Mitigation and Monitoring Plan included in Empire Wind's ITA application.

Empire Wind plans to deploy PAM arrays specific to mitigation and monitoring of marine mammals outside of the shutdown zone to optimize the PAM system's capabilities to monitor for the presence of animals potentially entering these zones. The exact configuration and number of PAM devices would depend on the size of the zone(s) being monitored, the amount of noise expected in the area, and the characteristics of the signals being monitored. More closely spaced hydrophones would allow for more directionality and, perhaps, range to the vocalizing marine mammals; however, this approach would add additional costs and greater levels of complexity to the project. Mysticetes, which would produce relatively loud and lower-frequency vocalizations, may be able to be heard with fewer hydrophones spaced at greater distances. However, detecting smaller cetaceans (such as mid-frequency delphinids; odontocetes) may necessitate that more hydrophones be spaced closer together given the shorter propagation range of the shorter, mid-frequency acoustic signals (*e.g.,* whistles and echolocation clicks). As there are no ''perfect fit'' single optimal array configurations, these set-ups would need to be considered on a case-by-case basis.

A Passive Acoustic Monitoring (PAM) Plan must be submitted to NMFS for review and approval at least 180 days prior to the planned start of monopile installations. PAM should follow standardized measurement, processing methods, reporting metrics, and metadata standards for offshore wind (Van Parijs *et al.,* 2021). The plan must describe all proposed PAM equipment, procedures, and protocols.

Cable Landfall and Onshore Substation C Marina Activities

Empire Wind would be required to implement the following procedures during all impact and vibratory pile driving activities associated with cable landfall construction and marina activities.

Empire Wind would be required to have a minimum of two PSOs on active duty during all pile driving associated with installation and removal. These PSOs would always be located at the best vantage point(s) on the pile driving platform or secondary platform in the immediate vicinity of the primary platform, in order to ensure that appropriate visual coverage is available of the entire clearance and shutdown zones and as much of the Level B harassment zone as possible. NMFS would not require the use of PAM for these activities.

PSOs would monitor for marine mammals 30 minutes before pile driving begins, throughout pile driving, and for 30 minutes after all pile driving activities have ceased. Pile driving may only commence when the clearance zones are determined to be clear of marine mammals, as determined by the Lead PSO, for at least 30 minutes immediately prior to initiation of impact or vibratory pile driving.

If a marine mammal is observed entering or within the respective shutdown zone after pile driving has begun, the PSO must call for a temporary shutdown of pile driving. Empire Wind must immediately cease pile driving if a PSO calls for shutdown, unless shutdown is not practicable due to imminent risk of injury or loss of life to an individual or pile refusal or instability. In this situation, Empire Wind must reduce hammer energy to the lowest level practicable and the reason(s) for not shutting down must be documented and reported to NMFS. Pile driving must not restart until either the marine mammal(s) has voluntarily left the specific clearance zones and has been visually or acoustically confirmed beyond that clearance zone, or, when specific time periods have elapsed with no further sightings or acoustic detections have occurred. The specific time periods are 15 minutes for small odontocetes and pinnipeds and 30 minutes for all other marine mammal species. In cases where these criteria are not met, pile driving may restart only if necessary to maintain pile stability at which time Empire Wind must use the lowest hammer energy practicable to maintain stability.

HRG Surveys

Per vessel, Empire Wind would be required to have at least one PSO on active duty during HRG surveys that are conducted during daylight hours (*i.e.,* from 30 minutes prior to sunrise through 30 minutes following sunset) and at least two PSOs during HRG surveys that are conducted during nighttime hours.

All PSOs would begin monitoring 30 minutes prior to the activation of SBPs; throughout use of these acoustic sources, and for 30 minutes after the use of the acoustic sources has ceased.

Given that multiple HRG vessels may be operating concurrently, any observations of marine mammals would be required to be communicated to PSOs on all nearby survey vessels.

SBPs would only commence when visual clearance zones are fully visible (*e.g.,* not obscured by darkness, rain, fog, etc.) and clear of marine mammals, as determined by the Lead PSO, for at least 30 minutes immediately prior to initiation of survey activities utilizing the specified acoustic sources. In any case when the clearance process has begun in conditions with good visibility, including via the use of night vision equipment (IR/thermal camera), and the Lead PSO has determined that the clearance zones are clear of marine mammals, survey operations would be allowed to commence (*i.e.,* no delay is required) despite periods of inclement weather and/or loss of daylight.

During daylight hours when survey equipment is not operating, Empire Wind would ensure that visual PSOs conduct, as rotation schedules allow, observations for comparison of sighting rates and behavior with and without use of the specified acoustic sources. Off-effort PSO monitoring must be reflected in the monthly PSO monitoring reports.

Once the survey has commenced, Empire Wind must shut down SBPs if a marine mammal enters a respective shutdown zone, except in cases when the shutdown zones become obscured for brief periods due to inclement weather, survey operations would be allowed to continue (*i.e.,* no shutdown is required) so long as no marine mammals have been detected. The shutdown requirement does not apply to small delphinids of the following genera: *Delphinus, Stenella, Lagenorhynchus,* and *Tursiops.* If there is uncertainty regarding the identification of a marine mammal species (*i.e.,* whether the observed marine mammal belongs to one of the delphinid genera for which shutdown is waived), the PSOs must use their best professional judgment in making the

decision to call for a shutdown. Shutdown is required if a delphinid that belongs to a genus other than those specified here is detected in the shutdown zone.

If a SBP is shut down for reasons other than mitigation (*e.g.,* mechanical difficulty) for less than 30 minutes, it would be allowed to be activated again without ramp-up only if PSOs have maintained constant observation and no additional detections of any marine mammal occurred within the respective shutdown zones.

Sound Field Verification (SFV)

During the installation of the first three monopile foundations and all piles associated with installation of the first OSS foundation, Empire Wind must empirically determine source levels, the ranges to the isopleths corresponding to the Level A harassment and Level B harassment thresholds and transmission loss coefficient(s). Empire Wind may also estimate ranges to the Level A harassment and Level B harassment isopleths by extrapolating from in situ measurements conducted at several distances from the piles monitored. Empire Wind must perform sound field measurements at four distances from the pile being driven, including, but not limited to, 750 m and the modeled Level B harassment zones to verify the accuracy of those modeled zones. The recordings will be continuous throughout the duration of all impact hammering of each pile monitored. The measurement systems will have a sensitivity appropriate for the expected sound levels from pile driving received at the nominal ranges throughout the installation of the pile. The frequency range of the system will cover the range of at least 20 Hz to 20 kHz. The system will be designed to have omnidirectional sensitivity and will be designed so that the predicted broadband received level of all impact pile-driving strikes exceed the system noise floor by at least 10 dB. The dynamic range of the system will be sufficient such that at each location, pile driving signals are not clipped and are not masked by noise floor.

If acoustic field measurements collected during installation of foundation piles indicate ranges to the isopleths corresponding to Level A harassment and Level B harassment thresholds are greater than the ranges predicted by modeling (assuming 10 dB attenuation), Empire Wind must implement additional noise mitigation measures prior to installing the next monopile. Initial additional measures may include improving the efficacy of the implemented noise mitigation technology (*e.g.,* BBC, DBBC) and/or modifying the piling schedule to reduce the sound source. Each sequential modification would be evaluated empirically by acoustic field measurements.

In the event that field measurements indicate ranges to isopleths corresponding to Level A harassment and Level B harassment thresholds are greater than the ranges predicted by modeling (assuming 10 dB attenuation), NMFS may expand the relevant harassment, clearance, and shutdown zones and associated monitoring protocols. If harassment zones are expanded beyond an additional 1,500 m, additional PSOs would be deployed on additional platforms with each observer responsible for maintaining watch in no more than 180 degrees and of an area with a radius no greater than 1,500 m.

If acoustic measurements indicate that ranges to isopleths corresponding to the Level A harassment and Level B harassment thresholds are less than the ranges predicted by modeling (assuming 10 dB attenuation), Empire Wind may request a modification of the clearance and shutdown zones for impact pile driving of monopiles and jacket foundation piles. For NMFS to consider a modification request, Empire Wind would have had to conduct SFV on three or more monopiles to verify that zone sizes are consistently smaller than those predicted by modeling (assuming 10 dB attenuation) and subsequent piles would be installed within and under similar conditions (*e.g.,* monitoring data collected during installation of a typical pile can not be used to adjust difficult-to-drive pile ranges). In addition, if a subsequent monopile installation location is selected that was not represented by previous three locations (*i.e.,* substrate composition, water depth), SFV would be required. Upon receipt of an interim SFV report, NMFS may adjust zones (*i.e.,* Level A harassment, Level B harassment, clearance, shutdown, and/or minimum visibility zone) to reflect SFV measurements.

Empire Wind will submit a SFV Plan to NOAA Fisheries for review and approval at least 180 days prior to planned start of pile driving. In addition to identify how foundation installation noise levels will be monitored, the SFV plan must also include how operational noise would be monitored. Empire Wind would be required to estimate source levels based on measurements in the near and far-field at a minimum of three locations from each foundation monitored. These data must be used to also identify estimated transmission loss rates. Operational parameters (*e.g.,* direct drive/gearbox information, turbine rotation rate) as well as sea state conditions and information on nearby anthropogenic activities (*e.g.,* vessels transiting or operating in the area) must be reported.

Reporting

Prior to initiation of project activities, Empire Wind would provide a report to NMFS (at *robert.pauline@noaa.gov* and *pr.itp.monitoringreports@noaa.gov*) documenting that all required training for Empire Wind personnel (*i.e.,* vessel crews, vessel captains, PSOs, and PAM operators) has been completed and provide the date that each in-water construction activity considered in this proposed rule (*i.e.,* foundation installation, cable landfall construction, marina activities, and HRG surveys) would occur.

NMFS would require standardized and frequent reporting from Empire Wind during the life of the proposed regulations and LOA. All data collected relating to the Empire Wind project would be recorded using industry-standard software installed on field laptops and/or tablets. Empire Wind would be required to submit weekly, monthly and annual reports as described below. For all monitoring efforts and marine mammal sightings, the following information would be collected and reported related to the activity being conducted:

- Date and time that monitored activity begins or ends;
- Construction activities occurring during each observation period;
- Watch status (*i.e.,* sighting made by PSO on/off effort, opportunistic, crew, alternate vessel/platform);
- PSO who sighted the animal;
- Time of sighting;
- Weather parameters (*e.g.,* wind speed, percent cloud cover, visibility);
- Water conditions (*e.g.,* sea state, tide state, water depth);
- All marine mammal sightings, regardless of distance from the construction activity;
- Species (or lowest possible taxonomic level possible);
- Pace of the animal(s);
- Estimated number of animals (minimum/maximum/high/low/best);
- Estimated number of animals by cohort (*e.g.,* adults, yearlings, juveniles, calves, group composition, etc.);
- Description (*i.e.,* as many distinguishing features as possible of each individual seen, including length, shape, color, pattern, scars or markings, shape and size of dorsal fin, shape of head, and blow characteristics);

- Description of any marine mammal behavioral observations (*e.g.,* observed behaviors such as feeding or traveling) and observed changes in behavior, including an assessment of behavioral responses thought to have resulted from the specific activity;
- Animal's closest distance and bearing from the pile being driven or specified HRG equipment and estimated time entered and spent within the Level A harassment and/or Level B harassment zones;
- Construction activity at time of sighting (*e.g.,* vibratory installation/removal, impact pile driving,, HRG survey), use of any noise attenuation device(s), and specific phase of activity (*e.g.,* ramp-up of HRG equipment, HRG acoustic source on/off, soft-start for pile driving, active pile driving, etc.);
- Marine mammal occurrence in Level A harassment or Level B harassment zones;
- Description of any mitigation-related action implemented, or mitigation-related actions called for but not implemented, in response to the sighting (*e.g.,* delay, shutdown, etc.) and time and location of the action; and
- Other human activity in the area.

For all real-time acoustic detections of marine mammals, the following must be recorded and included in weekly, monthly, annual, and final reports:

1. Location of hydrophone (latitude & longitude; in Decimal Degrees) and site name;
2. Bottom depth and depth of recording unit (in meters);
3. Recorder (model & manufacturer) and platform type (*i.e.,* bottom-mounted, electric glider, etc.), and instrument ID of the hydrophone and recording platform (if applicable);
4. Time zone for sound files and recorded date/times in data and metadata (in relation to UTC. *i.e.,* EST time zone is UTC–5);
5. Duration of recordings (start/end dates and times; in ISO 8601 format, yyyy-mm-ddTHH:MM:SS.sssZ);
6. Deployment/retrieval dates and times (in ISO 8601 format);
7. Recording schedule (must be continuous);
8. Hydrophone and recorder sensitivity (in dB *re. 1*µ*Pa*);
9. Calibration curve for each recorder;
10. Bandwidth/sampling rate (in Hz);
11. Sample bit-rate of recordings; and
12. Detection range of equipment for relevant frequency bands (in meters).

For each detection the following information must be noted:

13. Species identification (if possible);
14. Call type and number of calls (if known);
15. Temporal aspects of vocalization (date, time, duration, etc., date times in ISO 8601 format);
16. Confidence of detection (detected, or possibly detected);
17. Comparison with any concurrent visual sightings;
18. Location and/or directionality of call (if determined) relative to acoustic;
19. Location of recorder and construction activities at time of call;
20. Name and version of detection or sound analysis software used, with protocol reference;
21. Minimum and maximum frequencies viewed/monitored/used in detection (in Hz); and
22. Name of PAM operator(s) on duty.

Weekly Report—During foundation installation activities, Empire Wind would be required to compile and submit weekly marine mammals and pile driving activity reports to NMFS (*robert.pauline@noaa.gov and PR.ITP.monitoringreports@noaa.gov*) that document the daily start and stop of all pile driving activities, the start and stop of associated observation periods by PSOs, details on the deployment of PSOs, a record of all detections of marine mammals (acoustic and visual), any mitigation actions (or if mitigation actions could not be taken, provide reasons why), and details on the noise abatement system(s) (*e.g.,* bubble rate). Weekly reports would be due on Wednesday for the previous week (Sunday–Saturday). The weekly report would also identify which turbines become operational and when (a map must be provided). Once all foundation pile installation is complete, weekly reports would no longer be required.

Monthly Report—Empire Wind would be required to compile and submit monthly reports to NMFS (*robert.pauline@noaa.gov and PR.ITP.monitoringreports@noaa.gov*) that include a summary of all information in the weekly reports, including project activities carried out in the previous month, vessel transits (number, type of vessel, and route), number of piles installed, all detections of marine mammals, and any mitigative actions taken. Monthly reports would be due on the 15th of the month for the previous month. The monthly report would also identify which turbines become operational and when (a map must be provided). Once foundation pile installation is complete, monthly reports would no longer be required.

Annual Report—Empire Wind would be required to submit an annual PSO PAM report to NMFS (at *robert.pauline@noaa.gov* and *PR.ITP.monitoringreports@noaa.gov*) no later than 90 days following the end of a given calendar year describing, in detail, all of the information required in the monitoring section above. A final annual report would be prepared and submitted within 30 calendar days following receipt of any NMFS comments on the draft report. If no comments were received from NMFS within 60 calendar days of NMFS' receipt of the draft report, the report would be considered final.

Final Report—Empire Wind must submit its draft final report(s) to NMFS (*robert.pauline@noaa.gov* and *PR.ITP.monitoringreports@noaa.gov*) on all visual and acoustic monitoring conducted under the LOA within 90 calendar days of the completion of activities occurring under the LOA. A final report must be prepared and submitted within 30 calendar days following receipt of any NMFS comments on the draft report. If no comments are received from NMFS within 60 calendar days of NMFS' receipt of the draft report, the report shall be considered final. Information contained within this report is described at the beginning of this section.

Situational Reporting—Specific situations encountered during the development of the Empire Wind project would require immediate reporting. These situations and the relevant procedures include:

- If a North Atlantic right whale is detected via Empire Wind's PAM, the date, time, and location (*i.e.,* latitude and longitude of recorder) of the detection, as well as the recording platform that had the detection, must be reported to *nmfs.pacmdata@noaa.gov* as soon as feasible, no longer than 24 hours after the detection. Full detection data and metadata must be submitted monthly on the 15th of every month for the previous month via the web form on the NMFS North Atlantic right whale Passive Acoustic Reporting System website (*https://www.fisheries.noaa.gov/resource/document/passive-acoustic-reporting-system-templates*).
- If a North Atlantic right whale is observed at any time by PSOs or Empire Wind personnel, Empire Wind must immediately report sighting information to the NMFS North Atlantic Right Whale Sighting Advisory System (866–755–6622), to the U.S. Coast Guard via channel 16, and through the WhaleAlert app (*http://www.whalealert/org/*) as soon as feasible but no longer than 24 hours after the sighting. Information reported must include, at a minimum: time of sighting, location, and number of North Atlantic right whales observed.

• If a large whale is detected during vessel transit, the following information must be recorded and reported:

a. Time, date, and location;

b. The vessel's activity, heading, and speed;

c. Sea state, water depth, and visibility;

d. Marine mammal identification to the best of the observer's ability (*e.g.,* North Atlantic right whale, whale, dolphin, seal);

e. Initial distance and bearing to marine mammal from vessel and closest point of approach; and

f. Any avoidance measures taken in response to the marine mammal sighting.

• If a sighting of a stranded, entangled, injured, or dead marine mammal occurs, the sighting would be reported to NMFS OPR, the NMFS Greater Atlantic Stranding Coordinator for the New England/Mid-Atlantic area (866–755–6622 or the Dolphin and Whale 911 app) and the U.S. Coast Guard within 24 hours. If the injury or death was caused by a project activity, Empire Wind must immediately cease all activities until NMFS OPR 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 LOA. NMFS may impose additional measures to minimize the likelihood of further prohibited take and ensure MMPA compliance. Empire Wind may not resume their activities until notified by NMFS. The report must include the following information:

a. Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);

b. Species identification (if known) or description of the animal(s) involved;

c. Condition of the animal(s) (including carcass condition if the animal is dead);

d. Observed behaviors of the animal(s), if alive;

e. If available, photographs or video footage of the animal(s); and

f. General circumstances under which the animal was discovered.

• In the event of a vessel strike of a marine mammal by any vessel associated with the Empire Wind project, Empire Wind shall immediately report the strike incident to the NMFS OPR and the GARFO within and no later than 24 hours. Empire Wind must immediately cease all on-water activities until NMFS OPR 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 LOA. NMFS may impose additional measures to minimize the likelihood of further prohibited take and ensure MMPA compliance. Empire Wind may not resume their activities until notified by NMFS. The report must include the following information:

a. Time, date, and location (latitude/longitude) of the incident;

b. Species identification (if known) or description of the animal(s) involved;

c. Vessel's speed leading up to and during the incident;

d. Vessel's course/heading and what operations were being conducted (if applicable);

e. Status of all sound sources in use;

f. Description of avoidance measures/requirements that were in place at the time of the strike and what additional measures were taken, if any, to avoid strike;

g. Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, visibility) immediately preceding the strike;

h. Estimated size and length of animal that was struck;

i. Description of the behavior of the marine mammal immediately preceding and following the strike;

j. If available, description of the presence and behavior of any other marine mammals immediately preceding the strike;

k. Estimated fate of the animal (*e.g.,* dead, injured but alive, injured and moving, blood or tissue observed in the water, status unknown, disappeared); and

l. To the extent practicable, photographs or video footage of the animal(s).

Adaptive Management

The regulations governing the take of marine mammals incidental to Empire Wind's Wind's construction activities would contain an adaptive management component. The monitoring and reporting requirements in this rule are designed to provide NMFS with information that helps us better understand the impacts of the activities on marine mammals and informs our consideration of whether any changes to mitigation or monitoring are appropriate. The use of adaptive management allows NMFS to consider new information from different sources to determine (with input from Empire Wind regarding practicability) on an annual or biennial basis if mitigation or monitoring measures should be modified (including additions or deletions). Mitigation measures could be modified if new data suggests that such modifications would have a reasonable likelihood of reducing adverse effects to marine mammals and if the measures are practicable.

The following are some of the possible sources of applicable data to be considered through the adaptive management process: (1) Results from monitoring reports, as required by MMPA authorizations; (2) results from general marine mammal and sound research; and (3) any information which reveals that marine mammals may have been taken in a manner, extent, or number not authorized by these regulations or subsequent LOA. During the course of the rule, Empire Wind (and other LOA-holders conducting offshore wind development activities) would be required to participate in one or more adaptive management meetings convened by NMFS and/or BOEM, in which the above information would be summarized and discussed in the context of potential changes to the mitigation or monitoring measures.

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'' by mortality, serious injury, and Level A harassment or Level B harassment, we consider other factors, such as the likely nature of any behavioral responses (*e.g.,* intensity, duration), the context of any such responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of 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 environmental 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).

In the Estimated Take of Marine Mammals section, we identified the subset of potential effects that would be expected to qualify as takes under the MMPA, and then identified the maximum number of takes by Level A harassment and Level B harassment that we estimate are likely to occur based on the methods described. The impact that any given take would have is dependent on many case-specific factors that need to be considered in the negligible impact analysis (*e.g.,* the context of behavioral exposures such as duration or intensity of a disturbance, the health of impacted animals, the status of a species that incurs fitness-level impacts to individuals, etc.). In this proposed rule, we evaluate the likely impacts of the enumerated harassment takes that are proposed for authorization in the context of the specific circumstances surrounding these predicted takes. We also collectively evaluate this information, as well as other more taxa-specific information and mitigation measure effectiveness, in group-specific discussions that support our negligible impact conclusions for each stock. As described above, no serious injury or mortality is expected or proposed for authorization for any species or stock.

The Description of the Specified Activities section describes the specified activities proposed by Empire Wind that may result in take of marine mammals and an estimated schedule for conducting those activities. Empire Wind has provided a realistic construction schedule although we recognize schedules may shift for a variety of reasons (*e.g.,* weather or supply delays). However, the total amount of take would not exceed the 5 year totals and maximum annual total in any given year indicated in Tables 34 and 35, respectively.

We base our analysis and negligible impact determination (NID) on the maximum number of takes that have the potential to occur and are proposed to be authorized annually and across the 5-year LOA, if issued, and extensive qualitative consideration of other contextual factors that influence the degree of impact of the takes on the affected individuals and the number and context of the individuals affected. As stated before, the number of takes, both maximum annual and 5-year total, alone are only a part of the analysis.

To avoid repetition, we provide some general analysis in this Negligible Impact Analysis and Determination section that applies to all the species listed in Table 24 given that some of the anticipated effects of Empire Wind's construction activities on marine mammals are expected to be relatively similar in nature. Then, we subdivide into more detailed discussions for mysticetes, odontocetes, and pinnipeds which have broad life history traits that support an overarching discussion of some factors considered within the analysis for those groups (*e.g.,* habitat-use patterns, high-level differences in feeding strategies).

Last, we provide a negligible impact determination for each species or stock, providing species or stock-specific information or analysis, where appropriate, for example, for North Atlantic right whales given their population status. Organizing our analysis by grouping species or stocks that share common traits or that would respond similarly to effects of Empire Wind's proposed activities, and then providing species- or stock-specific information allows us to avoid duplication while ensuring that we have analyzed the effects of the specified activities on each affected species or stock. It is important to note that in the group or species sections, we base our negligible impact analysis on the maximum annual take that is predicted under the 5-year rule; however, the majority of the impacts are associated with monopile foundation and OSS foundation installation, which would occur largely within the first two years. The estimated take in the other years is expected to be notably less, which is reflected in the total take that would be allowable under the rule (see Tables 34, 35, and 36).

As described previously, no serious injury or mortality is anticipated or proposed for authorization in this rule. The amount of harassment Empire Wind has requested, and NMFS is proposing to authorize, is based on exposure models that consider the outputs of acoustic source and propagation models. Several conservative parameters and assumptions are ingrained into these models, such as assuming forcing functions that consider direct contact with piles (*i.e.,* no cushion allowances) and application of the highest monthly sound speed profile to all months within a given season. The exposure model results do not reflect any mitigation measures or avoidance response. The amount of take requested and proposed to be authorized also reflects careful consideration of other data (*e.g.,* PSO and group size data) and, for Level A harassment potential of some large whales, the consideration of mitigation measures. For all species, the amount of take proposed to be authorized represents the maximum amount of Level A harassment and Level B harassment that is likely to occur.

Behavioral Disturbance

In general, NMFS anticipates that impacts on an individual that has been harassed are likely to be more intense when exposed to higher received levels and for a longer duration (though this is in no way a strictly linear relationship for behavioral effects across species, individuals, or circumstances) and less severe impacts result when exposed to lower received levels and for a brief duration. However, there is also growing evidence of the importance of contextual factors such as distance from a source in predicting marine mammal behavioral response to sound—*i.e.,* sounds of a similar level emanating from a more distant source have been shown to be less likely to evoke a response of equal magnitude (*e.g.,* DeRuiter, 2012; Falcone *et al.,* 2017). As described in the Potential Effects to Marine Mammals and their Habitat section, the intensity and duration of any impact resulting from exposure to Empire Wind's activities is dependent upon a number of contextual factors including, but not limited to, sound source frequencies, whether the sound source is moving towards the animal, hearing ranges of marine mammals, behavioral state at time of exposure, status of individual exposed (*e.g.,* reproductive status, age class, health) and an individual's experience with similar sound sources. Ellison *et al.* (2012) and Moore and Barlow (2013), among others, emphasize the importance of context (*e.g.,* behavioral state of the animals, distance from the sound source) in evaluating behavioral responses of marine mammals to acoustic sources. Harassment of marine mammals may result in behavioral modifications (*e.g.,* avoidance, temporary cessation of foraging or communicating, changes in respiration or group dynamics, masking) or may result in auditory impacts such as hearing loss. In addition, some of the lower level physiological stress responses (*e.g.,* orientation or startle response, change in respiration, change in heart rate) discussed previously would likely co-occur with the behavioral modifications, although these physiological responses are more difficult to detect and fewer data exist relating these responses to specific received levels of sound. Takes by Level B harassment, then, may have a stress-related physiological component as well; however, we would not expect Empire Wind's activities to produce conditions of long-term and continuous exposure to noise leading to long-term physiological stress responses in marine

mammals that could affect reproduction or survival.

In the range of behavioral effects that might be expected to be part of a response that qualifies as an instance of Level B harassment by behavioral disturbance (which by nature of the way it is modeled/counted, occurs within one day), the less severe end might include exposure to comparatively lower levels of a sound, at a greater distance from the animal, for a few or several minutes. A less severe exposure of this nature could result in a behavioral response such as avoiding an area that an animal would otherwise have chosen to move through or feed in for some amount of time, or breaking off one or a few feeding bouts. More severe effects could occur if an animal gets close enough to the source to receive a comparatively higher level, is exposed continuously to one source for a longer time, or is exposed intermittently to different sources throughout a day. Such effects might result in an animal having a more severe flight response, and leaving a larger area for a day or more or potentially losing feeding opportunities for a day. However, such severe behavioral effects are expected to occur infrequently.

Many species perform vital functions, such as feeding, resting, traveling, and socializing on a diel cycle (24-hour cycle). Behavioral reactions to noise exposure, when taking place in a biologically important context, such as disruption of critical life functions, displacement, or avoidance of important habitat, are more likely to be significant if they last more than one day or recur on subsequent days (Southall *et al.,* 2007) due to diel and lunar patterns in diving and foraging behaviors observed in many cetaceans (Baird *et al.,* 2008, Barlow *et al.,* 2020, Henderson *et al.,* 2016, Schorr *et al.,* 2014). It is important to note the water depth in the Empire Wind project area is shallow (5 to 44 m) and deep diving species, such as sperm whales, are not expected to be engaging in deep foraging dives when exposed to noise above NMFS harassment thresholds during the specified activities. Therefore, we do not anticipate impacts to deep foraging behavior to be impacted by the specified activities.

It is also important to identify that the estimated number of takes does not necessarily equate to the number of individual animals Empire Wind expects to harass (which is lower), but rather to the instances of take (*i.e.,* exposures above the Level B harassment thresholds) that may occur. These instances may represent either brief exposures or seconds to minutes for HRG surveys) or, in some cases, longer durations of exposure within a day (*e.g.,* pile driving). Some individuals of a species may experience recurring instances of take over multiple days throughout the year, while some members of a species or stock may experience one exposure as they move through an area, which means that the number of individuals taken is smaller than the total estimated takes. In short, for species that are more likely to be migrating through the area and/or for which only a comparatively smaller number of takes are predicted (*e.g.,* some of the mysticetes), it is more likely that each take represents a different individual, whereas for non-migrating species with larger amounts of predicted take, we expect that the total anticipated takes represent exposures of a smaller number of individuals of which some would be taken across multiple days.

For the Empire Wind project, impact pile driving of foundation piles is most likely to result in a higher magnitude and severity of behavioral disturbance than other activities (*i.e.,* impact driving of casing pipe, vibratory pile driving, and HRG surveys). Foundation installation impact pile driving has higher source levels and longer duration than any nearshore pile driving activities. HRG survey equipment also produces much higher frequencies than pile driving, resulting in minimal sound propagation. While foundation installation impact pile driving is anticipated to be most impactful for these reasons, impacts are minimized through implementation of mitigation measures, including soft-start, use of a sound attenuation system, and the implementation of clearance that would facilitate a delay of pile driving if marine mammals were observed approaching or within areas that could be ensonified above sound levels that could result in Level B harassment. Given sufficient notice through the use of soft-start, marine mammals are expected to move away from a sound source that is annoying prior to becoming exposed to very loud noise levels. The requirement to couple visual monitoring and PAM during all clearance periods would increase the overall capability to detect marine mammals than one method alone. Occasional, milder behavioral reactions are unlikely to cause long-term consequences for individual animals or populations, and even if some smaller subset of the takes are in the form of a longer (several hours or a day) and more severe response, if they are not expected to be repeated over numerous or sequential days, impacts to individual fitness are not anticipated. Nearly all studies and experts agree that infrequent exposures of a single day or less are unlikely to impact an individual's overall energy budget (Farmer *et al.,* 2018; Harris *et al.,* 2017; King *et al.,* 2015; NAS 2017; New *et al.,* 2014; Southall *et al.,* 2007; Villegas-Amtmann *et al.,* 2015).

Temporary Threshold Shift (TTS)

TTS is one form of Level B harassment that marine mammals may incur through exposure to Empire Wind's activities and, as described earlier, the proposed takes by Level B harassment may represent takes in the form of behavioral disturbance, TTS, or both. As discussed in the Potential Effects to Marine Mammals and their Habitat section, in general, TTS can last from a few minutes to days, be of varying degree, and occur across different frequency bandwidths, all of which determine the severity of the impacts on the affected individual, which can range from minor to more severe. Impact and vibratory pile driving generate sounds in the lower frequency ranges (with most of the energy below 1–2 kHz, but with a small amount energy ranging up to 20 kHz); therefore, in general and all else being equal, we would anticipate the potential for TTS is higher in low-frequency cetaceans (*i.e.,* mysticetes) than other marine mammal hearing groups and would be more likely to occur in frequency bands in which they communicate. However, we would not expect the TTS to span the entire communication or hearing range of any species given the frequencies produced by pile driving do not span entire hearing ranges for any particular species. Additionally, though the frequency range of TTS that marine mammals might sustain would overlap with some of the frequency ranges of their vocalizations, the frequency range of TTS from Empire Wind's pile driving activities would not typically span the entire frequency range of one vocalization type, much less span all types of vocalizations or other critical auditory cues for any given species. However, the mitigation measures proposed by Empire Wind and proposed by NMFS, further reduce the potential for TTS in mysticetes.

Generally, both the degree of TTS and the duration of TTS would be greater if the marine mammal is exposed to a higher level of energy (which would occur when the peak dB level is higher or the duration is longer). The threshold for the onset of TTS was discussed previously (refer back to Table 4). However, source level alone is not a

predictor of TTS. An animal would have to approach closer to the source or remain in the vicinity of the sound source appreciably longer to increase the received SEL, which would be difficult considering the proposed mitigation and the nominal speed of the receiving animal relative to the stationary sources such as impact pile driving. The recovery time of TTS is also of importance when considering the potential impacts from TTS. In TTS laboratory studies (as discussed in the Potential Effects to Marine Mammals and their Habitat section), some using exposures of almost an hour in duration or up to 217 SEL, almost all individuals recovered within 1 day (or less, often in minutes) and we note that while the pile driving activities last for hours a day, it is unlikely that most marine mammals would stay in the close vicinity of the source long enough to incur more severe TTS. Overall, given the small number of times that any individual might incur TTS, the low degree of TTS and the short anticipated duration, and the unlikely scenario that any TTS overlapped the entirety of a critical hearing range, it is unlikely that TTS of the nature expected to result from Empire Wind's activities would result in behavioral changes or other impacts that would impact any individual's (of any hearing sensitivity) reproduction or survival.

Permanent Threshold Shift (PTS)

Empire Wind has requested, and NMFS proposed to authorize, a very small amount of take by PTS to some marine mammal individuals. The numbers of proposed annual takes by Level A harassment are relatively low for all marine mammal stocks and species: fin whale (2 takes), and minke whale (6). The only activities incidental to which we anticipate PTS may occur is from exposure to impact pile driving, which produce sounds that are both impulsive and primarily concentrated in the lower frequency ranges (below 1 kHz) (David, 2006; Krumpel *et al.,* 2021).

There are no PTS data on cetaceans and only one instance of PTS being induced in an older harbor seals (Reichmuth *et al.,* 2019); however, available TTS data (of mid-frequency hearing specialists exposed to mid- or high-frequency sounds (Southall *et al.,* 2007; NMFS 2018; Southall *et al.,* 2019)) suggest that most threshold shifts occur in the frequency range of the source up to one octave higher than the source. We would anticipate a similar result for PTS. Further, no more than a small degree of PTS is expected to be associated with any of the incurred Level A harassment, given it is unlikely that animals would stay in the close vicinity of a source for a duration long enough to produce more than a small degree of PTS.

PTS would consist of minor degradation of hearing capabilities occurring predominantly at frequencies one-half to one octave above the frequency of the energy produced by pile driving (*i.e.,* the low-frequency region below 2 kHz) (Cody and Johnstone, 1981; McFadden, 1986; Finneran, 2015), not severe hearing impairment. If hearing impairment occurs from either impact pile driving, it is most likely that the affected animal would lose a few decibels in its hearing sensitivity, which in most cases is not likely to meaningfully affect its ability to forage and communicate with conspecifics. However, given sufficient notice through use of soft-start prior to implementation of full hammer energy during impact pile driving, marine mammals are expected to move away from a sound source that is annoying prior to it resulting in severe PTS.

Auditory Masking or Communication Impairment

The ultimate potential impacts of masking on an individual are similar to those discussed for TTS (*e.g.,* decreased ability to communicate, forage effectively, or detect predators), but an important difference is that masking only occurs during the time of the signal, versus TTS, which continues beyond the duration of the signal. Also, though, masking can result from the sum of exposure to multiple signals, none of which might individually cause TTS. Fundamentally, masking is referred to as a chronic effect because one of the key potential harmful components of masking is its duration—the fact that an animal would have reduced ability to hear or interpret critical cues becomes much more likely to cause a problem the longer it is occurring. Also inherent in the concept of masking is the fact that the potential for the effect is only present during the times that the animal and the source are in close enough proximity for the effect to occur (and further, this time period would need to coincide with a time that the animal was utilizing sounds at the masked frequency). As our analysis has indicated, for this project we expect that impact pile driving foundations have the greatest potential to mask marine mammal signals, and this pile driving may occur for several, albeit intermittent, hours per day, for multiple days per year. Masking is fundamentally more of a concern at lower frequencies (which are pile driving dominant frequencies), because low frequency signals propagate significantly further than higher frequencies and because they are more likely to overlap both the narrower low frequency calls of mysticetes, as well as many non-communication cues related to fish and invertebrate prey, and geologic sounds that inform navigation. However, the area in which masking would occur for all marine mammal species and stocks (*e.g.,* predominantly in the vicinity of the foundation pile being driven) is small relative to the extent of habitat used by each species and stock. In summary, the nature of Empire Wind's activities, paired with habitat use patterns by marine mammals, does not support the likelihood that the level of masking that could occur would have the potential to affect reproductive success or survival.

Impacts on Habitat and Prey

Construction activities may result in fish and invertebrate mortality or injury very close to the source, and all activities (including HRG surveys) may cause some fish to leave the area of disturbance. It is anticipated that any mortality or injury would be limited to a very small subset of available prey and the implementation of mitigation measures such as the use of a noise attenuation system during impact pile driving would further limit the degree of impact. Behavioral changes in prey in response to construction activities could temporarily impact marine mammals' foraging opportunities in a limited portion of the foraging range but, because of the relatively small area of the habitat that may be affected at any given time (*e.g.,* around a pile being driven), the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences.

Cable presence and operation are not anticipated to impact marine mammal habitat as these would be buried, and any electromagnetic fields emanating from the cables are not anticipated to result in consequences that would impact marine mammals prey to the extent they would be unavailable for consumption.

The presence and operation of wind turbines within the lease area could have longer-term impacts on marine mammal habitat, as the project would result in the persistence of the structures within marine mammal habitat for more than 30 years. The presence and operation of an extensive number of structures such as wind turbines are, in general, likely to result in local and broader oceanographic effects in the marine environment, and

may disrupt dense aggregations and distribution of marine mammal zooplankton prey through altering the strength of tidal currents and associated fronts, changes in stratification, primary production, the degree of mixing, and stratification in the water column (Chen *et al.,* 2021, Johnson *et al.,* 2021, Christiansen *et al.,* 2022, Dorrell *et al.,* 2022). However, the scale of impacts is difficult to predict and may vary from hundreds of meters for local individual turbine impacts (Schultze *et al.,* 2020) to large-scale dipoles of surface elevation changes stretching hundreds of kilometers (Christiansen *et al.,* 2022).

As discussed in the Potential Effects to Marine Mammals and Their Habitat section, the Empire Wind offshore project would consist of no more than 147 wind turbine generators in New York coastal waters. While there are likely to be local oceanographic impacts from the presence and operation of the Empire Wind offshore project, meaningful oceanographic impacts relative to stratification and mixing that would significantly affect marine mammal habitat and prey over large areas in key foraging habitats are not anticipated. Although this area supports aggregations of zooplankton (baleen whale prey) that could be impacted if long-term oceanographic changes occurred, prey densities are typically significantly less in the Empire Wind project area than in known baleen whale foraging habitats to the east and north (*e.g.,* south of Nantucket and Martha's Vineyard, Great South Channel). For these reasons, if oceanographic features are affected by wind farm operation during the course of the proposed rule (approximately end of Year 1 through Year 5), the impact on marine mammal habitat and their prey is likely to be comparatively minor.

Mitigation To Reduce Impacts on All Species

This proposed rulemaking includes a variety of mitigation measures designed to minimize impacts on all marine mammals, with a focus on North Atlantic right whales (the latter is described in more detail below). For impact pile driving of foundation piles, eight overarching mitigation measures are proposed, which are intended to reduce both the number and intensity of marine mammal takes: (1) seasonal/time of day work restrictions; (2) use of multiple PSOs to visually observe for marine mammals (with any detection within designated zones triggering delay or shutdown); (3) use of PAM to acoustically detect marine mammals, with a focus on detecting baleen whales (with any detection within designated zones triggering delay or shutdown); (4) implementation of clearance zones; (5) implementation of shutdown zones; (6) use of soft-start; (7) use of noise attenuation technology; (8) maintaining situational awareness of marine mammal presence through the requirement that any marine mammal sighting(s) by Empire Wind project personnel must be reported to PSOs; and (9) sound field verification monitoring

When monopile foundation installation does occur, Empire Wind is committed to reducing the noise levels generated by impact pile driving to the lowest levels practicable and ensuring that they do not exceed a noise footprint above that which was modeled, assuming a 10-dB attenuation. Use of a soft-start would allow animals to move away from (*i.e.,* avoid) the sound source prior to applying higher hammer energy levels needed to install the pile (Empire Wind would not use a hammer energy greater than necessary to install piles). Clearance zone and shutdown zone implementation, required when marine mammals are within given distances associated with certain impact thresholds, would reduce the magnitude and severity of marine mammal take.

Empire Wind proposed, and NMFS would require, use a noise attenuation device (likely a double bubble curtain) during all foundation pile driving to ensure sound generated from the project does not exceed that modeled (assuming 10-dB reduction) distances to harassment isopleths and to minimize noise levels to the lowest level practicable. Double bubble curtains are successfully and widely applied across European wind development efforts, and are known to reduce noise levels more than a single bubble curtain alone (*e.g.,* see Bellman *et al.,* 2020).

Mysticetes

Five mysticete species (comprising five stocks) of cetaceans (North Atlantic right whale, humpback whale, fin whale, sei whale, and minke whale) are proposed to be taken by harassment. These species, to varying extents, utilize coastal New York, including the project area, for the purposes of migration and foraging.

Behavioral data on mysticete reactions to pile driving noise is scant. Kraus *et al.* (2019) predicted that the three main impacts of offshore wind farms on marine mammals would consist of displacement, behavioral disruptions, and stress. Broadly, we can look to studies that have focused on other noise sources such as seismic surveys and military training exercises, which suggest that exposure to loud signals can result in avoidance of the sound source (or displacement if the activity continues for a longer duration in a place where individuals would otherwise have been staying, which is less likely for mysticetes in this area), disruption of foraging activities (if they are occurring in the area), local masking around the source, associated stress responses, and impacts to prey, as well as TTS or PTS in some cases.

Mysticetes encountered in the Empire Wind project area are expected to be migrating through and/or foraging within the project area; the extent to which an animal engages in these behaviors in the area is species-specific and varies seasonally. Given that extensive feeding BIAs for the North Atlantic right whale, humpback whale, fin whale, sei whale, and minke whale exist to the east and north of the project area (LaBrecque *et al.,* 2015; Van Parijs *et al,* 2015), many mysticetes are expected to predominantly be migrating through the project area towards or from these feeding habitats. While we have acknowledged above that mortality, hearing impairment, or displacement of mysticete prey species may result locally from impact pile driving or, given the very short duration of and broad availability of prey species in the area and the availability of alternative suitable foraging habitat for the mysticete species most likely to be affected, any impacts on mysticete foraging would be expected to be minor. Whales temporarily displaced from the proposed project area would be expected to have sufficient remaining feeding habitat available to them, and would not be prevented from feeding in other areas within the biologically important feeding habitats. In addition, any displacement of whales or interruption of foraging bouts would be expected to be temporary in nature.

The potential for repeated exposures is dependent upon the residency time of whales, with migratory animals unlikely to be exposed on repeated occasions and animals remaining in the area to be more likely exposed repeatedly. Where relatively low amounts of species-specific proposed Level B harassment are predicted (compared to the abundance of each mysticete species or stock, such as is indicated in Table 36) and movement patterns suggest that individuals would not necessarily linger in a particular area for multiple days, each predicted take likely represents an exposure of a different individual; the behavioral impacts would, therefore, be expected to occur within a single day within a year—an amount that would not be expected to impact reproduction or survival. Alternatively, species with

longer residence time in the project area may be subject to repeated exposures across multiple days. In general, for this project, the duration of exposures would not be continuous throughout any given day and pile driving would not occur on all consecutive days within a given year, due to weather delays or any number of logistical constraints Empire Wind has identified. Species-specific analysis regarding potential for repeated exposures and impacts is provided below. Overall, we do not expect impacts to whales within project area habitat, including fin whales foraging in the fin whale feeding BIA north of the project area, to affect the fitness of any large whales.

Fin and minke whales are the only mysticete species for which PTS is anticipated and proposed to be authorized. As described previously, PTS for mysticetes from impact pile driving may overlap frequencies used for communication, navigation, or detecting prey. However, given the nature and duration of the activity, the mitigation measures, and likely avoidance behavior, any PTS is expected to be of a small degree, would be limited to frequencies where pile driving noise is concentrated (*i.e.,* only a small subset of their expected hearing range) and would not be expected to impact reproductive success or survival.

North Atlantic Right whales

North Atlantic right whales are listed as endangered under the ESA and, as described in the Effects to Marine Mammals and Their Habitat section, are threatened by a low population abundance, higher than average mortality rates, and lower than average reproductive rates. Recent studies have reported individuals showing high stress levels (*e.g.,* Corkeron *et al.,* 2017) and poor health, which has further implications on reproductive success and calf survival (Christiansen *et al.,* 2020; Stewart *et al.,* 2021; Stewart *et al.,* 2022). Given this, the status of the North Atlantic right whale population is of heightened concern and, therefore, merits additional analysis and consideration. NMFS proposes to authorize a maximum of 13 takes of North Atlantic right whales, by Level B harassment only, in any given year, with no more than 29 takes incidental to all construction activities over the 5-year period of effectiveness of this proposed rule.

As described above, the project area represents part of an important migratory area for right whales. Quintana-Rizzo *et al.* (2021) noted that southern New England, northeast of the project area, may be a stopover site for migrating right whales moving to or from southeastern calving grounds. The right whales observed during the study period were primarily concentrated in the northeastern and southeastern sections of the MA WEA during the summer (June–August) and winter (December–February). Right whale distribution did shift to the west into the RI/MA WEA in the spring (March–May). Overall, the Empire Wind project area contains habitat less frequently utilized by North Atlantic right whales than the more northerly Southern New England region.

In general, North Atlantic right whales in the project area are expected to be engaging in migratory behavior. Given the species' migratory behavior in the project area, we anticipate individual whales would be typically migrating through the area during most months when foundation installation would occur (given the seasonal restrictions on foundation installation from January through April, rather than lingering for extended periods of time). Other work that involves either much smaller harassment zones (*e.g.*, HRG surveys) or is limited in amount (cable landfall construction) may also occur during periods when North Atlantic right whales are using the habitat for migration. Therefore, it is likely that many of the takes would occur to separate individual whales, each exposed on no more than one day. It is important to note the activities occurring from December through May that may impact North Atlantic right whale would be primarily HRG surveys and cable landfall construction, neither of which would result in very high received levels. Across all years, while it is possible an animal could have been exposed during a previous year, the low amount of take proposed to be authorized during the 5-year period of the proposed rule makes this scenario possible but unlikely. However, if an individual were to be exposed during a subsequent year, the impact of that exposure is likely independent of the previous exposure given the duration between exposures.

North Atlantic right whales are presently experiencing an ongoing UME (beginning in June 2017). Preliminary findings support human interactions, specifically vessel strikes and entanglements, as the cause of death for the majority of North Atlantic right whales. Given the current status of the North Atlantic right whale, the loss of even one individual could significantly impact the population. No mortality, serious injury, or injury of North Atlantic right whales as a result of the project is expected or proposed to be authorized. Any disturbance to North Atlantic right whales due to Empire Wind's activities is expected to result in temporary avoidance of the immediate area of construction. As no injury, serious injury, or mortality is expected or authorized, and Level B harassment of North Atlantic right whales will be reduced to the level of least practicable adverse impact through use of mitigation measures, the authorized number of takes of North Atlantic right whales would not exacerbate or compound the effects of the ongoing UME in any way.

As described in the general Mysticete section above, impact pile driving of foundation piles is likely to result in the highest amount of annual take and is of greatest concern given loud source levels. This activity would likely be limited to two years, during times when North Atlantic right whales are not present in high numbers and are likely to be primarily migrating to more northern foraging grounds. The potential types, severity, and magnitude of impacts are also anticipated to mirror that described in the general mysticete section above, including avoidance (the most likely outcome), changes in foraging or vocalization behavior, masking, a small amount of TTS, and temporary physiological impacts (*e.g.,* change in respiration, change in heart rate). Importantly, the effects of the activities proposed by Empire Wind are expected to be sufficiently low-level and localized to specific areas as to not meaningfully impact important behaviors such as migratory behavior of North Atlantic right whales. As described above, no more than 13 takes would occur in any given year with no more than 29 takes occurring across the 5 years the proposed rule would be effective. If this number of exposures results in temporary behavioral reactions, such as slight displacement (but not abandonment) of migratory habitat or temporary cessation of feeding, it is unlikely to result in energetic consequences that could affect reproduction or survival of any individuals. Overall, NMFS expects that any harassment of North Atlantic right whales incidental to the specified activities would not result in changes to their migration patterns or foraging behavior as only temporary avoidance of an area during construction is expected to occur. As described previously, right whales migrating through and/or foraging in these areas are not expected to remain in this habitat for extensive durations, relative to habitats to the north such as Nantucket and Martha's Vineyard or the Great South Channel

(known core foraging habitats) (Quintana-Rizzo *et al.,* 2021), and that any temporarily displaced animals would be able to return to or continue to travel through and forage in these areas once activities have ceased.

Although acoustic masking may occur, based on the acoustic characteristics of noise associated with pile driving (*e.g.,* frequency spectra, short duration of exposure) and construction surveys (*e.g.,* intermittent signals), NMFS expects masking effects to be minimal (*e.g.,* impact or vibratory pile driving) to none (*e.g.,* HRG surveys). In addition, masking would likely only occur during the period of time that a North Atlantic right whale is in the relatively close vicinity of pile driving, which is expected to be intermittent within a day, and confined to the months in which North Atlantic right whales are at lower densities and primarily moving through the area, anticipated mitigation effectiveness, and likely avoidance behaviors. TTS is another potential form of Level B harassment that could result in brief periods of slightly reduced hearing sensitivity affecting behavioral patterns by making it more difficult to hear or interpret acoustic cues within the frequency range (and slightly above) of sound produced during impact pile driving; however, any TTS would likely be of low amount, be limited to frequencies where most construction noise is centered (below 2 kHz). NMFS expects that right whale hearing sensitivity would return to pre-exposure levels shortly after migrating through the area or moving away from the sound source.

As described in the Potential Effects to Marine Mammals and Their Habitat section, the distance of the receiver to the source influences the severity of response with greater distances typically eliciting less severe responses. Additionally, NMFS recognizes North Atlantic right whales migrating could be pregnant females (in the fall) and cows with older calves (in spring) and that these animals may slightly alter their migration course in response to any foundation pile driving; however, as described in the Potential Effects to Marine Mammals and Their Habitat section, we anticipate that course diversion would be of small magnitude. Hence, while some avoidance of the pile driving activities may occur, we anticipate any avoidance behavior of migratory right whales would be similar to that of gray whales (Tyack and Clark, 1983), on the order of hundreds of meters up to 1 to 2 km. This diversion from a migratory path otherwise uninterrupted by Empire Wind activities is not expected to result in meaningful energetic costs that would impact annual rates of recruitment of survival. NMFS expects that North Atlantic right whales would be able to avoid areas during periods of active noise production while not being forced out of this portion of their habitat.

North Atlantic right whale presence in the Empire Wind project area is year-round; however, abundance during summer months is lower compared to the winter months with spring and fall serving as ''shoulder seasons'' wherein abundance waxes (fall) or wanes (spring). Given this year-round habitat usage, in recognition that where and when whales may actually occur during project activities is unknown as it depends on the annual migratory behaviors, Empire Wind has proposed and NMFS is proposing to require a suite of mitigation measures designed to reduce impacts to North Atlantic right whales to the maximum extent practicable. These mitigation measures (*e.g.,* seasonal/daily work restrictions, vessel separation distances, reduced vessel speed) would not only avoid the likelihood of ship strikes but also would minimize the severity of behavioral disruptions by minimizing impacts (*e.g.,* through sound reduction using attenuation systems and reduced temporal overlap of project activities and North Atlantic right whales). This would further ensure that the number of takes by Level B harassment that are estimated to occur are not expected to affect reproductive success or survivorship via detrimental impacts to energy intake or cow/calf interactions during migratory transit. However, even in consideration of recent habitat-use and distribution shifts, Empire Wind would still be installing monopiles when the presence of North Atlantic right whales is expected to be lower.

As described in the Description of Marine Mammals in the Area of Specified Activities section, Empire Wind would be constructed within the North Atlantic right whale migratory corridor BIA, which represent areas and months within which a substantial portion of a species or population is known to migrate. The Empire Wind lease area is relatively small compared with the migratory BIA area (approximately 321 km^2 versus the size of the full North Atlantic right whale migratory BIA, 269,448 km^2). Because of this, overall North Atlantic right whale migration is not expected to be impacted by the proposed activities. There are no known North Atlantic right whale mating or calving areas within the project area. Prey species are mobile (*e.g.,* calanoid copepods can initiate rapid and directed escape responses) and are broadly distributed throughout the project area (noting again that North Atlantic right whale prey is not particularly concentrated in the project area relative to nearby habitats). Therefore, any impacts to prey that may occur are also unlikely to impact marine mammals.

The most significant measure to minimize impacts to individual North Atlantic right whales during monopile installations is the seasonal moratorium on impact pile driving of monopiles from January 1 through April 30 when North Atlantic right whale abundance in the project area is expected to be highest. NMFS also expects this measure to greatly reduce the potential for mother-calf pairs to be exposed to impact pile driving noise above the Level B harassment threshold during their annual spring migration through the project area from calving grounds to primary foraging grounds (*e.g.,* Cape Cod Bay). Further, NMFS expects that exposures to North Atlantic right whales would be reduced due to the additional proposed mitigation measures that would ensure that any exposures above the Level B harassment threshold would result in only short-term effects to individuals exposed. Impact pile driving may only begin in the absence of North Atlantic right whales (based on visual and passive acoustic monitoring). If impact pile driving has commenced, NMFS anticipates North Atlantic right whales would avoid the area, utilizing nearby waters to carry on pre-exposure behaviors. However, impact pile driving must be shut down if a North Atlantic right whale is sighted at any distance unless a shutdown is not feasible due to risk of injury or loss of life. Shutdown may occur anywhere if right whales are seen within or beyond the Level B harassment zone, further minimizing the duration and intensity of exposure. NMFS anticipates that if North Atlantic right whales go undetected and they are exposed to impact pile driving noise, it is unlikely a North Atlantic right whale would approach the impact pile driving locations to the degree that they would purposely expose themselves to very high noise levels. These measures are designed to avoid PTS and also reduce the severity of Level B harassment, including the potential for TTS. While some TTS could occur, given the proposed mitigation measures (*e.g.,* delay pile driving upon a sighting or acoustic detection and shutting down upon a sighting or acoustic detection), the potential for TTS to occur is low.

The proposed clearance and shutdown measures are most effective when detection efficiency is maximized,

as the measures are triggered by a sighting or acoustic detection. To maximize detection efficiency, Empire Wind proposed, and NMFS is proposing to require, the combination of PAM and visual observers (as well as communication protocols with other Empire Wind vessels, and other heightened awareness efforts such as daily monitoring of North Atlantic right whale sighting databases) such that as a North Atlantic right whale approaches the source (and thereby could be exposed to higher noise energy levels), PSO detection efficacy would increase, the whale would be detected, and a delay to commencing pile driving or shutdown (if feasible) would occur. In addition, the implementation of a soft-start would provide an opportunity for whales to move away from the source if they are undetected, reducing received levels. Further, Empire Wind will not install two monopile foundations or OSS foundations simultaneously. North Atlantic right whales would, therefore, not be exposed to concurrent impact pile driving on any given day and the area ensonified at any given time would be limited.

The temporary cofferdam Level B harassment zones are relatively small (1,985 m for EW 1 and 1,535 m for EW 2), the cofferdams would be installed within Narragansett Bay over a short timeframe (56 hours total; 28 hours for installation and 28 hours for removal). Therefore, it is unlikely that any North Atlantic right whales would be exposed to vibratory installation noises. Finally, for HRG surveys, the maximum distance to the Level B harassment isopleth is 50.05 m. The estimated take, by Level B harassment only, associated with HRG surveys is to account for any North Atlantic right whale sightings PSOs may miss when HRG acoustic sources are active. However, because of the short maximum distance to the Level B harassment isopleth (50.05 m), the requirement that vessels maintain a distance of 500 m from any North Atlantic right whales, the fact whales are unlikely to remain in close proximity to an HRG survey vessel for any length of time, and that the acoustic source would be shutdown if a North Atlantic right whale is observed within 500 m of the source, any exposure to noise levels above the harassment threshold (if any) would be very brief. To further minimize exposures, ramp-up of sub-bottom profilers must be delayed during the clearance period if PSOs detect a North Atlantic right whale (or any other ESA-listed species) within 500 m of the acoustic source. With implementation of the proposed mitigation requirements, take by Level A harassment is unlikely and, therefore, not proposed for authorization. Potential impacts associated with Level B harassment would include low-level, temporary behavioral modifications, most likely in the form of avoidance behavior. Given the high level of precautions taken to minimize both the amount and intensity of Level B harassment on North Atlantic right whales, it is unlikely that the anticipated low-level exposures would lead to reduced reproductive success or survival.

North Atlantic right whales are listed as endangered under the ESA with a declining population primarily due to vessel strike and entanglement. Again, NMFS is proposing to authorize no more than 13 instances of take, by Level B harassment only, within a given year with no more than 29 instances of take could occur over the 5-year effective period of the proposed rule, with the likely scenario that each instance of exposure occurs to a different individual (a small portion of the stock), and any individual North Atlantic right whale is likely to be disturbed at a low level. The magnitude and severity of harassment are not expected to result in impacts on the reproduction or survival of any individuals, let alone have impacts on annual rates of recruitment or survival of this stock. No mortality, serious injury, or Level A harassment is anticipated or proposed to be authorized. For these reasons, we have preliminarily determined, in consideration of all of the effects of the Empire Wind's activities combined, that the proposed authorized take would have a negligible impact on the North Atlantic stock of North Atlantic right whales.

Humpback Whales

Humpback whales potentially impacted by Empire Wind's activities do not belong to a DPS that is listed as threatened or endangered under the ESA. However, humpback whales along the Atlantic Coast have been experiencing an active UME as elevated humpback whale mortalities have occurred along the Atlantic coast from Maine through Florida since January 2016. Of the cases examined, approximately half had evidence of human interaction (ship strike or entanglement). The UME does not yet provide cause for concern regarding population-level impacts, and take from ship strike and entanglement is not proposed to be authorized. Despite the UME, the relevant population of humpback whales (the West Indies breeding population, or DPS of which the Gulf of Maine stock is a part) remains stable at approximately 12,000 individuals.

Empire Wind has requested, and NMFS has proposed to authorize, a limited amount of humpback whale harassment by Level B harassment. No mortality or serious injury is anticipated or proposed for authorization. Among the activities analyzed, impact pile driving is likely to result in the highest amount of annual take of humpback whales (0 takes by Level A harassment and 63 takes by Level B harassment) and is of greatest concern, given the associated loud source levels. A recent study examining humpback whale occurrence in the New York Bight area has shown that humpback whales exhibit extended occupancy (mean 37.6 days) in the Bight area and were likely to return from one year to the next (mean 31.3 percent). Whales were also seen at a variety of other sites in the New York Bight within the same year, suggesting that they may occupy this broader area throughout the feeding season. The majority of whales were seen during summer (July–September, 62.5 percent), followed by autumn (October–December, 23.5 percent) and spring (April–June, 13.9 percent) (Brown *et al.* 2022). These data suggest that the 0 and 63 maximum annual instances of predicted take by Level A harassment and Level B harassment, respectively, could consist of individuals exposed to noise levels above the harassment thresholds once during migration through the project area and/or individuals exposed on multiple days if they are utilizing the area as foraging habitat. Since the Lease Area (321 km^2) comprises only a minor portion of the New York Bight area (43,388 km^2), repeated takes of the same individuals would be unlikely given the availability of favorable foraging habitat across the Bight.

For all the reasons described in the Mysticete section above, we anticipate any potential TTS would be of short duration and concentrated at half or one octave above the frequency band of pile driving noise (most sound is below 2 kHz) which does not include the full predicted hearing range of baleen whales. If TTS is incurred, hearing sensitivity would likely return to pre-exposure levels shortly after exposure ends. Any masking or physiological responses would also be of low magnitude and severity for reasons described above.

Altogether, the low magnitude and severity of harassment effects is not expected to result in impacts on the reproduction or survival of any individuals, let alone have impacts on

annual rates of recruitment or survival of this stock. No mortality or serious injury is anticipated or proposed to be authorized. For these reasons, we have preliminarily determined, in consideration of all of the effects of Empire Wind's activities combined, that the proposed authorized take would have a negligible impact on the Gulf of Maine stock of humpback whales.

Fin Whales

The western North Atlantic stock of fin whales is listed as endangered under the ESA. The 5-year total amount of take, by Level A harassment and Level B harassment, of fin whales (n=2 and n=200, respectively) that NMFS proposes to authorize is low relative to the stock abundance. Any Level B harassment is expected to be in the form of behavioral disturbance, primarily resulting in avoidance of the project area where pile driving is occurring, and some low-level TTS and masking that may limit the detection of acoustic cues for relatively brief periods of time. Any potential PTS would be minor (limited to a few dB) and any TTS would be of short duration and concentrated at half or one octave above the frequency band of pile driving noise (most sound is below 2 kHz) which does not include the full predicted hearing range of fin whales. No serious injury or mortality is anticipated or proposed for authorization. As described previously, the project area is located 140 km southwest of a fin whale feeding BIA that is active from March to October. Impacts from any of the proposed activities to feeding activities, if any, would be minor. In addition, monopile installations have seasonal work restrictions, such that the temporal overlap between these project activities and the active BIA timeframe would exclude the months of March or April. There is no spatial overlap of the project area and the feeding BIA.

Because of the relatively low magnitude and severity of take proposed for authorization, the fact that no serious injury or mortality is anticipated, the temporary nature of the disturbance, and the availability of similar habitat and resources in the surrounding area, NMFS has preliminarily determined that the impacts of Empire Wind's activities on fin whales and the food sources that they utilize are not expected to cause significant impacts on the reproduction or survival of any individuals, let alone have impacts on annual rates of recruitment or survival of this stock.

Sei Whales

The Nova Scotia stock of sei whales is listed under the ESA. There are no known areas of specific biological importance in or around the project area, nor are there any UMEs. The actual abundance of this stock is likely significantly greater than what is reflected in each SAR because, as noted in the SARs, the most recent population estimate is primarily based on surveys conducted in U.S. waters and the stock's range extends well beyond the U.S. Exclusive Economic Zone (EEZ).

The 5-year total amount of take, by Level B harassment, proposed for authorization proposed for sei whales (8) is low. NMFS is not proposing to authorize take by Level A harassment. Similar to other mysticetes, we would anticipate the number of takes to represent individuals taken only once or, in rare cases two or three times, as most whales in the project area would be migrating. To a small degree, sei whales may forage in the project area, although the currently identified foraging habitats (BIAs) are 280 km northeast of the area in which Empire Wind's activities would occur (LaBrecque *et al.,* 2015). With respect to the severity of those individual takes by behavioral Level B harassment, we would anticipate impacts to be limited to low-level, temporary behavioral responses with avoidance and potential masking impacts in the vicinity of the turbine installation to be the most likely type of response. Any potential TTS would be of short duration and concentrated at half or one octave above the frequency band of pile driving noise (most sound is below 2 kHz) which does not include the full predicted hearing range of sei whales. Any avoidance of the project area due to Empire Wind's activities would be expected to be temporary.

Overall, the take by harassment proposed for authorization is of a low magnitude and severity and is not expected to result in impacts on the reproduction or survival of any individuals, let alone have impacts on annual rates of recruitment or survival of this stock. No mortality or serious injury is anticipated or proposed to be authorized. For these reasons, we have preliminarily determined, in consideration of all of the effects of the Empire Wind's activities combined, that the proposed authorized take would have a negligible impact on the Nova Scotia sei whale stock.

Minke Whales

The Canadian East Coast stock of minke whales is not listed under the ESA. There are no known areas of specific biological importance in or around the project area. Beginning in January 2017, elevated minke whale strandings have occurred along the Atlantic coast from Maine through South Carolina, with highest numbers in Massachusetts, Maine, and New York. This event does not provide cause for concern regarding population level impacts, as the likely population abundance is greater than 21,000 whales. No mortality or serious injury of this stock is anticipated or proposed for authorization.

The 5-year total amount of take, by Level A harassment and Level B harassment proposed for authorization for minke whales (n=6 and n=161, respectively) is relatively low. We anticipate the impacts of this harassment to follow those described in the general Mysticete section above. In summary, Level B harassment would be temporary, with primary impacts being temporary displacement of the project area but not abandonment of any migratory or foraging behavior. Overall, the low magnitude and severity of harassment effects is not expected to result in impacts on the reproduction or survival of any individuals, let alone have impacts on annual rates of recruitment or survival of this stock. No mortality or serious injury is anticipated or proposed to be authorized. Any potential PTS would be minor (limited to a few dB) and any TTS would be of short duration and concentrated at half or one octave above the frequency band of pile driving noise (most sound is below 2 kHz) which does not include the full predicted hearing range of minke whales. For these reasons, we have preliminarily determined, in consideration of all of the effects of the Empire Wind's activities combined, that the proposed authorized take would have a negligible impact on the Canadian East Coast stock of minke whales.

Odontocetes

In this section, we include information here that applies to all of the odontocete species and stocks addressed below, which are further divided into the following subsections: Sperm whales, Dolphins and small whales; and Harbor porpoises. These sub-sections include more specific information, as well as conclusions for each stock represented.

All of the takes of odontocetes proposed for authorization incidental to Empire Wind's specified activities are by Level B harassment incidental to pile driving and HRG surveys. No Level A harassment, or serious injury or

mortality, are anticipated or proposed. We anticipate that, given ranges of individuals (*i.e.,* that some individuals remain within a small area for some period of time), and non-migratory nature of some odontocetes in general (especially as compared to mysticetes), these takes are more likely to represent multiple exposures of a smaller number of individuals than is the case for mysticetes, though some takes may also represent one-time exposures to an individual.

Pile driving, particularly impact pile driving foundation piles, is likely to disturb odontocetes to the greatest extent, compared to HRG surveys and cable landfall and marina activities. While we do expect animals to avoid the area during pile driving, their habitat range is extensive compared to the area ensonified during pile driving.

As described earlier, Level B harassment may include direct disruptions in behavioral patterns (*e.g.,* avoidance, changes in vocalizations (from masking) or foraging), as well as those associated with stress responses or TTS. Odontocetes are highly mobile species and, similar to mysticetes, NMFS expects any avoidance behavior to be limited to the area near the pile being driven. While masking could occur during pile driving, it would only occur in the vicinity of and during the duration of the pile driving, and would not generally occur in a frequency range that overlaps most odontocete communication or echolocation signals. The mitigation measures (*e.g.,* use of sound attenuation systems, implementation of clearance and shutdown zones) would also minimize received levels such that the severity of any behavioral response would be expected to be less than exposure to unmitigated noise exposure.

Any masking or TTS effects are anticipated to be of low-severity. First, the frequency range of pile driving, the most impactful activity conducted by Empire Wind in terms of response severity, falls within a portion of the frequency range of most odontocete vocalizations. However, odontocete vocalizations span a much wider range than the low frequency construction activities proposed by Empire Wind. Further, as described above, recent studies suggest odontocetes have a mechanism to self-mitigate (*i.e.,* reduce hearing sensitivity) the impacts of noise exposure, which could potentially reduce TTS impacts. Any masking or TTS is anticipated to be limited and would typically only interfere with communication within a portion of an odontocete's range and as discussed earlier, the effects would only be expected to be of a short duration and, for TTS, a relatively small degree. Furthermore, odontocete echolocation occurs predominantly at frequencies significantly higher than low frequency construction activities; therefore, there is little likelihood that threshold shift would interfere with feeding behaviors. For HRG surveys, the sources operate at higher frequencies than pile driving. However, sounds from these sources attenuate very quickly in the water column, as described above; therefore, any potential for TTS and masking is very limited. Further, odontocetes (*e.g.,* common dolphins, spotted dolphins, bottlenose dolphins) have demonstrated an affinity to bow-ride actively surveying HRG surveys; therefore, the severity of any harassment, if it does occur, is anticipated to be minimal based on the lack of avoidance previously demonstrated by these species.

The waters off the coast of New York are used by several odontocete species; however, none (except the sperm whale) are listed under the ESA and there are no known habitats of particular importance. In general, odontocete habitat ranges are far-reaching along the Atlantic coast of the U.S., and the waters off of New York, including the project area, do not contain any particularly unique odontocete habitat features.

Sperm Whales

The Western North Atlantic stock of sperm whales spans the East Coast out into oceanic waters well beyond the U.S. EEZ. Although listed as endangered, the primary threat faced by the sperm whale (*i.e.,* commercial whaling) has been eliminated and, further, sperm whales in the western North Atlantic were little affected by modern whaling (Taylor *et al.,* 2008). Current potential threats to the species globally include vessel strikes, entanglement in fishing gear, anthropogenic noise, exposure to contaminants, climate change, and marine debris. There is no currently reported trend for the stock and, although the species is listed as endangered under the ESA, there are no specific issues with the status of the stock that cause particular concern (*e.g.,* no UMEs). There are no known areas of biological importance (*e.g.,* critical habitat or BIAs) in or near the project area.

No mortality, serious injury or Level A harassment is anticipated or proposed to be authorized for this species. Impacts would be limited to Level B harassment and would occur to only a very small number of individuals (maximum of 3 in any given year and 6 across all 5 years) incidental to pile driving and HRG surveys. Sperm whales are not common within the project area due to the shallow waters, and it is not expected that any noise levels would reach habitat in which sperm whales are common, including deep-water foraging habitat. If sperm whales do happen to be present in the project area during any activities related to the Empire Wind project, they would likely be only transient visitors and not engaging in any significant behaviors. This very low magnitude and severity of effects is not expected to result in impacts on the reproduction or survival of individuals, much less impact annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Empire Wind's activities combined, that the take proposed to be authorized would have a negligible impact on sperm whales.

Dolphins and Small Whales (Including Delphinids, Pilot Whales, and Harbor Porpoises)

There are no specific issues with the status of odontocete stocks that cause particular concern (*e.g.,* no recent UMEs). No mortality or serious injury is expected or proposed to be authorized for these stocks. Only Level B harassment is anticipated or proposed for authorization for any dolphin, small whale or harbor porpoise.

The maximum amount of take, by Level B harassment, proposed for authorization within any one year for all odontocetes cetacean stocks ranges from 1 to 9,870 instances. As described above for odontocetes broadly, we anticipate that a fair number of these instances of take in a day represent multiple exposures of a smaller number of individuals, meaning the actual number of individuals taken is lower. Although some amount of repeated exposure to some individuals is likely given the duration of activity proposed by Empire Wind, the number of takes, and the likely movement patterns of the affected species, the intensity of any Level B harassment combined with the availability of alternate nearby foraging habitat suggests that the likely impacts would not impact the reproduction or survival of any individuals.

Overall, the populations of all dolphins and small whale species and stocks for which we propose to authorize take are stable (no declining population trends), not facing existing UMEs, and the relatively low magnitude and severity of effects is not expected to result in impacts on the reproduction or survival of any individuals, much less

affect annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Empire Wind's activities combined, that the take proposed to be authorized would have a negligible impact on all dolphin and small whale species and stocks considered in this analysis.

Harbor Porpoises

The Gulf of Maine/Bay of Fundy stock of harbor porpoises is found predominantly in northern U.S. coastal waters (less than 150 m depth) and up into Canada's Bay of Fundy. Although the population trend is not known, there are no UMEs or other factors that cause particular concern for this stock. No mortality or non-auditory injury are anticipated or authorized for this stock. NMFS proposes to authorize a maximum of 243 takes by Level B harassment only for any given year; no takes by Level A harassment are anticipated for this species.

Regarding the severity of takes by behavioral Level B harassment, because harbor porpoises are particularly sensitive to noise, it is likely that a fair number of the responses could be of a moderate nature, particularly to pile driving. In response to pile driving, harbor porpoises are likely to avoid the area during construction, as previously demonstrated in Tougaard *et al.* (2009) in Denmark, in Dahne *et al.* (2013) in Germany, and in Vallejo *et al.* (2017) in the United Kingdom, although a study by Graham *et al.* (2019) may indicate that the avoidance distance could decrease over time. However, pile driving is scheduled to occur off the coast of New York and, given alternative foraging areas, any avoidance of the area by individuals is not likely to impact the reproduction or survival of any individuals.

PTS is not anticipated or proposed for authorization. With respect to TTS, the effects on an individual are likely relatively low given the frequency bands of pile driving (most energy below 2 kHz) compared to harbor porpoise hearing (150 Hz to 160 kHz peaking around 40 kHz). Specifically, TTS is unlikely to impact hearing ability in their more sensitive hearing ranges, or the frequencies in which they communicate and echolocate.

In summary, the amount of take proposed to be authorized across all 5 years is 565 by Level B harassment. While harbor porpoises are likely to avoid the area during any construction activity discussed herein, as demonstrated during European wind farm construction, the time of year in which work would occur is when harbor porpoises are not in high abundance, and any work that does occur would not result in the species' abandonment of the waters off of New York. The low-moderate magnitude and severity of harassment effects is not expected to result in impacts on the reproduction or survival of any individuals, let alone have impacts on annual rates of recruitment or survival of this stock. No mortality or serious injury is anticipated or proposed to be authorized. For these reasons, we have preliminarily determined, in consideration of all of the effects of Empire Wind's activities combined, that the proposed authorized take would have a negligible impact on the Gulf of Maine/Bay of Fundy stock of harbor porpoises.

Phocids (Harbor Seals, Gray Seals, and Harp Seals)

The harbor seal, gray seal, and harp seal are not listed under the ESA. Empire Wind requested, and NMFS proposes to authorize that no more than 678 harbor seals, 484 gray seals, and 4 harp seals by Level B harassment within any one year. Level A harassment is neither anticipated nor proposed for authorization. Harbor and gray seals occur in New York waters most often in winter, when impact pile driving would not occur. Harp seals are anticipated to be rare but could still occur in the project area. Seals are also more likely to be close to shore (*e.g.,* closer to the edge of the area ensonified above NMFS' harassment threshold), such that exposure to impact pile driving would be expected to be at comparatively lower levels. The majority of takes of these species is from monopile installations, vibratory pile driving associated with temporary cofferdam installation and removal, and HRG surveys. As described in the Potential Effects to Marine Mammals and Their Habitat section, construction of wind farms in Europe resulted in pinnipeds temporarily avoiding construction areas but returning within short time frames after construction was complete (Carroll *et al.,* 2010; Hamre *et al.,* 2011; Hastie *et al.,* 2015; Russell *et al.,* 2016; Brasseur *et al.,* 2010). Effects on pinnipeds that are taken by Level B harassment in the project area would likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring). Most likely, individuals would simply move away from the sound source and be temporarily displaced from those areas (see Lucke *et al.,* 2006; Edren *et al.,* 2010; Skeate *et al.,* 2012; Russell *et al.,* 2016). Given the low anticipated magnitude of impacts from any given exposure (*e.g.,* temporary avoidance), even repeated Level B harassment across a few days of some small subset of individuals, which could occur, is unlikely to result in impacts on the reproduction or survival of any individuals. Moreover, pinnipeds would benefit from the mitigation measures described in the Proposed Mitigation section.

Elevated numbers of harbor seal and gray seal mortalities were first observed in July 2018 and occurred across Maine, New Hampshire, and Massachusetts until 2020. Based on tests conducted so far, the main pathogen found in the seals belonging to that UME was phocine distemper virus, although additional testing to identify other factors that may be involved in this UME are underway. Currently, the only active UME is occurring in Maine with some harbor and gray seals testing positive for highly pathogenic avian influenza (HPAI) H5N1. Although elevated strandings continue, neither UME (alone or in combination) provide cause for concern regarding population-level impacts to any of these stocks. For harbor seals, the population abundance is over 61,000 and annual M/SI (339) is well below PBR (1,729) (Hayes *et al.,* 2020). The population abundance for gray seals in the United States is over 27,000, with an estimated overall abundance, including seals in Canada, of approximately 450,000. In addition, the abundance of gray seals is likely increasing in the U.S. Atlantic, as well as in Canada (Hayes *et al.,* 2020). For harp seals (no recent UME), the total U.S. fishery-related mortality and serious injury for this stock is very low relative to the stock size and can be considered insignificant and approaching zero mortality and serious injury rate (Hayes *et al.,* 2022). The harp seal stock abundance appears to have stabilized (Hayes *et al.,* 2022).

Overall, impacts from the Level B harassment take proposed for authorization incidental to Empire Wind's specified activities would be of relatively low magnitude and a low severity. These effects are not expected to result in impacts on the reproduction or survival of any individuals, let alone have impacts on annual rates of recruitment or survival of this stock. In consideration of all of the effects of Empire Wind's activities combined, we have preliminarily determined that the authorized take will have a negligible impact on harbor seals and gray seals.

Preliminary Negligible Impact Determination

No mortality or serious injury is anticipated to occur or proposed to be authorized. As described in the preliminary analysis above, the impacts resulting from Empire Wind's activities cannot be reasonably expected to, and are not reasonably likely to, adversely affect any of the species or stocks for which take is proposed for authorization through effects on annual rates of recruitment or survival. Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed mitigation and monitoring measures, NMFS preliminarily finds that the marine mammal take from all of Empire Wind's specified activities combined will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted above, only small numbers of incidental take 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 less 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.

NMFS proposes to authorize incidental take (by Level A harassment and Level B harassment) of 17 species of marine mammal (with 18 managed stocks). The maximum number of takes possible within any one year and proposed for authorization relative to the best available population abundance is less than one-third for all species and stocks potentially impacted (*i.e.,* less than 1 percent for 11 stocks and less than 5 percent for the remaining except for the common dolphin (5.71 percent) and the bottlenose dolphin northern migratory coastal (17.84 percent) as shown in Table 36.

Based on the analysis contained herein of the proposed activities (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

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 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 promulgation of rulemakings, NMFS consults internally whenever we propose to authorize take for endangered or threatened species, in this case with the NMFS Greater Atlantic Regional Field Office (GARFO).

NMFS is proposing to authorize the take of four marine mammal species which are listed under the ESA: the North Atlantic right, sei, fin, and sperm whale. The Permit and Conservation Division will request initiation of Section 7 consultation with GARFO for the issuance of this proposed rulemaking. NMFS will conclude the Endangered Species Act consultation prior to reaching a determination regarding the proposed issuance of the authorization. The proposed regulations and any subsequent LOA(s) would be conditioned such that, in addition to measures included in those documents, Empire Wind would also be required to abide by the reasonable and prudent measures and terms and conditions of a Biological Opinion and Incidental Take Statement, issued by NMFS, pursuant to Section 7 of the Endangered Species Act.

Proposed Promulgation

As a result of these preliminary determinations, NMFS proposes to promulgate a LOA to Empire Wind authorizing take, by Level A and B harassment, incidental to construction activities associated with the Empire Wind project offshore of New York for a 5-year period from January 22, 2024 through January 21, 2029, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Request for Additional Information and Public Comments

NMFS requests interested persons to submit comments, information, and suggestions concerning Empire Wind's request and the proposed regulations (see **ADDRESSES**). All comments will be reviewed and evaluated as we prepare the final rule and make final determinations on whether to issue the requested authorization. This proposed rule and referenced documents provide all environmental information relating to our proposed action for public review.

Recognizing, as a general matter, that this action is one of many current and future wind energy actions, we invite comment on the relative merits of the IHA, single-action rule/LOA, and programmatic multi-action rule/LOA approaches, including potential marine mammal take impacts resulting from this and other related wind energy actions and possible benefits resulting from regulatory certainty and efficiency.

Classification

Pursuant to the procedures established to implement Executive Order 12866, the Office of Management and Budget has determined that this proposed rule is not significant.

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), the Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. Empire Wind is the sole entity that would be subject to the requirements in these proposed regulations, and Empire Wind is not a small governmental jurisdiction, small organization, or small business, as defined by the RFA. Under the RFA, governmental jurisdictions are considered to be small if they are governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than 50,000. Because of this certification, a regulatory flexibility analysis is not required and none has been prepared.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act (PRA) unless that

collection of information displays a currently valid OMB control number. These requirements have been approved by OMB under control number 0648–0151 and include applications for regulations, subsequent LOA, and reports. Send comments regarding any aspect of this data collection, including suggestions for reducing the burden, to NMFS.

The Coastal Zone Management Act (CZMA) requires Federal actions within and outside the coastal zone that have reasonably foreseeable effects on any coastal use or natural resource of the coastal zone be consistent with the enforceable policies of a state's federally approved coastal management program. 16 U.S.C. 1456(c). Additionally, regulations implementing the CZMA require non-Federal applicants for Federal licenses or permits to submit a consistency certification to the state that declares that the proposed activity complies with the enforceable policies of the state's approved management program and will be conducted in a manner consistent with such program. As required, on June 24, 2021, Empire Wind submitted a Federal consistency certification to New York and voluntarily submitted a Federal consistency certification to New Jersey for approval of the Construction and Operations Plan (COP) by BOEM and the issuance of an Individual Permit by United States Army Corps of Engineers, under section 10 and 14 of the Rivers and Harbors Act and Section 404 of the Clean Water Act (15 CFR part 930, subpart E). New York began its review of the proposed activity pursuant to 15 CFR part 930, subpart D on November 18, 2022. NMFS has determined that Empire Wind's application for an authorization to allow the incidental, but not intentional, take of small numbers of marine mammals on the outer continental shelf is an unlisted activity and, thus, is not, at this time, subject to Federal consistency requirements in the absence of the receipt and prior approval of an unlisted activity review request from the state by the Director of NOAA's Office for Coastal Management.

List of Subjects in 50 CFR Part 217

Administrative practice and procedure, Endangered and threatened species, Fish, Fisheries, Marine mammals, Penalties, Reporting and recordkeeping requirements, Wildlife.

Dated: April 4, 2023.

Kelly Denit,

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

For reasons set forth in the preamble, NMFS proposes to amend 50 CFR part 217 as follows:

PART 217—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 217 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*

■ 2. Add subpart CC, consisting of §§ 217.280 through 217.289, to read as follows:

Subpart CC—Taking Marine Mammals Incidental to the Empire Wind Project, Offshore New York

Sec.

217.280 Specified activity and specified geographical region.
217.281 Effective dates.
217.282 Permissible methods of taking.
217.283 Prohibitions.
217.284 Mitigation requirements.
217.285 Requirements for monitoring and reporting.
217.286 Letter of Authorization.
217.287 Modifications of Letter of Authorization.
217.288—217.289 [Reserved]

Subpart CC—Taking Marine Mammals Incidental to the Empire Wind Project, Offshore New York

§ 217.280 Specified activity and specified geographical region.

(a) Regulations in this subpart apply only to the taking of marine mammals that occurs incidental to activities associated with construction of the Empire Wind Project by Empire Offshore Wind, LLC (Empire Wind) and those persons it authorizes or funds to conduct activities on its behalf in the area outlined in paragraph (b) of this section.

(b) The taking of marine mammals by Empire Wind may be authorized in a Letter of Authorization (LOA) only if it occurs in the Bureau of Ocean Energy Management (BOEM) lease area Outer Continental Shelf (OCS)–A–0512 Commercial Lease of Submerged Lands for Renewable Energy Development, along export cable routes, and at sea-to-shore transition points at South Brooklyn Marine Terminal, in Brooklyn, New York (EW1) and Long Island, NY (EW2) and at the Village of Island Park, NY (EW2).

(c) The taking of marine mammals by Empire Wind is only authorized if it occurs incidental to the following activities associated with the Empire Wind Project: installation of up to 147 wind turbine generators (WTG) and 2 offshore substation (OSS) foundations by impact pile driving; impact and vibratory pile driving associated with cable landfall construction and marina activities; and high-resolution geophysical (HRG) site characterization surveys.

§ 217.281 Effective dates.

Regulations in this subpart are effective from January 22, 2024, through January 21, 2029.

§ 217.282 Permissible methods of taking.

Under an LOA issued pursuant to §§ 216.106 and 217.286, Empire Wind, and those persons it authorizes or funds to conduct activities on its behalf, may incidentally, but not intentionally, take marine mammals within the area described in § 217.280(b) in the following ways, provided Empire Wind is in complete compliance with all terms, conditions, and requirements of the regulations in this subpart and the appropriate LOA:

(a) By Level B harassment associated with the acoustic disturbance of marine mammals by impact pile driving (WTG and OSS foundation installation), impact and vibratory pile driving during cable landfall construction and marina activities, and HRG site characterization surveys;

(b) By Level A harassment associated with the acoustic disturbance of marine mammals by impact pile driving WTG and OSS foundations;

(c) Take by mortality (death) or serious injury of any marine mammal species is not authorized; and

(d) The incidental take of marine mammals by the activities listed in paragraphs (a) and (b) of this section is limited to the following species:

TABLE 1 TO PARAGRAPH (d)

Marine mammal species	Scientific name	Stock
Fin whale	*Balaenoptera physalus*	Western North Atlantic.
Sei whale	*Balaenoptera borealis*	Nova Scotia.
Minke whale	*Balaenoptera acutorostrata*	Canadian East Stock.
North Atlantic right whale	*Eubalaena glacialis*	Western North Atlantic.

TABLE 1 TO PARAGRAPH (d)—Continued

Marine mammal species	Scientific name	Stock
Humpback whale	*Megaptera novaeangliae*	Gulf of Maine.
Sperm whale	*Physeter macrocephalus*	North Atlantic.
Atlantic spotted dolphin	*Stenella frontalis*	Western North Atlantic.
Atlantic white-sided dolphin	*Lagenorhynchus acutus*	Western North Atlantic.
Bottlenose dolphin	*Tursiops truncatus*	Western North Atlantic Offshore.
Common dolphin	*Delphinus delphis*	Western North Atlantic.
Harbor porpoise	*Phocoena phocoena*	Gulf of Maine/Bay of Fundy.
Long-finned pilot whale	*Globicephala melas*	Western North Atlantic.
Short-finned pilot whale	*Globicephala macrorhynchus*	Western North Atlantic.
Risso's dolphin	*Grampus griseus*	Western North Atlantic.
Gray seal	*Halichoerus grypus*	Western North Atlantic.
Harbor seal	*Phoca vitulina*	Western North Atlantic.
Harp seal	*Pagophilus groenlandicus*	Western North Atlantic.

§ 217.283 Prohibitions.

Except for the takings described in § 217.282 and authorized by an LOA issued under § 217.286 or § 217.287, it is unlawful for any person to do any of the following in connection with the activities described in this subpart:

(a) Violate, or fail to comply with, the terms, conditions, and requirements of this subpart or an LOA issued under §§ 217.286 and 217.287 of this subpart;

(b) Take any marine mammal not specified in § 217.282(c);

(c) Take any marine mammal specified in the LOA in any manner other than as specified in the LOA; or

(d) Take any marine mammal, as specified in § 217.282(c), after NMFS determines such taking results in more than a negligible impact on the species or stocks of such marine mammals.

§ 217.284 Mitigation requirements.

When conducting the activities identified in §§ 217.280(a) and 217.282, Empire Wind must implement the mitigation measures contained in this section and any LOA issued under § 217.286 or § 217.287. These mitigation measures include, but are not limited to:

(a) *General conditions.* The following measures apply to the Empire Wind Project:

(1) A copy of any issued LOA must be in the possession of Empire Wind and its designees, all vessel operators, visual protected species observers (PSOs), passive acoustic monitoring (PAM) operators, pile driver operators, and any other relevant designees operating under the authority of the issued LOA;

(2) Empire Wind must conduct briefings between construction supervisors, construction crews, and the PSO and PAM team prior to the start of all construction activities, and when new personnel join the work, in order to explain responsibilities, communication procedures, marine mammal monitoring and reporting protocols, and operational procedures. An informal guide must be included with the Marine Mammal Monitoring Plan to aid personnel in identifying species if they are observed in the vicinity of the project area;

(3) Empire Wind must instruct all vessel personnel regarding the authority of the PSO(s). Any disagreement between the Lead PSO and the vessel operator would only be discussed after shutdown has occurred;

(4) Empire Wind must ensure that any visual observations of an ESA-listed marine mammal are communicated to PSOs and vessel captains during the concurrent use of multiple project-associated vessels (of any size; *e.g.,* construction surveys, crew/supply transfers, *etc.*);

(5) If an individual from a species for which authorization has not been granted, or a species for which authorization has been granted but the authorized take number has been met, is observed entering or within the relevant Level B harassment zone for each specified activity, pile driving and HRG acoustic sources must be shut down immediately, unless shutdown would result in imminent risk of injury or loss of life to an individual or risk of damage to a vessel that creates risk of injury or loss of life for individuals or be delayed if the activity has not commenced. Impact and vibratory pile driving and initiation of HRG acoustic sources must not commence or resume until the animal(s) has been confirmed to have left the relevant clearance zone or the observation time has elapsed with no further sightings.

(6) Prior to and when conducting any in-water construction activities and vessel operations, Empire Wind personnel (*e.g.,* vessel operators, PSOs) must use available sources of information on North Atlantic right whale presence in or near the project area including daily monitoring of the Right Whale Sightings Advisory System, and monitoring of Coast Guard VHF Channel 16 throughout the day to receive notification of any sightings and/or information associated with any Slow Zones (*i.e.,* Dynamic Management Areas (DMAs) and/or acoustically-triggered slow zones) to provide situational awareness for both vessel operators and PSOs; and

(7) Any marine mammals observed within a clearance or shutdown zone must be allowed to remain in the area (*i.e.,* must leave of their own volition) prior to commencing pile driving activities or HRG surveys;

(8) Empire Wind must treat any large whale sighted by a PSO or acoustically detected by a PAM operator as if it were a North Atlantic right whale, unless a PSO or a PAM operator confirms it is another type of whale; and

(9) For in-water construction heavy machinery activities other than impact or vibratory pile driving, if a marine mammal is on a path towards or comes within 10 m of equipment, Empire Wind must cease operations until the marine mammal has moved more than 10 m on a path away from the activity to avoid direct interaction with equipment.

(b) *Vessel strike avoidance measures.* The following measures apply to all vessels associated with the Empire Wind Project:

(1) Prior to the start of construction activities, all vessel operators and crew must receive a protected species identification training that covers, at a minimum:

(i) Identification of marine mammals and other protected species known to occur or which have the potential to occur in the Empire Wind project area;

(ii) Training on making observations in both good weather conditions (*i.e.,* clear visibility, low winds, low sea states) and bad weather conditions (*i.e.,* fog, high winds, high sea states, with glare);

(iii) Training on information and resources available to the project

personnel regarding the applicability of Federal laws and regulations for protected species;

(iv) Observer training related to these vessel strike avoidance measures must be conducted for all vessel operators and crew prior to the start of in-water construction activities; and

(v) Confirmation of marine mammal observer training must be documented on a training course log sheet and reported to NMFS.

(2) All vessel operators and crews, regardless of their vessel's size, must maintain a vigilant watch for all marine mammals and slow down, stop their vessel, or alter course, as appropriate, to avoid striking any marine mammal;

(3) All vessels must have a visual observer on board who is responsible for monitoring the vessel strike avoidance zone for marine mammals. Visual observers may be PSO or crew members, but crew members responsible for these duties must be provided sufficient training by Empire Wind to distinguish marine mammals from other types of animals or objects and must be able to identify a marine mammal as a North Atlantic right whale, other whale (defined in this context as sperm whales or baleen whales other than North Atlantic right whales), or other marine mammal. Crew members serving as visual observers must not have duties other than observing for marine mammals while the vessel is operating over 10 knots (kts);

(4) Year-round and when a vessel is in transit, all vessel operators must continuously monitor U.S. Coast Guard VHF Channel 16, over which North Atlantic right whale sightings are broadcasted. At the onset of transiting and at least once every four hours, vessel operators and/or trained crew members must monitor the project's Situational Awareness System, WhaleAlert, and the Right Whale Sighting Advisory System (RWSAS) for the presence of North Atlantic right whales Any observations of any large whale by any Empire Wind staff or contractors, including vessel crew, must be communicated immediately to PSOs, PAM operator, and all vessel captains to increase situational awareness. Conversely, any large whale observation or detection via a sighting network (*e.g.,* Mysticetus) by PSOs or PAM operators must be conveyed to vessel operators and crew;

(5) Any observations of any large whale by any Empire Wind staff or contractor, including vessel crew, must be communicated immediately to PSOs and all vessel captains to increase situational awareness. Any large whale observation or detections via a sighting network (*e.g.,* Mysticetus) by PSOs or PAM operators will be conveyed to vessel operators and crew;

(6) All vessels must comply with existing NMFS vessel speed regulations in 50 CFR 224.105, as applicable, for North Atlantic right whales;

(7) All vessels must transit active Slow Zones, Dynamic Management Areas (DMAs), and Seasonal Management Areas (SMAs) at 10 kts or less;

(8) Between November 1st and April 30th, all vessels traveling to and from ports in New Jersey, New York, Maryland, Delaware, and Virginia must transit at 10 kts or less;

(9) All vessels, regardless of size, must immediately reduce speed to 10 kts or less when any large whale, mother/calf pairs, or large assemblages of non-delphinid cetaceans are observed (within 500 m) of an underway vessel;

(10) All vessels, regardless of size, must immediately reduce speed to 10 kts or less when a North Atlantic right whale is sighted, at any distance, by anyone on the vessel;

(11) All underway vessels (*e.g.,* transiting, surveying) operating at any speed must have a dedicated visual observer on duty at all times to monitor for marine mammals within a 180° direction of the forward path of the vessel (90° port to 90° starboard) located at the best vantage point for ensuring vessels are maintaining appropriate separation distances from marine mammals. Visual observers must be equipped with alternative monitoring technology for periods of low visibility (*e.g.,* darkness, rain, fog, etc.). The dedicated visual observer must receive prior training on protected species detection and identification, vessel strike minimization procedures, how and when to communicate with the vessel captain, and reporting requirements. Visual observers may be third-party observers (*i.e.,* NMFS-approved PSOs) or crew members. Observer training related to these vessel strike avoidance measures must be conducted for all vessel operators and crew prior to the start of vessel use;

(12) All vessels must maintain a minimum separation distance of 500 m from North Atlantic right whales. If underway, all vessels must steer a course away from any sighted North Atlantic right whale at 10 kts or less such that the 500-m minimum separation distance requirement is not violated. If a North Atlantic right whale is sighted within 500 m of an underway vessel, that vessel must shift the engine to neutral. Engines must not be engaged until the whale has moved outside of the vessel's path and beyond 500 m. If a whale is observed but cannot be confirmed as a species other than a North Atlantic right whale, the vessel operator must assume that it is a North Atlantic right whale.

(13) All vessels must maintain a minimum separation distance of 100 m from sperm whales and baleen whales other than North Atlantic right whales. If one of these species is sighted within 100 m of an underway vessel, that vessel must shift the engine to neutral. Engines must not be engaged until the whale has moved outside of the vessel's path and beyond 100 m;

(14) All vessels must maintain a minimum separation distance of 50 m from all delphinoid cetaceans and pinnipeds, with an exception made for those that approach the vessel (*e.g.,* bow-riding dolphins). If a delphinid cetacean or pinniped is sighted within 50 m of an underway vessel, that vessel must shift the engine to neutral, with an exception made for those that approach the vessel (*e.g.,* bow-riding dolphins). Engines must not be engaged until the animal(s) has moved outside of the vessel's path and beyond 50 m;

(15) When a marine mammal(s) is sighted while a vessel is underway, the vessel must take action as necessary to avoid violating the relevant separation distances (*e.g.,* attempt to remain parallel to the animal's course, avoid excessive speed or abrupt changes in direction until the animal has left the area). If a marine mammal(s) is sighted within the relevant separation distance, the vessel must shift the engine to neutral and not engage the engine(s) until the animal(s) outside and on a path away from the separation area. This does not apply to any vessel towing gear or any situation where respecting the relevant separation distance would be unsafe (*i.e.,* any situation where the vessel is navigationally constrained);

(16) All vessels underway must not divert or alter course to approach any marine mammal. Any vessel underway must avoid speed over 10 kts or abrupt changes in course direction until the animal is out of an on a path away from the separation distances; and

(17) If a vessel is traveling at greater than 10 kts, in addition to the required dedicated visual observer, Empire Wind must monitor the transit corridor in real-time with PAM prior to and during transits. If a North Atlantic right whale is detected via visual observation or PAM within or approaching the transit corridor, all crew transfer vessels must travel at 10 kts or less for 12 hours following the detection. Each subsequent detection triggers an additional 12-hour period at 10 kts or

less. A slowdown in the transit corridor expires when there has been no further visual or acoustic detection of North Atlantic right whales in the transit corridor for 12 hours;

(18) Empire Wind must submit a North Atlantic right whale vessel strike avoidance plan 90 days prior to commencement of vessel use. The plan will, at minimum, describe how PAM, in combination with visual observations, will be conducted to ensure the transit corridor is clear of right whales. The plan will also provide details on the vessel-based observer protocols on transiting vessels.

(c) *WTG and OSS foundation installation.* The following requirements apply to pile driving activities associated with the installation of WTG and OSS foundations:

(1) Foundation impact pile driving activities may not occur January 1 through April 30;

(2) Pile driving may not occur from December 1 through December 31, unless unanticipated delays due to weather or technical issues arise that necessitate extending pile driving into December. If impact pile driving must occur in December, Empire Wind must notify NOAA Fisheries in writing by September 1 that circumstances are expected to necessitate pile driving in December;

(3) Monopiles must be no larger than 11 m in diameter. Pin piles must be no larger than 2.5 m in diameter. During all monopile and pin pile installation, the minimum amount of hammer energy necessary to effectively and safely install and maintain the integrity of the piles must be used. Hammer energies must not exceed 5,500 kJ for monopile installation and 3,200 kJ for pin pile installation. No more than two monopile foundations or three pin piles for jacket foundations may be installed per day;

(4) Empire Wind must not initiate pile driving earlier than 1 hour after civil sunrise or later than 1.5 hours prior to civil sunset, unless Empire Wind submits, and NMFS approves, an Alternative Monitoring Plan as part of the Pile Driving and Marine Mammal Monitoring Plan that reliably demonstrates the efficacy of their night vision devices;

(5) Empire Wind must deploy dual noise attenuation systems that are capable of achieving, at a minimum, 10-dB of sound attenuation, during all impact pile driving of monopile and pin piles:

(i) A single bubble curtain must not be used unless paired with another noise attenuation device;

(ii) A big double bubble curtain may be used without being paired with another noise attenuation device;

(iii) The bubble curtain(s) must distribute air bubbles using an air flow rate of at least 0.5 $m^3/(min*m)$. The bubble curtain(s) must surround 100 percent of the piling perimeter throughout the full depth of the water column. In the unforeseen event of a single compressor malfunction, the offshore personnel operating the bubble curtain(s) must make appropriate adjustments to the air supply and operating pressure such that the maximum possible sound attenuation performance of the bubble curtain(s) is achieved;

(iv) The lowest bubble ring must be in contact with the seafloor for the full circumference of the ring, and the weights attached to the bottom ring must ensure 100-percent seafloor contact;

(v) No parts of the ring or other objects may prevent full seafloor contact; and

(vi) Construction contractors must train personnel in the proper balancing of airflow to the ring. Construction contractors must submit an inspection/performance report for approval by Empire Wind within 72 hours following the performance test. Empire Wind must then submit that report to NMFS; and

(vii) Corrections to the bubble ring(s) to meet the performance standards in this paragraph (c)(5) must occur prior to impact pile driving of monopiles and pin piles. If Empire Wind uses a noise mitigation device in addition to the bubble curtain, Empire Wind must maintain similar quality control measures as described in this paragraph (c)(2);

(6) Empire Wind must have a minimum of two PSOs actively observing marine mammals before, during, and after the installation of all foundation piles (*i.e.,* pin piles and monopiles). Concurrently, at least one PAM operator must be actively monitoring for marine mammals before, during and after impact pile driving with PAM;

(7) All visual PSOs and PAM operators used for the Empire Wind project must meet the requirements and qualifications described in § 217.285(a) through (e), as applicable to the specified activity;

(8) Empire Wind must establish and implement clearance and shutdown zones (all distances to the perimeter are the radii from the center of the pile being driven) as described in the LOA for all monopile and pin pile installation;

(9) Empire Wind must use visual PSOs and PAM operators to monitor the area around each foundation pile before, during and after pile driving. PSOs must visually monitor clearance zones for marine mammals for a minimum of 60 minutes prior to commencing pile driving. At least one PAM operator must review data from at least 24 hours prior to pile driving and actively monitor hydrophones for 60 minutes prior to pile driving. Prior to initiating soft-start procedures, all clearance zones must be confirmed to be free of marine mammals for 30 minutes immediately prior to starting a soft-start of pile driving;

(10) PSOs must be able to visually clear (*i.e.,* confirm no marine mammals are present) an area that extends around the pile being driven. The entire minimum visibility zone must be visible (*i.e.,* not obscured by dark, rain, fog, etc.) for a full 60 minutes immediately prior to commencing impact pile driving (minimum visibility zone size dependent on season);

(11) If a marine mammal is observed acoustically detected within the relevant clearance zone prior to the initiation of impact pile driving activities, pile driving must be delayed and must not begin until either the marine mammal(s) has voluntarily left the specific clearance zones and have been visually or acoustically confirmed beyond that clearance zone, or, when specific time periods have elapsed with no further sightings or acoustic detections. The specific time periods are 15 minutes for small odontocetes and pinnipeds and 30 minutes for all other marine mammal species;

(12) The clearance zone may only be declared clear if no confirmed North Atlantic right whale acoustic detections (in addition to visual) have occurred within the PAM clearance zone during the 60-minute monitoring period. Any large whale sighting by a PSO or detected by a PAM operator that cannot be identified as a non-North Atlantic right whale must be treated as if it were a North Atlantic right whale;

(13) If a marine mammal is observed entering or within the respective shutdown zone, as defined in the LOA, after impact pile driving has begun, the PSO must call for a temporary shutdown of impact pile driving;

(14) Empire Wind must immediately cease pile driving if a PSO calls for shutdown, unless shutdown is not practicable due to imminent risk of injury or loss of life to an individual or pile refusal or instability. In this situation, Empire Wind must reduce hammer energy to the lowest level practicable and the reason(s) for not

shutting down must be documented and reported to NMFS;

(15) Pile driving must not restart until either the marine mammal(s) has voluntarily left the specific clearance zones and has been visually or acoustically confirmed beyond that clearance zone, or, when specific time periods have elapsed with no further sightings or acoustic detections have occurred. The specific time periods are 15 minutes for small odontocetes and pinnipeds and 30 minutes for all other marine mammal species. In cases where these criteria are not met, pile driving may restart only if necessary to maintain pile stability at which time Empire Wind must use the lowest hammer energy practicable to maintain stability;

(16) If impact pile driving has been shut down due to the presence of a North Atlantic right whale, pile driving may not restart until the North Atlantic right whale is no longer observed or 30 minutes has elapsed since the last detection;

(17) Empire Wind must utilize a soft-start protocol for impact pile driving of monopiles by performing 4–6 strikes per minute at 10 to 20 percent of the maximum hammer energy, for a minimum of 20 minutes;

(18) Soft-start must occur at the beginning of monopile installation and at any time following a cessation of impact pile driving of 30 minutes or longer;

(19) If a marine mammal is detected within or about to enter the applicable clearance zones, prior to the beginning of soft-start procedures, impact pile driving must be delayed until the animal has been visually observed exiting the clearance zone or until a specific time period has elapsed with no further sightings. The specific time periods are 15 minutes for small odontocetes and pinnipeds and 30 minutes for all other species;

(20) PAM operators must assist the visual PSOs in monitoring by conducting PAM activities 60 minutes prior to any impact pile driving, at all times during pile driving, and for 30 minutes after pile driving completion for the appropriate size PAM clearance zone (dependent on season). The entire minimum visibility zone must be clear for at least 30 minutes, with no marine mammal detections within the visual or PAM clearance zones prior to the start of impact pile driving. PAM operators must immediately communicate all detections of marine mammals at any distance (*i.e.,* not limited to the Level B harassment zones) to the Lead PSO, including any determination regarding species identification, distance, and bearing and the degree of confidence in the determination;

(21) Any acoustic monitoring must complement visual monitoring efforts and must cover an area of at least the Level B harassment zone around each monopile foundation;

(22) Empire Wind must submit a Pile Driving and Marine Mammal Monitoring Plan to NMFS for review and approval at least 180 days before the start of any pile driving. The plan must include final project design related to pile driving (*e.g.,* number and type of piles, hammer type, noise attenuation systems, anticipated start date, etc.) and all information related to PSO and PAM monitoring protocols;

(23) Empire Wind must submit a Passive Acoustic Monitoring Plan to NMFS for review and approval at least 180 days prior to the planned start of monopile installation. The plan must describe all proposed PAM equipment, procedures, and protocols. The authorization to take marine mammals is contingent upon NMFS' approval of the PAM Plan;

(24) Empire Wind must conduct sound field verification (SFV) on the first three monopiles installed and all piles associated with the first OSS foundation installed. Subsequent SFV is required should additional piles be driven that are anticipated to produce louder sound fields than those previously measured;

(25) Empire Wind must conduct SFV after construction is complete to estimate turbine operational source levels based on measurements in the near and far-field at a minimum of three locations from each foundation monitored. These data must be used to also identify estimated transmission loss rates;

(26) Empire Wind must submit a sound field verification (SFV) plan to NOAA Fisheries for review and approval at least 180 days prior to planned start of pile driving that identifies how Empire Wind will comply with the following requirements:

(i) Empire Wind must empirically determine source levels, the ranges to the isopleths corresponding to the Level A harassment and Level B harassment thresholds in meters, and the transmission loss coefficient(s). Empire Wind may also estimate ranges to the Level A harassment and Level B harassment isopleths by extrapolating from *in situ* measurements conducted at several distances from the piles monitored;

(ii) Empire Wind must perform sound field measurements at four distances from the pile being driven, including, but not limited to, 750 m and the modeled Level B harassment zones to verify the accuracy of those modeled zones;

(iii) The recordings must be continuous throughout the duration of all impact hammering of each pile monitored;

(iv) The measurement systems must have a sensitivity appropriate for the expected sound levels from pile driving received at the nominal ranges throughout the installation of the pile;

(v) The frequency range of the system must cover the range of at least 20 Hz to 20 kHz;

(vi) The system will be designed to have omnidirectional sensitivity and will be designed so that the predicted broadband received level of all impact pile-driving strikes exceed the system noise floor by at least 10 dB. The dynamic range of the system must be sufficient such that at each location, pile driving signals are not clipped and are not masked by noise floor; and

(vii) Identify operational noise levels and transmission loss rates.

(27) If acoustic field measurements collected during installation of foundation piles indicate ranges to the isopleths, corresponding to Level A harassment and Level B harassment thresholds, are greater than the ranges predicted by modeling (assuming 10 dB attenuation), Empire Wind must implement additional noise mitigation measures prior to installing the next monopile. Each modification must be evaluated empirically by acoustic field measurements;

(28) In the event that field measurements indicate ranges to isopleths, corresponding to Level A harassment and Level B harassment thresholds, are greater than the ranges predicted by modeling (assuming 10 dB attenuation), NMFS may expand the relevant harassment, clearance, and shutdown zones and associated monitoring protocols;

(29) If harassment zones are expanded beyond an additional 1,500 m, additional PSOs would be deployed on additional platforms with each observer responsible for maintaining watch in no more than 180 degrees and of an area with a radius no greater than 1,500 m;

(30) If acoustic measurements indicate that ranges to isopleths corresponding to the Level A harassment and Level B harassment thresholds are less than the ranges predicted by modeling (assuming 10 dB attenuation), Empire Wind may request to NMFS a modification of the clearance and shutdown zones for impact pile driving of monopiles and jacket foundation piles;

(31) For NMFS to consider a modification request for reduced zone sizes, Empire Wind must have had to conduct SFV on three or more monopiles to verify that zone sizes are consistently smaller than those predicted by modeling (assuming 10 dB attenuation) and subsequent piles would be installed within and under similar conditions (*e.g.,* monitoring data collected during installation of a typical pile can not be used to adjust difficult-to-drive pile ranges); and

(32) If a subsequent monopile installation location is selected that was not represented by the previous three locations (*i.e.,* substrate composition, water depth), SFV would be required.

(d) *Cable landfall construction and marina activities.* The following requirements apply to cable landfall and marina pile driving activities:

(1) Empire Wind must conduct impact and vibratory pile driving during daylight hours only;

(2) Empire Wind must have a minimum of two PSOs on active duty during any installation and removal of the temporary cofferdams and goal posts. These PSOs must be located at the best vantage point(s) on the vibratory pile driving platform or secondary platform in the immediate vicinity of the vibratory pile driving platform, in order to ensure that appropriate visual coverage is available for the entire visual clearance zone and as much of the Level B harassment zone, as possible;

(3) If a marine mammal is observed entering or within the respective shutdown zone, as defined in the LOA, after pile driving has begun, the PSO must call for a temporary shutdown of pile driving;

(4) Empire Wind must immediately cease pile driving if a PSO calls for shutdown, unless shutdown is not practicable due to imminent risk of injury or loss of life to an individual or pile refusal or instability. In this situation, Empire Wind must reduce hammer energy to the lowest level practicable and the reason(s) for not shutting down must be documented and reported to NMFS; and

(5) Pile driving must not restart until either the marine mammal(s) has voluntarily left the specific clearance zones and has been visually or acoustically confirmed beyond that clearance zone, or, when specific time periods have elapsed with no further sightings or acoustic detections have occurred. The specific time periods are 15 minutes for small odontocetes and pinnipeds and 30 minutes for all other marine mammal species. In cases where these criteria are not met, pile driving may restart only if necessary to maintain pile stability at which time Empire Wind must use the lowest hammer energy practicable to maintain stability.

(e) *HRG surveys.* The following requirements apply to HRG surveys operating sub bottom profilers (SBPs):

(1) Per vessel, Empire Wind would be required to have at least one PSO on active duty during HRG surveys that are conducted during daylight hours (*i.e.,* from 30 minutes prior to sunrise through 30 minutes following sunset) and at least two PSOs during HRG surveys that are conducted during nighttime hours;

(2) Empire Wind must deactivate acoustic sources during periods where no data are being collected, except as determined to be necessary for testing. Unnecessary use of the acoustic source(s) is prohibited;

(3) All personnel with responsibilities for marine mammal monitoring must participate in joint, onboard briefings that would be led by the vessel operator and the Lead PSO, prior to the beginning of survey activities. The briefing must be repeated whenever new relevant personnel (*e.g.,* new PSOs, acoustic source operators, relevant crew) join the survey operation before work commences;

(4) PSOs must begin visually monitoring clearance and shutdown zones 30 minutes prior to the initiation of the specified acoustic source (*i.e.,* ramp-up, if applicable), during the HRG activities, and for 30 minutes after the use of the specified acoustic source has ceased;

(5) Empire Wind is required to ramp-up sub-bottom profilers (SBPs) prior to commencing full power (unless the equipment operates on a binary on/off switch) and only when visual clearance zones are fully visible (*e.g.,* not obscured by darkness, rain, fog, etc.) and clear of marine mammals, as determined by the Lead PSO, for at least 30 minutes immediately prior to the initiation of survey activities using a specified acoustic source;

(6) Prior to a ramp-up procedure starting, the operator must notify the Lead PSO of the planned start of the ramp-up. This notification time must not be less than 60 minutes prior to the planned ramp-up activities as all relevant PSOs must monitor the clearance zone for 30 minutes prior to the initiation of ramp-up;

(7) Prior to starting the survey and after receiving confirmation from the PSOs that the clearance zone is clear of any marine mammals, Empire Wind must ramp-up sources to half power for 5 minutes and then proceed to full power, unless the source operates on a binary on/off switch in which case ramp-up is not required. Ramp-up activities must be delayed if a marine mammal(s) enters its respective shutdown zone. Ramp-up may only be reinitiated if the animal(s) has been observed exiting its respective shutdown zone or until 15 minutes for small odontocetes and pinnipeds, and 30 minutes for all other species;

(8) Empire Wind must implement a 30-minute clearance period of the clearance zones immediately prior to the commencing of the survey or when there is more than a 30-minute break in survey activities or PSO monitoring;

(9) If a marine mammal is observed within a clearance zone during the clearance period, ramp-up or acoustic surveys may not begin until the animal(s) has been observed voluntarily exiting its respective clearance zone or until a specific time period has elapsed with no further sighting. The specific time period is 15 minutes for small odontocetes and seals, and 30 minutes for all other species;

(10) In any case when the clearance process has begun in conditions with good visibility, including via the use of night vision equipment (IR/thermal camera), and the Lead PSO has determined that the clearance zones are clear of marine mammals, survey operations would be allowed to commence (*i.e.,* no delay is required) despite periods of inclement weather and/or loss of daylight;

(11) Once the survey has commenced, Empire Wind must shut down SBPs if a marine mammal enters a respective shutdown zone, except in cases when the shutdown zones become obscured for brief periods due to inclement weather, survey operations would be allowed to continue (*i.e.,* no shutdown is required) so long as no marine mammals have been detected. The shutdown requirement does not apply to small delphinids of the following genera: *Delphinus, Stenella, Lagenorhynchus,* and *Tursiops.* If there is uncertainty regarding the identification of a marine mammal species (*i.e.,* whether the observed marine mammal belongs to one of the delphinid genera for which shutdown is waived), the PSOs must use their best professional judgment in making the decision to call for a shutdown. Shutdown is required if a delphinid that belongs to a genus other than those specified here is detected in the shutdown zone;

(12) If SBPs have been shutdown due to the presence of a marine mammal, the use of SBPs not commence or resume until the animal(s) has been confirmed to have left the Level B harassment zone

or until a full 15 minutes (for small odontocetes and seals) or 30 minutes (for all other marine mammals) have elapsed with no further sighting;

(13) Empire Wind must immediately shutdown any SBP acoustic source if a marine mammal is sighted entering or within its respective shutdown zones;

(14) If a SBP is shut down for reasons other than mitigation (*e.g.,* mechanical difficulty) for less than 30 minutes, it would be allowed to be activated again without ramp-up only if:

(i) PSOs have maintained constant observation; and

(ii) No additional detections of any marine mammal occurred within the respective shutdown zones;

(17) If a SBP was shut down for a period longer than 30 minutes, then all clearance and ramp-up procedures must be initiated; and

(18) If multiple HRG vessels are operating concurrently, any observations of marine mammals must be communicated to PSOs on all nearby survey vessels.

(f) *Trawl Surveys.* The following measures apply to all trawl surveys:

(1) All captains and crew conducting fishery surveys will be trained in marine mammal detection and identification. Marine mammal monitoring will be conducted by the captain and/or a member of the scientific crew before (within 1 nautical mile (nm) and 15 minutes prior to deploying gear), during, and after haul back;

(2) Survey gear will be deployed as soon as possible once the vessel arrives on station;

(3) Empire Wind and/or its cooperating institutions, contracted vessels, or commercially-hired captains must implement the following ''move-on'' rule: If marine mammals are sighted within 1 nm of the planned location and 15 minutes before gear deployment, Empire Wind and/or its cooperating institutions, contracted vessels, or commercially-hired captains, as appropriate, may decide to move the vessel away from the marine mammal to a different section of the sampling area if the animal appears to be at risk of interaction with the gear, based on best professional judgment. If, after moving on, marine mammals are still visible from the vessel, Empire Wind and/or its cooperating institutions, contracted vessels, or commercially-hired captains may decide to move again or to skip the station;

(4) If a marine mammal is deemed to be at risk of interaction after the gear is set, all gear will be immediately removed from the water;

(5) Empire Wind will maintain visual monitoring effort during the entire period of time that gear is in the water (*i.e.,* throughout gear deployment, fishing, and retrieval). If marine mammals are sighted before the gear is fully removed from the water, Empire Wind will take the most appropriate action to avoid marine mammal interaction;

(6) Trawls must have a limited tow time of 20 minutes (and depth);

(7) Empire Wind must open the codend of the trawl net close to the deck/sorting area to avoid damage to animals that may be caught in gear; and

(8) Trawl nets must be fully cleaned and repaired (if damaged) before setting again; and

(9) Any lost gear associated with the fishery surveys must be reported to the NOAA Greater Atlantic Regional Fisheries Office Protected Resources Division within 48 hours.

§ 217.285 Requirements for monitoring and reporting.

(a) *Protected Species Observer (PSO) and PAM operator qualifications.* The following measures apply to PSOs and PAM operators:

(1) Empire Wind must use independent, dedicated, qualified PSOs, meaning that the PSOs must be employed by a third-party observer provider, must have no tasks other than to conduct observational effort, collect data, and communicate with and instruct relevant vessel crew with regard to the presence of protected species and mitigation requirements;

(2) PSOs must successfully complete relevant training, including completion of all required coursework and passing a written and/or oral examination developed for the training;

(3) PSOs must have successfully attained a bachelor's degree from an accredited college or university with a major in one of the natural sciences, a minimum of 30 semester hours or equivalent in the biological sciences, and at least one undergraduate course in math or statistics. The educational requirements may be waived if the PSO has acquired the relevant skills through alternate experience. Requests for such a waiver shall be submitted to NMFS and must include written justification. Alternate experience that may be considered includes, but is not limited to: Secondary education and/or experience comparable to PSO duties; previous work experience conducting academic, commercial, or government sponsored marine mammal surveys; or previous work experience as a PSO; the PSO should demonstrate good standing and consistently good performance of PSO duties;

(4) PSOs must have visual acuity in both eyes (with correction of vision being permissible) sufficient enough to discern moving targets on the water's surface with the ability to estimate the target size and distance (binocular use is allowable); Ability to conduct field observations and collect data according to the assigned protocols; Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations; writing skills sufficient to document observations, including but not limited to, the number and species of marine mammals observed, the dates and times of when in-water construction activities were conducted, the dates and time when in-water construction activities were suspended to avoid potential incidental injury of marine mammals from construction noise within a defined shutdown zone, and marine mammal behavior; and the 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;

(5) All PSOs must be approved by NMFS. Empire Wind must submit PSO resumes for NMFS' review and approval at least 60 days prior to commencement of in-water construction activities requiring PSOs. Resumes must include dates of training and any prior NMFS approval, as well as dates and description of last experience, and must be accompanied by information documenting successful completion of an acceptable training course. NMFS shall be allowed three weeks to approve PSOs from the time that the necessary information is received by NMFS, after which PSOs meeting the minimum requirements will automatically be considered approved;

(6) PSOs must have visual acuity in both eyes (with correction of vision being permissible) sufficient enough to discern moving targets on the water's surface with the ability to estimate the target size and distance (binocular use is allowable);

(7) All PSOs must be trained in marine mammal identification and behaviors and must be able to conduct field observations and collect data according to assigned protocols. Additionally, PSOs must have the ability to work with all required and relevant software and equipment necessary during observations;

(8) At least one PSO on active duty for each activity (*i.e.,* foundation installation, cable landfall and marina activities, and HRG surveys) must be designated as the ''Lead PSO''. The Lead PSO must have a minimum of 90 days

of at-sea experience working in an offshore environment and is required to have no more than eighteen months elapsed since the conclusion of their last at-sea experience; and

(9) PAM operators must complete specialized training for operating PAM systems and must demonstrate familiarity with the PAM system on which they must be working. PSOs may act as both acoustic operators and visual observers (but not simultaneously), so long as they demonstrate that their training and experience are sufficient to perform each task.

(b) *General PSO requirements.* The following measures apply to PSOs during all project activities:

(1) All PSOs must be located at the best vantage point(s) on the primary vessel in order to obtain 360° visual coverage of the entire clearance and shutdown zones around the vessels, and as much of the Level B harassment zone as possible;

(2) During all visual observation periods, PSOs must use high magnification (25x) binoculars, standard handheld (7x) binoculars, and the naked eye to search continuously for marine mammals. During impact pile driving, at least one PSO on the primary pile driving must be equipped with Big Eye binoculars (*e.g.,* 25 x 150; 2.7 view angle; individual ocular focus; height control) of appropriate quality. These must be pedestal mounted on the deck at the best vantage point that provides for optimal sea surface observation and PSO safety;

(3) During periods of low visibility (*e.g.,* darkness, rain, fog, poor weather conditions, etc.), PSOs must use alternative technologies (*i.e.,* infrared or thermal cameras) to monitor the shutdown and clearance zones;

(4) PSOs must not exceed four consecutive watch hours on duty at any time, must have a two-hour (minimum) break between watches, and must not exceed a combined watch schedule of more than 12 hours in a 24-hour period;

(5) Any PSO has the authority to call for a delay or shutdown of project activities.

(6) Any visual observations of ESA-listed marine mammals must be communicated immediately to PSOs and vessel captains associated with other vessels to increase situational awareness; and

(7) Empire Wind's personnel and PSOs are required to use available sources of information on North Atlantic right whale presence to aid in monitoring efforts. These include daily monitoring of the Right Whale Sightings Advisory System, consulting of the WhaleAlert app, and monitoring of the Coast Guard's VHF Channel 16 throughout the day to receive notifications of any sightings and information associated with any Dynamic Management Areas, to plan construction activities and vessel routes, if practicable, to minimize the potential for co-occurrence with North Atlantic right whales.

(c) *PSO and PAM operator requirements during WTG and OSS foundation installation.* The following measures apply to PSOs and PAM operators during monopile and OSS foundation installation:

(1) At least two PSOs must be actively observing marine mammals before, during, and after installation of foundation piles (monopiles). At least two PSOs must be stationed and observing on the pile driving vessel. Concurrently, at least one acoustic monitoring PSO (*i.e.,* passive acoustic monitoring (PAM) operator) must be actively monitoring for marine mammals with PAM before, during and after impact pile driving;

(2) All on-duty visual PSOs must remain in contact with the on-duty PAM operator, who would monitor the PAM systems for acoustic detections of marine mammals in the area.

(3) If PSOs cannot visually monitor the minimum visibility zone at all times using the equipment described in paragraph (b)(1)(ii) of this section, impact pile driving operations must not commence or must shutdown if they are currently active;

(4) All PSOs must begin monitoring 60 minutes prior to pile driving, during, and for 30 minutes after an activity. The impact pile driving of monopiles must only commence when the minimum visibility zone is fully visible (*e.g.,* not obscured by darkness, rain, fog, etc.) and the clearance zones are clear of marine mammals for at least 30 minutes, as determined by the Lead PSO, immediately prior to the initiation of impact pile driving;

(5) For North Atlantic right whales, any visual or acoustic detection must trigger a delay to the commencement of pile driving. In the event that a large whale is sighted or acoustically detected that cannot be confirmed by species, it must be treated as if it were a North Atlantic right whale;

(6) Empire Wind must prepare and submit a Pile Driving and Marine Mammal Monitoring Plan to NMFS for review and approval at least 180 days before the start of any pile driving. The plans must include final pile driving project design (*e.g.,* number and type of piles, hammer type, noise attenuation systems, anticipated start date, *etc.*) and all information related to PAM PSO monitoring protocols for pile-driving and visual PSO protocols for all activities;

(8) Empire Wind must conduct PAM for at least 24 hours immediately prior to foundation installation pile driving activities;

(9) During use of any real-time PAM system, at least one PAM operator must be designated to monitor each system by viewing data or data products that would be streamed in real-time or in near real-time to a computer workstation and monitor;

(10) PAM operators may be located on a vessel or remotely on-shore but must have the appropriate equipment (*i.e.,* computer station equipped with a data collection software system (*i.e.,* Mysticetus or similar system and acoustic data analysis software) available wherever they are stationed;

(11) Visual PSOs must remain in contact with the PAM operator currently on duty regarding any animal detection that might be approaching or found within the applicable zones no matter where the PAM operator is stationed (*i.e.,* onshore or on a vessel); and

(12) PAM operators must be on watch for a maximum of four consecutive hours, followed by a break of at least two hours between watches, and may not exceed a combined watch schedule of more than 12 hours in a single 24-hour period.

(d) *PSO requirements during cable landfall construction and marina activities.* The following measures apply to PSOs during pile driving associated with cable landfall construction and marina activities:

(1) At least two PSOs must be on active duty during all activities related to the installation and removal of cofferdams, goal posts, and casing pipes;

(2) These PSOs must be located at the best vantage points on the pile driving platform or secondary platform in the immediate vicinity of the pile driving;

(3) PSOs must ensure that there is appropriate visual coverage for the entire clearance and shutdown zones and as much of the Level B harassment zone as possible; and

(4) PSOs must monitor the clearance zone for the presence of marine mammals for 30 minutes before, throughout pile driving, and for 30 minutes after all pile driving activities have ceased. Pile driving must only commence when visual clearance zones are fully visible (*e.g.,* not obscured by darkness, rain, fog, *etc.*) and clear of marine mammals, as determined by the Lead PSO, for at least 30 minutes immediately prior to initiation of impact or vibratory pile driving.

(e) *PSO requirements during HRG surveys.* The following measures apply to PSOs during HRG surveys using SBPs:

(1) At least one PSO must be on active duty monitoring during HRG surveys conducted during daylight (*i.e.,* from 30 minutes prior to sunrise through 30 minutes following sunset) and at least two PSOs must be on activity duty monitoring during HRG surveys conducted at night;

(2) During periods of low visibility (*e.g.,* darkness, rain, fog, *etc.*), PSOs must use alternative technology (*i.e.,* infrared/thermal camera) to monitor the clearance and shutdown zones;

(3) PSOs on HRG vessels must begin monitoring 30 minutes prior to activating SBPs during the use of these acoustic sources, and for 30 minutes after use of these acoustic sources has ceased;

(4) Any observations of marine mammals must be communicated to PSOs on all nearby survey vessels during concurrent HRG surveys; and

(5) During daylight hours when survey equipment is not operating, Empire Wind must ensure that visual PSOs conduct, as rotation schedules allow, observations for comparison of sighting rates and behavior with and without use of the specified acoustic sources. Off-effort PSO monitoring must be reflected in the monthly PSO monitoring reports.

(f) *Reporting.* Empire Wind must comply with the following reporting measures:

(1) Prior to initiation of project activities, Empire Wind must demonstrate in a report submitted to NMFS (at *robert.pauline@noaa.gov* and*pr.itp.monitoringreports@noaa.gov*) that all required training for Empire Wind personnel (including the vessel crews, vessel captains, PSOs, and PAM operators) has been completed;

(2) Empire Wind must use a standardized reporting system during the effective period of this subpart and LOA. All data collected related to the Empire Wind Project must be recorded using industry-standard softwares (*e.g.,* Mysticetus or a similar software) that is installed on field laptops and/or tablets. Empire Wind must submit weekly (during foundation installation only), monthly and annual reports as described below. For all monitoring efforts and marine mammal sightings, Empire Wind must collect the following information:

(i) Date and time that monitored activity begins or ends;

(ii) Construction activities occurring during each observation period;

(iii) Watch status (*i.e.,* sighting made by PSO on/off effort, opportunistic, crew, alternate vessel/platform);

(iv) PSO who sighted the animal;

(v) Time of sighting;

(vi) Weather parameters (*e.g.,* wind speed, percent cloud cover, visibility);

(vii) Water conditions (*e.g.,* sea state, tide state, water depth);

(viii) All marine mammal sightings, regardless of distance from the construction activity;

(ix) Species (or lowest possible taxonomic level possible);

(x) Pace of the animal(s);

(xi) Estimated number of animals (minimum/maximum/high/low/best);

(xii) Estimated number of animals by cohort (*e.g.,* adults, yearlings, juveniles, calves, group composition, etc.);

(xiii) Description (*i.e.,* as many distinguishing features as possible of each individual seen, including length, shape, color, pattern, scars or markings, shape and size of dorsal fin, shape of head, and blow characteristics);

(xiv) Description of any marine mammal behavioral observations (*e.g.,* observed behaviors such as feeding or traveling) and observed changes in behavior, including an assessment of behavioral responses thought to have resulted from the specific activity;

(xv) Animal's closest distance and bearing from the pile being driven or specified HRG equipment and estimated time entered or spent within the Level A harassment and/or Level B harassment zones;

(xvi) Activity at time of sighting (*e.g.,* vibratory installation/removal, impact pile driving, construction survey), use of any noise attenuation device(s), and specific phase of activity (*e.g.,* ramp-up of HRG equipment, HRG acoustic source on/off, soft-start for pile driving, active pile driving, *etc.*);

(xvii) Marine mammal occurrence in Level A harassment or Level B harassment zones;

(xviii) Description of any mitigation-related action implemented, or mitigation-related actions called for but not implemented, in response to the sighting (*e.g.,* delay, shutdown, etc.) and time and location of the action; and

(xix) Other human activity in the area.

(3) If a marine mammal is acoustically detected during PAM monitoring, the following information must be recorded and reported to NMFS:

(i) Location of hydrophone (latitude & longitude; in Decimal Degrees) and site name;

(ii) Bottom depth and depth of recording unit (in meters);

(iii) Recorder (model & manufacturer) and platform type (*i.e.,* bottom-mounted, electric glider, etc.), and instrument ID of the hydrophone and recording platform (if applicable);

(iv) Time zone for sound files and recorded date/times in data and metadata (in relation to UTC. *i.e.,* EST time zone is UTC–5);

(v) Duration of recordings (start/end dates and times; in ISO 8601 format, yyyy-mm-ddTHH:MM:SS.sssZ);

(vi) Deployment/retrieval dates and times (in ISO 8601 format);

(vii) Recording schedule (must be continuous);

(viii) Hydrophone and recorder sensitivity (in dB *re. 1*μ*Pa*);

(ix) Calibration curve for each recorder;

(x) Bandwidth/sampling rate (in Hz);

(xi) Sample bit-rate of recordings; and,

(xii) Detection range of equipment for relevant frequency bands (in meters);

(4) Information required for each detection, the following information must be noted:

(i) Species identification (if possible);

(ii) Call type and number of calls (if known);

(iii) Temporal aspects of vocalization (date, time, duration, etc.; date times in ISO 8601 format);

(iv) Confidence of detection (detected, or possibly detected);

(v) Comparison with any concurrent visual sightings;

(vi) Location and/or directionality of call (if determined) relative to acoustic recorder or construction activities;

(vii) Location of recorder and construction activities at time of call;

(viii) Name and version of detection or sound analysis software used, with protocol reference;

(ix) Minimum and maximum frequencies viewed/monitored/used in detection (in Hz); and

(x) Name of PAM operator(s) on duty.

(5) Empire Wind must compile and submit weekly reports to NMFS (at *robert.pauline@noaa.gov* and *PR.ITP.monitoringreports@noaa.gov*) that document the daily start and stop of all pile driving and HRG survey, the start and stop of associated observation periods by PSOs, details on the deployment of PSOs, a record of all detections of marine mammals (acoustic and visual), any mitigation actions (or if mitigation actions could not be taken, provide reasons why), and details on the noise attenuation system(s) used and its performance. Weekly reports are due on Wednesday for the previous week (Sunday–Saturday) and must include the information required under this section. The weekly report must also identify which turbines become operational and when (a map must be provided). Once all foundation pile installation is completed, weekly reports are no longer required;

(6) Empire Wind must compile and submit monthly reports to NMFS (at *robert.pauline@noaa.gov* and *PR.ITP.monitoringreports@noaa.gov*) that include a summary of all information in the weekly reports, including project activities carried out in the previous month, vessel transits (number, type of vessel, and route), number of piles installed, all detections of marine mammals, and any mitigative action taken. Monthly reports are due on the 15th of the month for the previous month. The monthly report must also identify which turbines become operational and when (a map must be provided). Once foundation installation is complete, monthly reports are no longer required;

(7) Empire Wind must submit an annual report to NMFS (at *robert.pauline@noaa.gov* and *PR.ITP.monitoringreports@noaa.gov*) no later than 90 days following the end of a given calendar year. Empire Wind must provide a final report within 30 days following resolution of comments on the draft report. The report must detail the following information:

(i) The total number of marine mammals of each species/stock detected and how many were within the designated Level A harassment and Level B harassment zones with comparison to authorized take of marine mammals for the associated activity type;

(ii) Marine mammal detections and behavioral observations before, during, and after each activity;

(iii) What mitigation measures were implemented (*i.e.,* number of shutdowns or clearance zone delays, etc.) or, if no mitigative actions was taken, why not;

(iv) Operational details (*i.e.,* days of impact and vibratory pile driving, days/amount of HRG survey effort etc.);

(v) Any PAM systems used;

(vi) The results, effectiveness, and which noise attenuation systems were used during relevant activities (*i.e.,* impact pile driving);

(vii) Summarized information related to Situational Reporting; and

(viii) Any other important information relevant to the Empire Wind Project, including additional information that may be identified through the adaptive management process.

(ix) The final annual report must be prepared and submitted within 30 calendar days following the receipt of any comments from NMFS on the draft report. If no comments are received from NMFS within 60 calendar days of NMFS' receipt of the draft report, the report must be considered final.

(8) Empire Wind must submit its draft final report to NMFS (at *robert.pauline@noaa.gov* and *PR.ITP.monitoringreports@noaa.gov*) on all visual and acoustic monitoring conducted under the LOA within 90 calendar days of the completion of activities occurring under the LOA. A final report must be prepared and submitted within 30 calendar days following receipt of any NMFS comments on the draft report. If no comments are received from NMFS within 30 calendar days of NMFS' receipt of the draft report, the report shall be considered final.

(9) Empire Wind must submit situational reports if the following circumstances occur:

(i) If a North Atlantic right whale is observed at any time by PSOs or personnel on or in the vicinity of any project vessel, or during vessel transit, Empire Wind must immediately report sighting information to the NMFS North Atlantic Right Whale Sighting Advisory System (866) 755–6622, through the WhaleAlert app (*http://www.whalealert/org/*), and to the U.S. Coast Guard via channel 16, as soon as feasible but no longer than 24 hours after the sighting. Information reported must include, at a minimum: time of sighting, location, and number of North Atlantic right whales observed.

(ii) When an observation of a large whale occurs during vessel transit, the following information must be recorded and reported to NMFS:

(A) Time, date, and location (latitude/longitude; in Decimal Degrees);

(B) The vessel's activity, heading, and speed;

(C) Sea state, water depth, and visibility;

(D) Marine mammal identification to the best of the observer's ability (*e.g.,* North Atlantic right whale, whale, dolphin, seal);

(E) Initial distance and bearing to marine mammal from vessel and closest point of approach; and

(F) Any avoidance measures taken in response to the marine mammal sighting.

(iii) If a North Atlantic right whale is detected via PAM, the date, time, location (*i.e.,* latitude and longitude of recorder) of the detection as well as the recording platform that had the detection must be reported to *nmfs.pacmdata@noaa.gov* as soon as feasible, but no longer than 24 hours after the detection. Full detection data and metadata must be submitted monthly on the 15th of every month for the previous month via the webform on the NMFS North Atlantic right whale Passive Acoustic Reporting System website (*https://www.fisheries.noaa.gov/resource/document/passive-acoustic-reporting-system-templates*);

(iv) In the event that the personnel involved in the activities defined in § 217.280(a) discover a stranded, entangled, injured, or dead marine mammal, Empire Wind must immediately report the observation to the NMFS Office of Protected Resources (OPR), the NMFS Greater Atlantic Stranding Coordinator for the New England/Mid-Atlantic area (866–755–6622), and the U.S. Coast Guard within 24 hours. If the injury or death was caused by a project activity, Empire Wind must immediately cease all activities until NMFS OPR 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 LOA. NMFS may impose additional measures to minimize the likelihood of further prohibited take and ensure MMPA compliance. Empire Wind may not resume their activities until notified by NMFS. The report must include the following information:

(A) Time, date, and location (latitude/longitude; in Decimal Degrees) of the first discovery (and updated location information if known and applicable);

(B) Species identification (if known) or description of the animal(s) involved;

(C) Condition of the animal(s) (including carcass condition if the animal is dead);

(D) Observed behaviors of the animal(s), if alive;

(E) If available, photographs or video footage of the animal(s); and

(F) General circumstances under which the animal was discovered.

(v) In the event of a vessel strike of a marine mammal by any vessel associated with the Empire Wind Project, Empire Wind must immediately report the strike incident to the NMFS OPR and the NMFS Greater Atlantic Regional Fisheries Office (GARFO) within and no later than 24 hours. Empire Wind must immediately cease all on-water activities until NMFS OPR 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 LOA. NMFS may impose additional measures to minimize the likelihood of further prohibited take and ensure MMPA compliance. Empire Wind may not resume their activities until notified by NMFS. The report must include the following information:

(A) Time, date, and location (latitude/longitude; in Decimal Degrees) of the incident;

(B) Species identification (if known) or description of the animal(s) involved;

(C) Vessel's speed leading up to and during the incident;

(D) Vessel's course/heading and what operations were being conducted (if applicable);

(E) Status of all sound sources in use;

(F) Description of avoidance measures/requirements that were in place at the time of the strike and what additional measures were taken, if any, to avoid strike;

(G) Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, visibility) immediately preceding the strike;

(H) Estimated size and length of animal that was struck;

(I) Description of the behavior of the marine mammal immediately preceding and following the strike;

(J) If available, description of the presence and behavior of any other marine mammals immediately preceding the strike;

(K) Estimated fate of the animal (*e.g.,* dead, injured but alive, injured and moving, blood or tissue observed in the water, status unknown, disappeared); and

(L) To the extent practicable, photographs or video footage of the animal(s).

§ 217.286 Letter of Authorization.

(a) To incidentally take marine mammals pursuant to this subpart, Empire Wind must apply for and obtain an LOA.

(b) An LOA, unless suspended or revoked, may be effective for a period of time not to exceed the January 21, 2029, the expiration date of this subpart.

(c) In the event of projected changes to the activity or to mitigation and monitoring measures required by an LOA, Empire Wind must apply for and obtain a modification of the LOA as described in § 217.287.

(d) The LOA must set forth:

(1) Permissible methods of incidental taking;

(2) Means of effecting the least practicable adverse impact (*i.e.,* mitigation) on the species, its habitat, and on the availability of the species for subsistence uses; and

(3) Requirements for monitoring and reporting.

(e) Issuance of the LOA must be based on a determination that the level of taking must be consistent with the findings made for the total taking allowable under this subpart.

(f) Notice of issuance or denial of an LOA must be published in the **Federal Register** within 30 days of a determination.

§ 217.287 Modifications of Letter of Authorization.

(a) An LOA issued under §§ 217.282 and 217.286 or § 217.287 for the activity identified in § 217.280(a) shall be modified upon request by the applicant, provided that:

(1) The proposed specified activity and mitigation, monitoring, and reporting measures, as well as the anticipated impacts, are the same as those described and analyzed for this subpart (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section), and

(2) NMFS determines that the mitigation, monitoring, and reporting measures required by the previous LOA under this subpart regulations were implemented.

(b) For a LOA modification request by the applicant that include changes to the activity or the mitigation, monitoring, or reporting (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section) that do not change the findings made for this subpart or result in no more than a minor change in the total estimated number of takes (or distribution by species or years), NMFS may publish a notice of proposed LOA in the **Federal Register**, including the associated analysis of the change, and solicit public comment before issuing the LOA.

(c) An LOA issued under §§ 217.282 and 217.286 or § 217.287 for the activities identified in § 217.280(a) may be modified by NMFS under the following circumstances:

(1) Through adaptive management, NMFS may modify (including augment) the existing mitigation, monitoring, or reporting measures (after consulting with Empire Wind regarding the practicability of the modifications, if doing so creates a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring set forth in the preamble for these regulations;

(i) Possible sources of data that could contribute to the decision to modify the mitigation, monitoring, or reporting measures in an LOA:

(A) Results from Empire Wind's monitoring from the previous year(s);

(B) Results from other marine mammals and/or sound research or studies;

(C) Any information that reveals marine mammals may have been taken in a manner, extent or number not authorized by this subpart or subsequent LOA; and

(ii) If, through adaptive management, the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS shall publish a notice of proposed LOA in the **Federal Register** and solicit public comment;

(2) If NMFS determines that an emergency exists that poses a significant risk to the well-being of the species or stocks of marine mammals specified in the LOA issued pursuant to §§ 217.282 and 217.286 or § 217.287, an LOA may be modified without prior notice or opportunity for public comment. Notice would be published in the **Federal Register** within thirty days of the action.

§§ 217.288–217.289 [Reserved]

[FR Doc. 2023–07417 Filed 4–12–23; 8:45 am]

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Part IV

Environmental Protection Agency

40 CFR Part 63
National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2019–0178; FRL–7055–03–OAR]

RIN 2060–AU37

National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is proposing amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Commercial Sterilization Facilities source category. The EPA is proposing decisions concerning the risk and technology review (RTR), including proposing amendments pursuant to the technology review for certain point source emissions and proposing amendments pursuant to the risk review to specifically address ethylene oxide (EtO) emissions from point source and room air emissions from all commercial sterilization facilities. The EPA is also proposing amendments to correct and clarify regulatory provisions related to emissions during periods of startup, shutdown, and malfunction (SSM), including removing general exemptions for periods of SSM and adding work practice standards for periods of SSM where appropriate. Lastly, the EPA is proposing to revise monitoring and performance testing requirements and to add provisions for electronic reporting of performance test results and reports, performance evaluation reports, and compliance reports. We estimate that, if finalized, these proposed amendments would reduce EtO emissions from this source category by 19 tons per year (tpy) and reduce risks to public health to acceptable levels.

DATES: Comments must be received on or before June 12, 2023. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before May 15, 2023.

Public hearing: The EPA will hold virtual public hearings on May 2 and May 3, 2023. See **SUPPLEMENTARY INFORMATION** for information on the public hearings.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OAR–2019–0178, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2019–0178 in the subject line of the message.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2019–0178.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA–HQ–OAR–2019–0178, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand/Courier Delivery:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Jonathan Witt, Sector Policies and Programs Division (E143–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5645; and email address: *witt.jon@epa.gov.* For specific information regarding the risk modeling methodology, contact Matt Woody, Health and Environmental Impacts Division (C539–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–1535; and email address: *woody.matt@epa.gov.*

SUPPLEMENTARY INFORMATION:

Participation in virtual public hearing. The public hearings will be held via virtual platform on May 2 and May 3, 2023, and will convene at 11:00 a.m. Eastern Time (ET) and conclude at 7:00 p.m. ET each day. On each hearing day, the EPA may close a session 15 minutes after the last pre-registered speaker has testified if there are no additional speakers. The EPA will announce further details at *https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities.* If the EPA receives a high volume of registrations for the public hearing, we may continue the public hearing on May 4, 2023.

The EPA will begin pre-registering speakers for the hearing no later than 1 business day following the publication of this document in the **Federal Register**. To register to speak at the virtual hearing, please use the online registration form available at *https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities* or contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov.* The last day to pre-register to speak at the hearing will be April 24, 2023. Prior to the hearing, the EPA will post a general agenda that will list pre-registered speakers in approximate order at: *https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities.*

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing. However, please plan for the hearings to run either ahead of schedule or behind schedule.

Each commenter will have 4 minutes to provide oral testimony. The EPA encourages commenters to submit a copy of their oral testimony as written comments to the rulemaking docket.

The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral testimony and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing will be posted online at *https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities.* While the EPA expects the hearing to go forward as set forth above, please monitor our website or contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov* to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

If you require the services of a translator or special accommodation such as audio description, please pre-

register for the hearing with the public hearing team and describe your needs by April 18, 2023. The EPA may not be able to arrange accommodations without advanced notice.

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2019–0178. All documents in the docket are listed in *https://www.regulations.gov/.* 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. With the exception of such material, publicly available docket materials are available electronically in *Regulations.gov.* All publicly available docket materials are available in hard copy at the EPA Docket Center, EPA WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

Instructions. Direct your comments to Docket ID No. EPA–HQ–OAR–2019–0178. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov/,* including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit electronically to *https://www.regulations.gov/* any information that you consider to be CBI or other information whose disclosure is restricted by statute. This type of information should be submitted as discussed below.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

The *https://www.regulations.gov/* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov/,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

The EPA is soliciting comment on numerous aspects of this action. The EPA has indexed each comment solicitation with an alpha-numeric identifier (*e.g.,* ''C–1,'' ''C–2,'' ''C–3'') to provide a consistent framework for effective and efficient provision of comments. Accordingly, the EPA asks that commenters include the corresponding identifier when providing comments relevant to that comment solicitation. The EPA asks that commenters include the identifier in either a heading, or within the text of each comment (*e.g.,* ''In response to solicitation of comment C–1, . . .'') to make clear which comment solicitation is being addressed. The EPA emphasizes that the Agency is not limiting comment to these identified areas and encourages provision of any other comments relevant to this action.

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/.* Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI and note the docket ID. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

Our preferred method to receive CBI is for it to be transmitted electronically using email attachments, File Transfer Protocol (FTP), or other online file sharing services (*e.g.,* Dropbox, OneDrive, Google Drive). Electronic submissions must be transmitted directly to the OAQPS CBI Office at the email address *oaqpscbi@epa.gov* and, as described above, should include clear CBI markings and note the docket ID. If assistance is needed with submitting large electronic files that exceed the file size limit for email attachments, and if you do not have your own file sharing service, please email *oaqpscbi@epa.gov* to request a file transfer link. If sending CBI information through the postal service, please send it to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA–HQ–OAR–2019–0178. The mailed CBI material should be double wrapped and clearly marked. Any CBI markings should not show through the outer envelope.

Preamble acronyms and abbreviations. Throughout this document 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:

ADAF age-dependent adjustment factor
AEGL acute exposure guideline level
AERMOD air dispersion model used by the HEM model
AIHA American Industrial Hygiene Association
APCD air pollution control device
ARV aeration room vent
ASME American Society of Mechanical Engineers
ATSDR Agency for Toxic Substances and Disease Registry
CAA Clean Air Act
CalEPA California EPA
CBI Confidential Business Information

CEMS continuous emissions monitoring system
CEV chamber exhaust vent
CFR Code of Federal Regulations
cfs cubic feet per second
dscfm dry standard cubic feet per minute
EJ environmental justice
EPA Environmental Protection Agency
ERPG emergency response planning guideline
ERT Electronic Reporting Tool
EtO ethylene oxide
FIFRA Federal Insecticide, Fungicide, and Rodenticide Act
FR Federal Register
FTIR Fourier Transform Infrared Spectroscopy
GACT generally available control technology
GC gas chromatography
HAP hazardous air pollutant(s)
HCl hydrochloric acid
HEM Human Exposure Model
HF hydrogen fluoride
HQ hazard quotient
ICR Information Collection Request
IRIS Integrated Risk Information System
ISO International Organization for Standardization
km kilometer
lb/hr pounds per hour
LEL lower explosive limit
MACT maximum achievable control technology
MIR maximum individual risk
mg/L milligrams per liter
NAICS North American Industry Classification System
NDO natural draft opening
NEI National Emissions Inventory
NESHAP national emission standards for hazardous air pollutants
NIST National Institute of Standards and Technology
NTTAA National Technology Transfer and Advancement Act
OAQPS Office of Air Quality Planning and Standards
OMB Office of Management and Budget
PB–HAP hazardous air pollutants known to be persistent
and bio-accumulative in the environment
PID Proposed Interim Decision
ppbv parts per billion by volume
ppm parts per million
ppmv parts per million by volume
PoAHSM post-aeration handling of sterilized material
POM polycyclic organic matter
PpO propylene oxide
PRA Paperwork Reduction Act
PrAHSM pre-aeration handling of sterilized material
PS Performance Specification
PTE permanent total enclosure
RAC room air change
RBLC RACT/BACT/LAER Clearinghouse
REL reference exposure level
RDL Representative detection level
RFA Regulatory Flexibility Act
RfC reference concentration
RTR risk and technology review
SAB Science Advisory Board
SBAR Small Business Advocacy Review
SCV sterilization chamber vent
SSM startup, shutdown, and malfunction
TOSHI target organ-specific hazard index
tpy tons per year
TRIM.FaTE Total Risk Integrated Methodology, Environmental Fate, Transport, and Ecological Exposure
UF uncertainty factor
UPL upper prediction limit
µg/m3 microgram per cubic meter
URE unit risk estimate
VCS voluntary consensus standards
WebFIRE Web Factor and Information Retrieval

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I. General Information

A. Executive Summary

1. Purpose of the Regulatory Action

The EPA is proposing to revise the NESHAP for Commercial Sterilization Facilities by both amending existing standards and establishing additional standards for this source category, exercising authority under multiple provisions of section 112 of the Clean Air Act (CAA). First, the EPA is proposing emission standards under CAA sections 112(d)(2)–(3) or (d)(5) for a number of currently unregulated emission sources of EtO. Second, the EPA is proposing risk-based standards under CAA section 112(f)(2) in order to protect public health with an ample margin of safety. Third, the EPA is proposing emission standards under CAA section 112(d)(6) based on the Agency's review of developments in practices, processes, and control technologies for this source category.

This proposed rulemaking reflects the EtO toxicological assessment that the EPA's Integrated Risk Information System (IRIS) Program completed in December 2016,[1] which indicated that EtO is a far more potent carcinogen than EPA had understood at the time of the previous RTR for this source category. There are 86 commercial sterilization facilities in this source category, many of which are located near residences, schools, and other public facilities. Many of these facilities are also located in communities with environmental justice (EJ) concerns. The EPA has determined that approximately 23 of these facilities pose elevated lifetime cancer risks to the surrounding communities, some of which are exceptionally high. Throughout this rulemaking process, we have engaged in

[1] *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide,* December 2016, EPA/635/R–16/350Fc.

outreach activities to these communities, along with their state and local governments.

This important action, if finalized, will reduce EtO emissions and lifetime cancer risks in multiple communities across the country, including communities with EJ concerns, and it proposes to update our standards considering proven and cost-effective control technologies that are already in use at some facilities in this source category. Recognizing that EPA now has additional information about the health risks of EtO that was not available at the time of the last RTR, and in order to ensure that EPA's standards for this source category adequately protect public health, we have also conducted a second residual risk review under CAA section 112(f)(2), as discussed in section I.A.3 of this preamble.

In deciding whether to conduct a second residual risk review, we considered the advantages of EtO reductions and the distribution of those reductions consistent with the clear goal of CAA section 112(f)(2) to protect the most exposed and susceptible populations, which in this case include communities with EJ concerns. While commercial medical device sterilizers provide a critical benefit for the health of all, sparing Americans who live near commercial sterilization facilities the disproportionate risk of being significantly harmed by toxic pollution is also essential.

Commercial sterilization facilities play a vital role in maintaining an adequate supply of medical devices. According to the U.S. Food and Drug Administration (FDA), ''Literature shows that about fifty percent of all sterile medical devices in the U.S. are sterilized with ethylene oxide.'' FDA also notes that, ''For many medical devices, sterilization with ethylene oxide may be the only method that effectively sterilizes and does not damage the device during the sterilization process.'' [2] In developing this proposed rule, EPA has given careful consideration to the important function these facilities serve, drawing from extensive engagement with industry stakeholders as well as Federal agencies with expertise in and responsibility for the medical supply chain.

In order to ensure EPA's actions with respect to this source category are based on the most accurate and complete information possible, we have had many interactions with the EtO commercial sterilization industry in recent years, including meetings, requests for information, and outreach specific to this proposed rulemaking. This has enabled EPA to work from the best possible information when conducting the analyses to support this proposed rulemaking, including the current configuration of facilities and the performance of control technologies that are currently used.

We have engaged with the U.S. Department of Health and Human Services, particularly FDA, regarding the potential impacts of this proposal on commercial sterilization facilities. These discussions have focused on identifying and addressing any potential concerns regarding the potential impact on the availability of certain medical devices that are sterilized with EtO where alternative sterilization methods are not readily available, including those that are (1) Experiencing or at risk of experiencing a shortage, (2) in high demand as a result of the COVID–19 pandemic, (3) used in pediatric services, and/or (4) sterilized exclusively at a particular facility.

In this rulemaking, we are proposing a set of standards that we believe are achievable and reflect techniques and control technologies that are currently used within the industry. We are also proposing to provide sufficient time to enable these facilities to continue sterilizing essential products while installing and testing new control systems and associated equipment that will afford ample protection for nearby communities. In terms of potential impacts to the medical device supply chain, we project that the largest impacts are limited to a handful of companies, and those that are also involved in sterilizing the types of medical devices previously mentioned are already in the planning stage for additional controls.

2. Summary of the Major Provisions of the Regulatory Action in Question

The EPA is proposing numeric emission limits, operating limits, and management practices under CAA sections 112(d)(2)–(3), (d)(5), and (d)(6) for EtO emissions from certain emission sources and is also proposing standards under CAA section 112(f)(2) for certain emission sources in order to ensure that the standards provide an ample margin of safety to protect public health.

For the following emission sources that are currently unregulated,[3] the EPA is proposing to set standards under CAA sections 112(d)(2)–(3) or (d)(5): sterilization chamber vent (SCV), aeration room vent (ARV), and chamber exhaust vent (CEV) at facilities where EtO use is less than 1 tpy, ARV and CEV at facilities where EtO use is at least 1 tpy but less than 10 tpy, CEV at facilities where EtO use is at least 10 tpy,[4] and room air emissions.[5]

Next, based on the EPA's assessment of the residual risk after considering the emission reductions from the current standards in subpart O, as well as the proposed standards for the currently unregulated sources, the EPA is proposing more stringent standards to address risk for the following types of sources under CAA section 112(f)(2):

- SCVs at facilities where EtO use is at least 40 tpy.
- SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy.
- SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy.
- Group 2 room air emissions [6] at area source facilities where EtO use is at least 20 tpy.

Finally, under CAA section 112(d)(6), the EPA is proposing to revise standards for the following sources that are regulated in the current 40 CFR part 63, subpart O:

- SCVs at facilities where EtO use is at least 10 tpy.
- SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy.
- ARVs at facilities where EtO use is at least 10 tpy.

To demonstrate compliance with the emission limits, the EPA is proposing

[2] *https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices.*

[3] In 1992, pursuant to CAA section 112(c)(1), the EPA published a list of major and area sources for regulation under CAA section 112, including major and area sources of commercial sterilizers. 57 FR 31576, 31586 (July 16, 1992). Area sources of commercial sterilizers were listed for regulation under CAA section 112(c)(3) based on the EPA's finding that it presents a threat of adverse effects to human health or the environment (by such sources individually or in the aggregate) warranting regulation under that section. *Id.* at 31586.

[4] The standards for CEVs were originally promulgated on December 6, 1994. Following promulgation of the rule, the EPA suspended certain compliance deadlines and ultimately removed the standards for CEVs due to safety concerns. In the late 1990s, there were multiple explosions at EtO commercial sterilization facilities using oxidizers to control emissions from the CEV. For CEVs, it was determined that the primary contributing issue leading to the explosions was that EtO concentrations were above a safe level (*i.e.,* above the lower explosive limit (LEL)) within the CEV gas streams. The EPA could not conclude at the time that the CEVs could be safely controlled, so the standards for CEVs were removed on November 2, 2001 (66 FR 55583) and have not been re-instated.

[5] As discussed in section II.F.1, room air emissions include emissions resulting from indoor EtO storage, EtO dispensing, vacuum pump operation, pre-aeration handling of sterilized material, and post-aeration handling of sterilized material.

[6] As discussed in section III.B.8, Group 2 room air emissions cover post-aeration handling of sterilized material.

capture requirements. The EPA is also proposing that facilities either monitor with an EtO continuous emissions monitoring system (CEMS) or conduct initial and annual performance tests with continuous parameter monitoring.

3. EPA Authority

The EPA notes that it completed a residual risk and technology review under CAA sections 112(f)(2) and 112(d)(6), respectively, for this source category in 2006 (71 FR 17712). While CAA section 112(f)(2) requires only a one-time risk review, which is to be conducted within eight years of the date the initial standards are promulgated, it does not limit the EPA's discretion or authority to conduct another risk review should the EPA consider that such review is warranted. As discussed in more detail in section III.C of this preamble, as our understanding of the health effects of EtO developed, the EPA conducted a second residual risk review under CAA section 112(f)(2) for commercial sterilization facilities using ethylene oxide in order to ensure that the standards provide an ample margin of safety to protect public health.

As discussed in further detail in section III.C, this second residual risk review also encompasses certain area sources for which EPA did not evaluate residual risk in its 2006 rulemaking. Although CAA section 112(f)(5) states that a risk review is not required for categories of area sources subject to generally available control technology (GACT) standards, it does not prohibit such review. In 2006, the EPA undertook a CAA section 112(f)(2) analysis only for area source emissions standards that were issued as maximum achievable control technology (MACT) standards and exercised its discretion under CAA section 112(f)(5) to not do a CAA section 112(f)(2) analysis for those emission points for which GACT standards were established (67 FR 17715). However, as the EPA made clear in that prior risk assessment, ''[w]e have the authority to revisit (and revise, if necessary) any rulemaking if . . . significant improvements to science [suggest that] the public is exposed to significant increases in risk as compared to the [2006 risk assessment].'' *Id.* In light of the updated unit risk estimate (URE) for EtO, which is approximately 60 times greater than the value the EPA used in its previous risk assessment, the EPA is now exercising its discretionary authority to conduct another CAA section 112(f)(2) analysis and to include in this analysis area sources of commercial sterilizers using EtO for which the EPA has promulgated, or is now proposing, GACT standards.

Section 112(d)(6) of the CAA also requires the EPA to review and revise, as necessary, standards promulgated under CAA section 112 at least every 8 years, taking into account developments in practices, processes, and control technologies. The EPA last completed this required technology review for the Ethylene Oxide Commercial Sterilization NESHAP (40 CFR 63, subpart O) in 2006. Accordingly, in this proposed action the EPA is also conducting a CAA section 112(d)(6) review for this source category.

4. Costs and Benefits

Table 1 of this preamble summarizes the costs of this proposed action for 40 CFR part 63, subpart O (Ethylene Oxide Commercial Sterilization NESHAP).

TABLE 1—SUMMARY OF COSTS OF THE PROPOSED STANDARDS

[2021 Dollars]

Requirement	Total capital investment	Total annualized capital costs	Total annual operation and maintenance costs	Total annual cost
Permanent total enclosure	$65,798,622	$6,577,542	$430,729	$7,008,271
Additional gas/solid reactors	133,890,631	13,384,341	18,991,555	32,375,896
Cycle revalidations	0	0	2,490,000	2,490,000
Monitoring and testing	19,925,046	2,936,022	8,232,973	11,168,996
Recordkeeping and reporting	0	0	8,618,124	[1] 15,166,922
Total	219,614,299	22,897,905	38,763,381	68,210,084

[1] This includes $6,548,798 of one-time annual costs for reading the rule, developing record systems, and initial title V permitting.

Consistent with the compliance deadlines proposed in this rule, EPA has assumed for purposes of this analysis that all capital costs and one-time annual costs would be incurred within 18 months of the publication of a final rule. The capital costs for permanent total enclosure (PTE) and additional gas/solid reactors were annualized to 20 years. We estimate that, if finalized, these proposed amendments would reduce EtO emissions from this source category by 19 tpy. Table 2 of this preamble summarizes the cancer risk reductions that would result from the proposed amendments.

TABLE 2—SUMMARY OF CANCER RISK REDUCTIONS

	Current cancer risks	Cancer risks if proposed amendments are finalized
Maximum Individual Risk (MIR) [1]	6,000-in-1 million	100-in-1 million.
Number of People with Cancer Risks >100-in-1 million	18,000	0.
Number of People with Cancer Risks ≥1-in-1 million	8.3 million	1.26 million. [2]
Estimated Annual Cancer Incidence (cases per year)	0.9	0.1.

[1] The MIR is defined as the cancer risk associated with a lifetime of continuous exposure at the highest concentration of HAP where people are likely to live.

[2] As discussed in section III, this value may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment.

As indicated in Table 2, EPA projects that the standards in the proposed rule would significantly reduce incremental lifetime cancer risks associated with emissions of EtO from this source category. Currently, EPA estimates that the maximum increase in lifetime cancer risk associated with any facility in this source category is 6,000-in-1 million, and that approximately 18,000 people are exposed to EtO from this source category at levels that would correspond to a lifetime cancer risk of greater than 100-in-1-million (which is EPA's presumptive upper bound for acceptable health risks). Under the proposed rule, no individual would be exposed to EtO at levels that correspond to a lifetime cancer risk of greater than 100-in-1 million, and the number of people with a potential risk of greater than or equal to 1-in-1 million would be reduced by approximately 85 percent.

See section IV of this preamble for further discussion of the costs and a discussion of the benefits of the proposed standards. See section III.G of this preamble for discussion of the proposed revisions to monitoring, recordkeeping, reporting, and testing requirements. See section III.C and III.D for discussion of the risk assessment results.

B. Does this action apply to me?

The standards in 40 CFR part 63, subpart O, regulate emissions of EtO from existing and new commercial sterilization operations. Table 3 of this preamble lists the NESHAP and some examples of regulated industrial categories that are the subject of this proposal. Table 3 is not intended to be exhaustive, but rather provides a guide for readers regarding the entities that this proposed action is likely to affect. The proposed standards, once promulgated, will be directly applicable to the affected sources. Federal, state, local, and tribal government entities would not be affected by this proposed action. As defined in the *Initial List of Categories of Sources Under Section 112(c)(1) of the Clean Air Act Amendments of 1990* (see 57 FR 31576, July 16, 1992) and *Documentation for Developing the Initial Source Category List, Final Report* (see EPA–450/3–91–030, July 1992), the Commercial Sterilization Facilities source category is any facility engaged in the use of EtO as a sterilant and fumigant following the production of various products (*e.g.,* medical equipment and supplies) and in miscellaneous sterilization and fumigation operations at both major and area sources. These commercial sterilization facilities use EtO as a sterilant for heat- or moisture-sensitive materials and as a fumigant to control microorganisms. Materials may be sterilized at the facility that produces or uses the product, or by contract sterilizers (*i.e.,* firms under contract to sterilize products manufactured by other companies).

TABLE 3—NESHAP AND INDUSTRIAL CATEGORIES AFFECTED BY THIS PROPOSED ACTION

Industrial category	NESHAP	NAICS code [1]
Surgical and Medical Instrument Manufacturing	40 CFR part 63, subpart O	339112
Surgical Appliance and Supplies Manufacturing	40 CFR part 63, subpart O	339113
Pharmaceutical Preparation Manufacturing	40 CFR part 63, subpart O	325412
Spice and Extract Manufacturing	40 CFR part 63, subpart O	311942
Dried and Dehydrated Food Manufacturing	40 CFR part 63, subpart O	311423
Packaging and Labeling Services	40 CFR part 63, subpart O	561910

[1] North American Industry Classification System.

C. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this action is available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at *https://www.epa.gov/ethylene-oxide-emissions-standards-sterilization-facilities.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the proposal and key technical documents at this same website.

A memorandum showing the rule edits that would be necessary to incorporate the changes to 40 CFR part 63, subpart O, proposed in this action is available in the docket (Docket ID No. EPA–HQ–OAR–2019–0178). Following signature by the EPA Administrator, the EPA also will post a copy of this document to *https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities.*

II. Background

A. What is the statutory authority for this action?

The statutory authority for this action is provided by sections 112 and 301 of the Clean Air Act (CAA), as amended (42 U.S.C. 7401 *et seq.*). 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 MACT and GACT standards set under CAA section 112 every 8 years and revise the standards as necessary taking into account any ''developments in practices, processes, or control technologies.'' This review is commonly referred to as the ''technology review.'' The discussion that follows identifies the most relevant statutory sections and briefly explains the contours of the methodology used to implement these statutory requirements. A more comprehensive discussion appears in the document titled *CAA Section 112 Risk and Technology Reviews: Statutory Authority and Methodology,* in the docket for this rulemaking.

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 GACT in lieu of MACT standards. For categories of major sources and any area source categories subject to MACT standards, the second stage in standard-setting focuses on identifying and addressing any remaining (*i.e.,* ''residual'') risk pursuant to CAA section 112(f). Section 112(f) specifically states that EPA ''shall not be required'' to conduct risk review under this subsection for categories of area sources subject to GACT standards but does not limit the EPA's authority or discretion from conducting such review. As discussed in more detail in section III.C of this preamble, in light of the updated URE regarding EtO, the EPA is choosing to exercise that discretion.

The second stage in standard-setting focuses on identifying and addressing any remaining (*i.e.,* ''residual'') risk pursuant to CAA section 112(f). For source categories subject to MACT standards, section 112(f)(2) of the CAA requires the EPA to determine whether promulgation of additional standards is needed to provide an ample margin of safety to protect public health or to prevent an adverse environmental effect. Section 112(d)(5) of the CAA provides that this residual risk review is not required for categories of area sources subject to GACT standards. Section 112(f)(2)(B) of the CAA further expressly preserves the EPA's use of the two-step approach for developing standards to address any residual risk and the Agency's interpretation of ''ample margin of safety'' developed in the *National Emissions Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants* (Benzene NESHAP) (54 FR 38044, September 14, 1989). The EPA notified Congress in the Residual Risk Report that the Agency intended to use the Benzene NESHAP approach in making CAA section 112(f) residual risk determinations (EPA–453/R–99–001, p. ES–11). The EPA subsequently adopted this approach in its residual risk determinations and the United States Court of Appeals for the District of Columbia Circuit upheld the EPA's interpretation that CAA section 112(f)(2) incorporates the approach established in the Benzene NESHAP. *See NRDC* v. *EPA,* 529 F.3d 1077, 1083 (D.C. Cir. 2008).

The approach incorporated into the CAA and used by the EPA to evaluate residual risk and to develop standards under CAA section 112(f)(2) is a two-step approach. In the first step, the EPA determines whether risks are acceptable. This determination ''considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual lifetime [cancer] risk (MIR)[7] of approximately 1-in-10 thousand.'' (54 FR 38045) If risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level without considering costs. In the second step of the approach, the EPA considers whether the emissions standards provide an ample margin of safety to protect public health ''in consideration of all health information, including the number of persons at risk levels higher than approximately 1-in-1 million, as well as other relevant factors, including costs and economic impacts, technological feasibility, and other factors relevant to each particular decision.'' *Id.* The EPA must promulgate emission standards necessary to provide an ample margin of safety to protect public health or determine that the standards being reviewed provide an ample margin of safety without any revisions. After conducting the ample margin of safety analysis, we consider whether a more stringent standard is necessary to prevent an adverse environmental effect, taking into consideration costs, energy, safety, and other relevant factors.

CAA section 112(d)(6) separately 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 also 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 is this source category and how does the current NESHAP regulate its HAP emissions?

On July 16, 1992, pursuant to CAA section 112(c)(1), the EPA listed certain major and area sources of HAP for regulation, including both major and area sources of commercial sterilization facilities. 57 FR 31576, 31592. As explained in that document, area sources of commercial sterilization facilities were listed pursuant to CAA section 112(c)(3) based on a finding of a threat of adverse effects from commercial sterilizers using EtO. *Id* at 31588. In 1994, the EPA promulgated the Ethylene Oxide Emissions Standards for Sterilization Facilities NESHAP, 40 CFR part 63, subpart O (referred to in this proposed rulemaking as the EtO Commercial Sterilization NESHAP) (59 FR 62589), which is codified at 40 CFR part 63, subpart O. The EtO Commercial Sterilization NESHAP regulates EtO emitted from commercial sterilization facilities. The current NESHAP regulates point sources of emissions, specifically SCVs and ARVs, at facilities that use at least 1 ton of EtO in sterilization or fumigation operations in each 12-month period. In a **Federal Register** document published on July 16, 1992 (57 FR 31576), the EPA listed for regulation both major and area sources of EtO commercial sterilization and fumigation operations pursuant to CAA section 112(c)(1) and 112(c)(3) (based on a finding of a threat of adverse effects), respectively.

EtO commercial sterilization covers the sterilizer process that uses EtO to sterilize or fumigate materials (*e.g.,* medical equipment and supplies, spices, and other miscellaneous products and items). The original

[7] Although defined as ''maximum individual risk,'' MIR refers only to cancer risk. MIR, one metric for assessing cancer risk, is the estimated risk if an individual were exposed to the maximum level of a pollutant for a lifetime.

rulemaking addressed EtO emissions originating from three emission points: SCV, ARV, and CEV. The SCV evacuates EtO from the sterilization chamber following sterilization, fumigation, and any subsequent gas washes before the chamber door is opened. The ARV evacuates EtO-laden air from the aeration room or chamber that is used to facilitate off-gassing of the sterile product and packaging. The CEV evacuates EtO-laden air from the sterilization chamber after the chamber door is opened for product unloading following the completion of sterilization and associated gas washes. Other sources of emissions within this source category are room air emissions from equipment used to charge EtO into sterilization chambers, as well as residual EtO desorbing from sterilized products within the facility, but the EtO Commercial Sterilization NESHAP does not include standards for these emissions.

In the chamber EtO sterilization process, products and items to be sterilized are placed in a chamber and exposed to EtO gas at a predetermined concentration, temperature, humidity, and pressure for a period of time known as the dwell period. Following the dwell period, the EtO gas is evacuated from the chamber, and the sterilized materials are then aerated to remove residual EtO from the product. After the aeration step, sterilized materials are typically moved to a shipping/warehouse area for storage until they are ready to be distributed to the customer. Sterilizer process equipment and emission control configurations vary across facilities. The most common sterilizer process equipment configuration includes a separate sterilizer chamber, separate aeration room, and chamber exhaust on the sterilizer chamber (also referred to as a back-vent). Another common configuration includes a combination sterilizer where the sterilization and aeration steps of the process occur within the same chamber, though this configuration may or may not have a chamber exhaust.

Another EtO sterilization process is single-item sterilization where small individual items are sterilized in sealed pouches. EtO gas is introduced into the sealed pouch, either by injection or use of an EtO ampule, and the sealed pouch is then placed in a chamber where the sterilization step and aeration step occur.

Multiple control technologies were available for EtO commercial sterilization at the time the EtO Commercial Sterilization NESHAP was promulgated (December 1994). Control technologies for SCVs included: acid-water scrubbers; thermal oxidizer/flares; catalytic oxidizers; condensers/reclaimers; and a combination packed bed scrubber and gas-solid reactor (dry bed reactor) systems. Control technologies for CEVs included: packed bed scrubber; catalytic oxidizer; gas-solid reactor; and a combination packed bed scrubber and gas-solid reactor. Control technologies for ARVs included: acid-water scrubber, catalytic oxidizer, and gas-solid reactor.

In 2006, the EPA finalized a residual risk review and a technology review under CAA section 112(f)(2) and CAA section 112(d)(6), respectively (71 FR 17712, April 7, 2006). No changes were made to the EtO Commercial Sterilization NESHAP in that action.

The emission standards that currently apply to sterilization facilities covered by 40 CFR part 63, subpart O, are shown in Table 4:

TABLE 4—CURRENT ETO STANDARDS FOR COMMERCIAL STERILIZERS

Existing and new sources subcategory (in any consecutive 12-month period) [1]	Sterilization chamber vent (SCV)	Aeration room vent (ARV)	Chamber exhaust vent (CEV) [2]
Sources using 10 tons or more of EtO	99 percent emission reduction (see 40 CFR 63.362(c)).	1 part per million (ppm) maximum outlet concentration or 99 percent emission reduction (see 40 CFR 63.362(d)).	No control.
Sources using 1 ton or more of EtO but less than 10 tons of EtO.	99 percent emission reduction (see 40 CFR 63.362(c)).	No control	No control.
Sources using less than 1 ton of EtO	No control required; minimal recordkeeping requirements apply (see 40 CFR 63.367(c))).	No control required; minimal recordkeeping requirements apply (see 40 CFR 63.367(c))).	No control required; minimal recordkeeping requirements apply (see 40 CFR 63.367(c))).

[1] Determined on a rolling 12-month basis.
[2] The CEV emission source was included in the original standard but was later eliminated from the 40 CFR part 63, subpart O, regulation in 2001.

We note that hospital sterilizers are regulated under a different NESHAP (40 CFR part 63, subpart WWWWW), which is not addressed in this rulemaking.[8] We are aware of the potential risk posed by EtO emissions from this source category and will address hospital sterilizers in a future rulemaking.

C. What data collection activities were conducted to support this action?

The EPA used several sources to develop the list of existing commercial sterilization facilities. We began with the facility list used during the previous RTR and supplemented that with facilities identified in the 2017 National Emissions Inventory (NEI), as well as facilities identified using the Office of Enforcement and Compliance Assurance's Enforcement and Compliance History Online tool (*https://echo.epa.gov*). We then reviewed available Federal, state, and local data to determine whether any of these facilities had closed or ceased using EtO for sterilization purposes. We also asked our EPA regional offices to identify any commercial sterilization facilities that we missed, and when we conducted the December 2019 CAA section 114 questionnaire and September 2021 CAA section 114 Information Collection Request (ICR) (discussed below), we asked the parent companies to identify

[8] Hospitals are defined at 40 CFR 63.10448 to mean facilities that provide medical care and treatment for patients who are acutely ill or chronically ill on an inpatient basis under supervision of licensed physicians and under nursing care offered 24 hours per day. Hospitals include diagnostic and major surgery facilities but exclude doctor's offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals on an outpatient basis.

any commercial sterilization facilities they owned that we did not identify. This review and analysis produced the final facility list of 86 commercial sterilization facilities. A complete list of known commercial sterilization facilities is available in the document titled *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2022 Risk and Technology Review Proposed Rule,* which is available in the docket for this rulemaking.

For this RTR, the EPA investigated developments in practices, processes, and control technologies through communications and direct discussions with EPA regional offices, state and local agencies, Small Business Environmental Assistance Program personnel, industry representatives, and trade association representatives. Details of these conversations are included in the memorandum titled *Technical Support Document for Proposed Rule—Industry Profile, Review of Unregulated Emissions, CAA Section 112(d)(6) Technology Review, and CAA Section 112(f) Risk Assessment for the Ethylene Oxide Emissions Standards for Sterilization Facilities NESHAP (Technical Support Document),* available in the docket for this action (Docket ID No. EPA–HQ–OAR–2019–0178). The EPA conducted literature reviews, operating permit reviews, internet web searches, and site visits; published an Advanced Notice of Proposed Rulemaking (84 FR 67889, December 12, 2019); reviewed public comments received; sent requests for information to industry under the authority of CAA section 114; and searched the EPA's Technology Transfer Network Clean Air Technology Center—RACT/BACT/LAER Clearinghouse (RBLC) database.

The RBLC provides several options for searching the permit database online to locate applicable control technologies. We queried the RBLC database for specific commercial sterilization Process Type 99.004 (Commercial Sterilization Facilities), as well as a related source category, Process Type 99.008 (Hospital Sterilization Facilities). In querying results dating back to January 1, 2006 (the date of the residual risk and initial technology review), no results were returned when searching for Process Type 99.004 and no results were returned for Process Type 99.008. None of these searches returned relevant information on developments in practices, processes, or control technologies used in EtO commercial sterilization facilities. Full details of the RBLC database search in support of this technology review are included in the *Technical Support Document,* available in the docket for this action (Docket ID No. EPA–HQ–OAR–2019–0178). Prior to this proposed rulemaking, the EPA engaged in outreach activities to communities we expect to be impacted most by the rulemaking.[9] Any information related to these outreach activities that we receive prior to the conclusion of the comment period will be considered as part of the final rulemaking, along with direct comments on this proposed rulemaking. Any updated emissions information received during the EPA's ongoing public outreach activities that may change the projected impacts for these populations will be considered as part of the final rulemaking, as well as direct comments received on this proposed rulemaking.

The EPA issued two requests to gather information about process equipment, control technologies, and emissions from facilities in the source category. In December 2019, the EPA issued a CAA section 114 request to a small number of entities that were operating 42 facilities at the time (now 39) to gather information, including information about types of process equipment, sterilization cycles, control technologies, EtO usage and storage, room areas, movements of sterilized products, and EtO concentration data. We also included requests for facility documents (*e.g.,* process flow diagrams, air permits, air permit applications, process and instrumentation diagrams), performance test reports, parametric monitoring data, startup shutdown and malfunction plans, and EtO residual studies in products. These entities were selected because, collectively, they comprised a significant portion of the sterilization industry. All respondents completed the questionnaire and submitted responses to the EPA in February 2020. Additionally, in September 2021, the EPA issued an information collection request (ICR), pursuant to CAA section 114, to gather information from all facilities in the EtO commercial sterilization category. Additional questions in the September 2021 ICR included information on non-EtO sterilization techniques and stand-alone, non-co-located warehouses or distribution centers.[10] The facilities not included in the December 2019 request were asked to respond to the full set of questions, and those facilities were only asked to provide responses to the additional questions. Responses to the ICR were due in November 2021.

The Agency made the data results from the two questionnaires available as part of a Freedom of Information Act request.[11] The EPA used the collected information to assist in filling data gaps, establish the baseline emissions and control levels for purposes of the regulatory reviews, identify the most effective control measures, and estimate the environmental impacts associated with the regulatory options considered and reflected in this proposed action. The responses to the December 2019 and September 2021 questionnaires are listed in the memorandum titled *Documentation of Database Containing Information from Responses to the December 2019 Questionnaire and the September 2021 Section 114 for the Ethylene Oxide Commercial Sterilization NESHAP Review,* which is available in the docket for this rulemaking. The information not claimed as CBI by respondents and received in time to be included in this proposal is available in the database titled *Data Received from Information Collection Requests for the Commercial Sterilization Facilities Source Category,* which is available in the docket for this rulemaking.

D. How do we consider risk in our decision-making?

As discussed in section II.A of this preamble and in the Benzene NESHAP, in evaluating and developing standards under CAA section 112(f)(2), we apply a two-step approach to determine whether or not risks are acceptable and to determine if the standards provide an ample margin of safety to protect public health. As explained in the Benzene NESHAP, ''the first step judgment on acceptability cannot be reduced to any single factor'' and, thus, ''[t]he Administrator believes that the acceptability of risk under section 112 is best judged on the basis of a broad set of health risk measures and information.'' (54 FR 38046). Similarly, with regard to the ample margin of safety determination, ''the Agency again considers all of the health risk and other health information considered in the first step. Beyond that information, additional factors relating to the

[9] *https://www.epa.gov/newsreleases/epa-launches-community-engagement-efforts-new-ethylene-oxide-risk-information.*

[10] The EPA is not proposing requirements for these facilities as part of this action. However, the EPA plans to evaluate the data received and determine what requirements these facilities should be subject to, if any.

[11] Results from the December 2019 questionnaire are available at *https://foiaonline.gov/foiaonline/action/public/submissionDetails?trackingNumber=EPA-2020-004133&type=Request,* and results from the September 2021 ICR are available at *https://foiaonline.gov/foiaonline/action/public/submissionDetails?trackingNumber=EPA-2022-003690&type=Request.*

appropriate level of control will also be considered, including cost and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors.'' *Id.*

The Benzene NESHAP approach provides flexibility regarding the factors the EPA may consider in making determinations and how the EPA may weigh those factors for each source category. The EPA conducts a risk assessment that provides estimates of the MIR posed by emissions of HAP that are carcinogens from each source in the source category, the hazard index for chronic exposures to HAP with the potential to cause noncancer health effects, and the hazard quotient (HQ) for acute exposures to HAP with the potential to cause noncancer health effects.[12] The assessment also provides estimates of the distribution of cancer risk within the exposed populations, cancer incidence, and an evaluation of the potential for an adverse environmental effect. The scope of the EPA's risk analysis is consistent with the explanation in the EPA's response to comments on our policy under the Benzene NESHAP. The policy chosen by the Administrator permits consideration of multiple measures of health risk. Not only can the MIR figure be considered, but also incidence, the presence of non-cancer health effects, and the uncertainties of the risk estimates. In this way, the effect on the most exposed individuals can be reviewed as well as the impact on the general public. These factors can then be weighed in each individual case. This approach complies with the *Vinyl Chloride* mandate that the Administrator ascertain an acceptable level of risk to the public by employing his expertise to assess available data. It also complies with the congressional intent behind the CAA, which did not exclude the use of any particular measure of public health risk from the EPA's consideration with respect to CAA section 112 regulations, and thereby implicitly permits consideration of any and all measures of health risk which the Administrator, in his judgment, believes are appropriate to determining what will ''protect the public health'' (54 FR 38057). Thus, the level of the MIR is only one factor to be weighed in determining acceptability of risk. The Benzene NESHAP explained that ''an MIR of approximately one in 10 thousand should ordinarily be the upper end of the range of acceptability. As risks increase above this benchmark, they become presumptively less acceptable under CAA section 112, and would be weighed with the other health risk measures and information in making an overall judgment on acceptability. Or, the Agency may find, in a particular case, that a risk that includes an MIR less than the presumptively acceptable level is unacceptable in the light of other health risk factors.'' *Id.* at 38045. In other words, risks that include an MIR above 100-in-1 million may be determined to be acceptable, and risks with an MIR below that level may be determined to be unacceptable, depending on all of the available health information. Similarly, with regard to the ample margin of safety analysis, the EPA stated in the Benzene NESHAP that: ''EPA believes the relative weight of the many factors that can be considered in selecting an ample margin of safety can only be determined for each specific source category. This occurs mainly because technological and economic factors (along with the health-related factors) vary from source category to source category.'' *Id.* at 38061. We also consider the uncertainties associated with the various risk analyses, as discussed earlier in this preamble, in our determinations of acceptability and ample margin of safety.

The EPA notes that it has not considered certain health information to date in making residual risk determinations. At this time, we do not attempt to quantify the HAP risk that may be associated with emissions from other facilities that do not include the source category under review, mobile source emissions, natural source emissions, persistent environmental pollution, or atmospheric transformation in the vicinity of the sources in the category.

The EPA understands the potential importance of considering an individual's total exposure to HAP in addition to considering exposure to HAP emissions from the source category and facility. We recognize that such consideration may be particularly important when assessing noncancer risk, where pollutant-specific exposure health reference levels (*e.g.,* reference concentrations (RfCs)) are based on the assumption that thresholds exist for adverse health effects. For example, the EPA recognizes that, although exposures attributable to emissions from a source category or facility alone may not indicate the potential for increased risk of adverse noncancer health effects in a population, the exposures resulting from emissions from the facility in combination with emissions from all of the other sources (*e.g.,* other facilities) to which an individual is exposed may be sufficient to result in an increased risk of adverse noncancer health effects. In May 2010, the Science Advisory Board (SAB) advised the EPA ''that RTR assessments will be most useful to decision makers and communities if results are presented in the broader context of aggregate and cumulative risks, including background concentrations and contributions from other sources in the area.'' [13]

In response to the SAB recommendations, the EPA incorporates cumulative risk analyses into its RTR risk assessments. The Agency (1) Conducts facility-wide assessments, which include source category emission points, as well as other emission points within the facilities; (2) combines exposures from multiple sources in the same category that could affect the same individuals; and (3) for some persistent and bioaccumulative pollutants, analyzes the ingestion route of exposure. In addition, the RTR risk assessments consider aggregate cancer risk from all carcinogens and aggregated noncancer HQs for all noncarcinogens affecting the same target organ or target organ system.

Although we are interested in placing source category and facility-wide HAP risk in the context of total HAP risk from all sources combined in the vicinity of each source, we are concerned about the uncertainties of doing so. Estimates of total HAP risk from emission sources other than those that we have studied in depth during this RTR review would have significantly greater associated uncertainties than the source category or facility-wide estimates. Such aggregate or cumulative assessments would compound those uncertainties, making the assessments too unreliable.

E. How does the EPA perform the technology review?

Our technology review primarily focuses on the identification and evaluation of developments in practices, processes, and control technologies that have occurred since the MACT and GACT standards were promulgated. Where we identify such developments, we analyze their technical feasibility, estimated costs, energy implications, and non-air environmental impacts. We also consider the emission reductions

[12] The MIR is defined as the cancer risk associated with a lifetime of continuous exposure at the highest concentration of HAP where people are likely to live. The HQ is the ratio of the potential HAP exposure concentration to the noncancer dose-response value. The HI is the sum of HQs for HAP that affect the same target organ or organ system.

[13] Recommendations of the SAB Risk and Technology Review Methods Panel are provided in their report, which is available at: *https://www.epa.gov/sites/default/files/2021-02/documents/epa-sab-10-007-unsigned.pdf.*

associated with applying each development. This analysis informs our decision of whether it is ''necessary'' to revise the emissions standards. In addition, we consider the appropriateness of applying controls to new sources versus retrofitting existing sources. For this exercise, we consider any of the following to be a ''development'':

- Any add-on control technology or other equipment that was not identified and considered during development of the original MACT and GACT standards;
- Any improvements in add-on control technology or other equipment (that were identified and considered during development of the original MACT and GACT standards) that could result in additional emissions reduction;
- Any work practice or operational procedure that was not identified or considered during development of the original MACT and GACT standards;
- Any process change or pollution prevention alternative that could be broadly applied to the industry and that was not identified or considered during development of the original MACT and GACT standards; and
- Any significant changes in the cost (including cost effectiveness) of applying controls (including controls the EPA considered during the development of the original MACT and GACT standards).

In addition to reviewing the practices, processes, and control technologies that were considered at the time we originally developed or last reviewed the NESHAP, we review a variety of data sources in our investigation of potential practices, processes, or controls to consider. We also review the NESHAP and the available data to determine if there are any unregulated emissions of HAP within the source category and evaluate these data for use in developing new emission standards. See sections II.C and II.D of this preamble for information on the specific data sources that were reviewed as part of the technology review.

F. How do we estimate risk posed by the source category?

In this section, we provide a complete description of the types of analyses that we generally perform during the risk assessment process. In some cases, we do not perform a specific analysis because it is not relevant. For example, in the absence of emissions of HAP known to be persistent and bioaccumulative in the environment (PB–HAP), we would not perform a multipathway exposure assessment. Where we do not perform an analysis, we state that we do not and provide the reason. While we present all of our risk assessment methods, we only present risk assessment results for the analyses actually conducted (see section IV.B of this preamble).

The EPA conducts a risk assessment that provides estimates of the MIR for cancer posed by the HAP emissions from each source in the source category, the hazard index for chronic exposures to HAP with the potential to cause noncancer health effects, and the HQ for acute exposures to HAP with the potential to cause noncancer health effects. The assessment also provides estimates of the distribution of cancer risk within the exposed populations, cancer incidence, and an evaluation of the potential for an adverse environmental effect. The eight sections that follow this paragraph describe how we estimated emissions and conducted the risk assessment. The docket for this rulemaking contains the following document that provides more information on the risk assessment inputs and models: *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2022 Risk and Technology Review Proposed Rule.* The methods used to assess risk (as described in the eight primary steps below) are consistent with those described by the EPA in the document reviewed by a panel of the EPA's SAB in 2009, and described in the SAB review report issued in 2010. They are also consistent with the key recommendations contained in that report.

1. How did we estimate actual emissions and identify the emissions release characteristics?

Commercial sterilizers using EtO were listed for regulation in 1992 as described in section II.B of this preamble. The standards in the current NESHAP subpart O are based on facilities' EtO usage amount. Specifically, 40 CFR part 63, subpart O, contains SCV and ARV standards for facilities where EtO use is at least 10 tpy and a separate SCV standard for facilities where EtO use is at least 1 tpy but less than 10 tpy. Currently there are 86 facilities in the source category. Based on actual EtO usage data, 47 facilities are sterilization sources where EtO use is at least 10 tpy, 20 facilities are sterilization sources where EtO use is at least 1 tpy but less than 10 tpy, and 19 facilities are sterilization sources where EtO use is less than 1 tpy. The EPA also identified, based on permits and responses to the December 2019 questionnaire and September 2021 ICR, 11 research facilities, as defined under CAA 112(c)(7), which are not part of the source category.

For these facilities, the emissions information that was derived from the 2014 NEI was, in general, found to be insufficient to set appropriate standards. Most notably, for most facilities, room air emissions were not accounted for in the NEI. In addition, 28 facilities had no Emissions Inventory System ID and, therefore, no emissions data to pull from the NEI. Therefore, the EPA generated new EtO emissions data as described below. The complete Commercial Sterilization facility list is available in Appendix 1 of the document titled *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2022 Risk and Technology Review Proposed Rule,* which is available in the docket for this rulemaking.

In general, emissions were estimated using a mass balance approach, beginning with annual EtO use (*i.e.,* the previous consecutive 12-month period of EtO use). Where available, the latest annual EtO usage for each facility was used. Where we lacked data, we assumed that the facility was using 50 percent of the maximum usage listed in state and local permits because this is the industry average. Then, EtO use was apportioned to the different emission process groups using emission factors. Emission sources from Commercial Sterilization Facilities include SCVs, ARVs, CEVs, and room air emission sources (descriptions of SCV, ARV, and CEV emission sources are provided in section II.B). The room air emission sources are:

- Indoor EtO storage: EtO drums and cylinders are often stored in storage areas inside the facility, and emissions may occur from improperly sealed/leaking drums and cylinders into the storage room area.
- EtO dispensing: This includes connecting pressurized lines from the storage drum or cylinder valve to the sterilization chamber to charge EtO to the process cycle. EtO is often moved from the drum to the sterilizer chamber using nitrogen. EtO drums or cylinders may sit in a separate room for dispensing, or the drum or cylinder may be placed near the sterilization chamber. In either scenario, emissions may occur from connectors and valves on the pressurized lines that connect the storage drum or cylinder to the chamber.
- Vacuum pump operation: These are often used to evacuate sterilization chambers before the chamber door is opened. The vacuum pump feeds into a separation tank where the recirculating

pump fluid is returned to the pump and the EtO and other gases (nitrogen and air) are vented to a control system or to the atmosphere. Emissions from leaks may occur from the vacuum pump during operation.

- Pre-aeration handling of sterilized material (PrAHSM): Following the sterilization cycle, emissions may occur from the sterilized materials when moving the material from the sterilization chamber to the aeration room or when holding the material within the facility areas. PrAHSM includes activities such as removing the sterilized materials from the sterilization chamber, transferring sterilized materials from the sterilization chamber to the aeration room, placing or holding of sterilized materials outside of process equipment for short periods of time, and, at some facilities, during aeration transfers where there are primary and secondary aeration chambers. Emissions may occur from off-gassing of residual EtO that is contained in the materials following exposure to EtO.
- Post-aeration handling of sterilized material (PoAHSM): Following the aeration step, emissions may continue to occur from the sterilized and aerated materials when moving the material and holding the material within the facility areas. PoAHSM includes activities such as removing the sterilized/aerated materials from the aeration room, transferring the sterilized/aerated materials from the aeration room to holding areas, placing or holding of the sterilized/aerated materials in a quarantine area while awaiting confirmation of sterility, and holding of sterilized/aerated materials in shipping and warehouse areas at the facility. Emissions may occur from continued off-gassing of residual EtO that remains in the materials even after the aeration step.
- Non-oxidizer air pollution control device (APCD) area: Non-oxidizer APCDs, such as acid-water scrubbers and gas-solid reactors, are typically housed within the sterilization building. Through the responses to the section 114 requests, we learned that elevated EtO concentrations were observed in the rooms where these APCDs were located. This is likely due to equipment leaks and/or emissions not being fully captured or routed under negative pressure.

In the original rulemaking, we assumed there were no room air emissions. Using the emission source apportionment data available at that time, we assumed that 95 percent of the EtO usage was emitted through the SCV, 2 percent was emitted through the CEV, and 3 percent was emitted through the ARV.[14] The EPA now understands that in addition to emissions from point sources such as SCVs, CEVs, and ARVs, room air emissions also occur at commercial sterilization facilities. In recent years, the industry has assumed a range of room air emissions, anywhere from 0.01 to 1.5 percent of total usage. However, there is little to no documentation for these assumptions or what emission sources were included. In 2019, the EPA examined ambient air monitoring data collected around a commercial sterilization facility in Willowbrook, Illinois, and derived a room air emissions factor that equates to approximately 0.6 percent of total EtO usage.[15]

Under this rule review, the EPA reassessed the emission apportionment across the emission sources at commercial sterilization facilities. The EPA analyzed the responses from the December 2019 questionnaire and September 2021 ICR to update the fraction of EtO that is apportioned to SCV, ARV, CEV, and room air emissions.

- The data for the ARV analyses included flow rate (or room volume combined with air changeover rate), EtO concentration, and average aeration room temperature to estimate ARV emissions.
- The data for the CEV analyses included flow rate, EtO concentration, and the sterilizer chamber temperature to estimate CEV emissions.
- The data for the room area analyses included the flow rate, EtO concentration, temperature information, and annual operating hours to estimate the EtO emission for each emission source.

The estimated EtO emissions were compared to the annual actual EtO usage to develop the fraction of EtO use that goes to each emission source before controls. Under the recent emission source apportionment analysis, the EPA determined 4 percent of EtO used goes to the ARV, 1 percent goes to the CEV, 0.1 percent goes to EtO dispensing, 0.1 percent goes to vacuum pump operations, 0.2 percent goes to pre-aeration handling of sterilized material, 0.2 percent goes to post-aeration handling of sterilized material, and 0.04 percent goes to non-oxidizer APCD operation. We estimate that another 1 percent of EtO used leaves the facility still in the product. The portion of EtO usage that is emitted from SCV is the balance of the EtO usage (*i.e.,* 93.36 percent). However, the value varies depending on the equipment configuration (traditional sterilizer chamber, combination chamber, etc.) and may range from 93.36 to 98.32 percent. The EPA was not able to quantify what percentage of EtO use is emitted from indoor EtO storage, which could result in a slight underestimation of the risk. Based on our review of the data, we do not believe that emissions from indoor EtO storage are significant. See memorandum *Development of Ethylene Oxide Usage Fractions for Ethylene Oxide Commercial Sterilization—Proposal,* which is available in the docket for this rulemaking.

Finally, the performance of the control systems used to reduce emissions, if available, was considered. Data from the CAA section 114 requests, as well as state and local permitting data, were also used to develop the other parameters needed to perform the risk modeling analysis, including the emissions release characteristics, such as stack heights, stack diameters, flow rates, temperatures, and emission release point locations.

The RTR emissions dataset developed using the data and estimates described immediately above was refined following an extensive quality assurance check of source locations, emission release point parameters, and annual emission estimates. The EPA reviewed the locations of emission release points at each facility and revised each record as needed to ensure that all release points were located correctly. If an emission release point was located outside of the facility fenceline or on an obviously incorrect location within the fenceline (*e.g.,* parking lot, lake, etc.) then the emission release point was relocated to either the true location of the equipment, if known, or the approximate center of the facility.

The emission release point parameters for stacks in the modeling input files include stack height, exit gas temperature, stack diameter, exit gas velocity, and exit gas flow rate. If emission release point parameters were outside of typical quality assurance range checks or missing, then an investigation was done to determine whether these values were accurate. If this information could not be found, then surrogate values were assigned based on similar values observed for the control device and process group. In some cases, missing emission release point parameters were calculated using

[14] U.S. EPA. *Ethylene Oxide Emissions from Commercial Sterilization/Fumigation Operations, Background Information for Proposed Standards.* EPA Publication No. EPA–453/D–93–016. October 1992.

[15] *https://www.epa.gov/sites/default/files/2019-08/documents/appendix_1_to_the_sterigenics_willowbrook_risk_assessment.pdf,* Table 1.

other parameters within the modeling input file. For example, missing exit gas flow rates were calculated using the reported diameter and velocity.

Additionally, the EPA compared the emission release point type (*i.e.,* fugitive, stack) to the emission unit and process descriptions for the modeling file records. In cases where information was conflicting (*i.e.,* equipment leaks being modeled as a vertical stack, or process vent emissions being modeled as a fugitive area), we updated the emission release point type to the appropriate category and supplemented the appropriate emission release parameters using either permitted values, when available, or default values.

2. How do we conduct dispersion modeling, determine inhalation exposures, and estimate individual and population inhalation risk?

Both long-term and short-term inhalation exposure concentrations and health risk from the source category addressed in this proposal were estimated using the Human Exposure Model (HEM). The HEM performs three primary risk assessment activities: (1) Conducting dispersion modeling to estimate the concentrations of HAP in ambient air, (2) estimating long-term and short-term inhalation exposures to individuals residing within 50 kilometers (km) of the modeled sources, and (3) estimating individual and population-level inhalation risk using the exposure estimates and quantitative dose-response information.

a. Dispersion Modeling

AERMOD, the air dispersion model used by the HEM model, is one of the EPA's preferred models for assessing air pollutant concentrations from industrial facilities. To perform the dispersion modeling and to develop the preliminary risk estimates, HEM draws on three data libraries. The first is a library of meteorological data, which is used for dispersion calculations. This library includes hourly surface and upper air observations for years ranging from 2016–2019 from over 800 meteorological stations, selected to provide coverage of the United States and Puerto Rico. A second library of United States Census Bureau census block internal point locations and populations provides the basis of human exposure calculations (U.S. Census, 2010). In addition, for each census block, the census library includes the elevation and controlling hill height, which are also used in dispersion calculations. A third library of pollutant-specific dose-response values is used to estimate health risk. These are discussed below.

b. Risk From Chronic Exposure to HAP

In developing the risk assessment for chronic exposures, we use the estimated annual average ambient air concentrations of each HAP emitted by each source in the source category. The HAP air concentrations at each nearby census block centroid located within 50 km of the facility are a surrogate for the chronic inhalation exposure concentration for all the people who reside in that census block. A distance of 50 km is consistent with both the analysis supporting the 1989 Benzene NESHAP (54 FR 38044) and the limitations of Gaussian dispersion models, including AERMOD.

For each facility, we calculate the MIR as the cancer risk associated with a continuous lifetime (24 hours per day, 7 days per week, 52 weeks per year, 70 years) exposure to the maximum concentration at the centroid of each inhabited census block. We calculate individual cancer risk by multiplying the estimated lifetime exposure to the ambient concentration of each HAP (in $\mu g/m^3$) by its URE. The URE is an upper-bound estimate of an individual's incremental risk of contracting cancer over a lifetime of exposure to a concentration of 1 microgram of the pollutant per cubic meter of air. For residual risk assessments, we generally use UREs from the EPA's IRIS. For carcinogenic pollutants without IRIS values, we look to other reputable sources of cancer dose-response values, often using CalEPA UREs, where available. In cases where new, scientifically credible dose-response values have been developed in a manner consistent with EPA guidelines and have undergone a peer review process similar to that used by the EPA, we may use such dose-response values in place of, or in addition to, other values, if appropriate. The pollutant-specific dose-response values used to estimate health risk are available at *https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants.*

To estimate individual lifetime cancer risks associated with exposure to HAP emissions from each facility in the source category, we sum the risks for each of the carcinogenic HAP emitted by the modeled facility. We estimate cancer risk at every census block within 50 km of every facility in the source category. The MIR is the highest individual lifetime cancer risk estimated for any of those census blocks. In addition to calculating the MIR, we estimate the distribution of individual cancer risks for the source category by summing the number of individuals within 50 km of the sources whose estimated risk falls within a specified risk range. We also estimate annual cancer incidence by multiplying the estimated lifetime cancer risk at each census block by the number of people residing in that block, summing results for all of the census blocks, and then dividing this result by a 70-year lifetime.

To assess the risk of noncancer health effects from chronic exposure to HAP, we calculate either an HQ or a target organ-specific hazard index (TOSHI). We calculate an HQ when a single noncancer HAP is emitted. Where more than one noncancer HAP is emitted, we sum the HQ for each of the HAP that affects a common target organ or target organ system to obtain a TOSHI. The HQ is the estimated exposure divided by the chronic noncancer dose-response value, which is a value selected from one of several sources. The preferred chronic noncancer dose-response value is the EPA RfC, defined as ''an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime'' (*https://iaspub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&vocabName=IRIS%20Glossary*). In cases where an RfC from the EPA's IRIS is not available or where the EPA determines that using a value other than the RfC is appropriate, the chronic noncancer dose-response value can be a value from the following prioritized sources, which define their dose-response values similarly to the EPA: (1) the Agency for Toxic Substances and Disease Registry (ATSDR) Minimal Risk Level (*https://www.atsdr.cdc.gov/minimalrisklevels/index.html*); (2) the CalEPA Chronic Reference Exposure Level (REL) (*https://oehha.ca.gov/air/crnr/notice-adoption-air-toxics-hot-spots-program-guidance-manual-preparation-health-risk-0*); or (3) as noted above, a scientifically credible dose-response value that has been developed in a manner consistent with the EPA guidelines and has undergone a peer review process similar to that used by the EPA. The pollutant-specific dose-response values used to estimate health risks are available at *https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants.*

c. Risk From Acute Exposure to HAP That May Cause Health Effects Other Than Cancer

For each HAP for which appropriate acute inhalation dose-response values are available, the EPA also assesses the potential health risks due to acute exposure. For these assessments, the EPA makes conservative assumptions about emission rates, meteorology, and exposure location. As part of our efforts to continually improve our methodologies to evaluate the risks that HAP emitted from categories of industrial sources pose to human health and the environment, we revised our treatment of meteorological data to use reasonable worst-case air dispersion conditions in our acute risk screening assessments instead of worst-case air dispersion conditions. This revised treatment of meteorological data and the supporting rationale are described in more detail in *Residual Risk Assessment for Commercial Sterilization Facilities Source Category in Support of the 2022 Technology Review Proposed Rule* and in Appendix 5 of the report: Technical Support Document for Acute Risk Screening Assessment. This revised approach has been used in this proposed rule and in all other RTR rulemakings proposed on or after June 3, 2019.

To assess the potential acute risk to the maximally exposed individual, we use the peak hourly emission rate for each emission point, reasonable worst-case air dispersion conditions (*i.e.,* 99th percentile), and the point of highest off-site exposure. Specifically, we assume that peak emissions from the source category and reasonable worst-case air dispersion conditions co-occur and that a person is present at the point of maximum exposure.

To characterize the potential health risks associated with estimated acute inhalation exposures to a HAP, we generally use multiple acute dose-response values, including acute RELs, acute exposure guideline levels (AEGLs), and emergency response planning guidelines (ERPG) for 1-hour exposure durations, if available, to calculate acute HQs. The acute HQ is calculated by dividing the estimated acute exposure concentration by the acute dose-response value. For each HAP for which acute dose-response values are available, the EPA calculates acute HQs.

An acute reference exposure level (REL) is defined as ''the concentration level at or below which no adverse health effects are anticipated for a specified exposure duration.'' Acute RELs are based on the most sensitive, relevant, adverse health effect reported in the peer-reviewed medical and toxicological literature. They are designed to protect the most sensitive individuals in the population through the inclusion of margins of safety. Because margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health impact. AEGLs represent threshold exposure limits for the general public and are applicable to emergency exposures ranging from 10 minutes to 8 hours. They are guideline levels for ''once-in-a-lifetime, short-term exposures to airborne concentrations of acutely toxic, high-priority chemicals.'' *Id.* at 21. The AEGL–1 is specifically defined as ''the airborne concentration (expressed as ppm or milligrams per cubic meter) of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.'' The document also notes that ''Airborne concentrations below AEGL–1 represent exposure levels that can produce mild and progressively increasing but transient and nondisabling odor, taste, and sensory irritation or certain asymptomatic, nonsensory effects.'' *Id.* AEGL–2 are defined as ''the airborne concentration (expressed as parts per million or milligrams per cubic meter) of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.'' *Id.*

ERPGs are developed by the American Industrial Hygiene Association (AIHA) for emergency planning and are intended to be health-based guideline concentrations for single exposures to chemicals. The ERPG–1 is the maximum airborne concentration, established by AIHA, below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing other than mild transient adverse health effects or without perceiving a clearly defined, objectionable odor. Similarly, the ERPG–2 is the maximum airborne concentration, established by AIHA, below which it is believed that nearly all individuals could be exposed for up to one hour without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action.

An acute REL for 1-hour exposure durations is typically lower than its corresponding AEGL–1 and ERPG–1. Even though their definitions are slightly different, AEGL–1s are often the same as the corresponding ERPG–1s, and AEGL–2s are often equal to ERPG–2s. The maximum HQs from our acute inhalation screening risk assessment typically result when we use the acute REL for a HAP. In cases where the maximum acute HQ exceeds 1, we also report the HQ based on the next highest acute dose-response value (usually the AEGL–1 and/or the ERPG–1).

For this source category, an acute emissions multiplier value of 1.2 was used because, overall, sterilization operations tend to be steady-state without much variation. A further discussion of why this factor was chosen can be found in Appendix 1 of the document titled *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2022 Risk and Technology Review Proposed Rule,* available in the docket for this rulemaking.

In our acute inhalation screening risk assessment, acute impacts are deemed negligible for HAP for which acute HQs are less than or equal to 1, and no further analysis is performed for these HAP. In cases where an acute HQ from the screening step is greater than 1, we assess the site-specific data to ensure that the acute HQ is at an off-site location. For this source category, all acute HQs were less than or equal to 1, and no further analysis was performed.

3. How do we conduct the multipathway exposure and risk screening assessment?

The EPA conducts a tiered screening assessment examining the potential for significant human health risks due to exposures via routes other than inhalation (*i.e.,* ingestion). We first determine whether any sources in the source category emit any HAP known to be persistent and bioaccumulative in the environment, as identified in the EPA's Air Toxics Risk Assessment Library (see Volume 1, Appendix D, at *https://www.epa.gov/fera/risk-assessment-and-modeling-air-toxics-risk-assessment-reference-library*).

For the Commercial Sterilization Facilities source category, we did not identify emissions of any PB–HAP. Because we did not identify any PB–HAP emissions, no further evaluation of multipathway risk was conducted for this source category.

4. How do we assess risks considering emissions control options?

In addition to assessing baseline inhalation risks and screening for potential multipathway risks, we also estimate risks considering the potential emission reductions that would be achieved by the control options under consideration. In these cases, the expected emission reductions are applied to the specific HAP and emission points in the RTR emissions dataset to develop corresponding estimates of risk and incremental risk reductions.

5. How do we conduct the environmental risk screening assessment?

The EPA conducts a screening assessment to examine the potential for an adverse environmental effect. Section 112(a)(7) of the CAA defines ''adverse environmental effect'' as ''any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas.''

The EPA focuses on eight HAP, which are referred to as ''environmental HAP,'' in its screening assessment: six PB–HAP and two acid gases. The PB–HAP included in the screening assessment are arsenic compounds, cadmium compounds, dioxins/furans, polycyclic organic matter (POM), mercury (both inorganic mercury and methyl mercury), and lead compounds. The acid gases included in the screening assessment are hydrochloric acid (HCl) and hydrogen fluoride (HF).

For the Commercial Sterilization Facilities source category, we did not identify emissions of any environmental HAP. Because we did not identify any environmental HAP emissions, no further evaluation of environmental risk was conducted for this source category.

6. How do we conduct facility-wide assessments?

To put the source category risks in context, we typically examine the risks from the entire ''facility,'' where the facility includes all HAP-emitting operations within a contiguous area and under common control. In other words, we examine the HAP emissions not only from the source category emission points of interest, but also emissions of HAP from all other emission sources at the facility for which we have data. For this source category, we conducted the facility-wide assessment using a dataset compiled from the 2017 NEI. The source category records of that NEI dataset were removed, evaluated, and updated as described in section II.C of this preamble: What data collection activities were conducted to support this action? Once a quality assured source category dataset was available, it was placed back with the remaining records from the NEI for that facility. The facility-wide file was then used to analyze risks due to the inhalation of HAP that are emitted ''facility-wide'' for the populations residing within 50 km of each facility, consistent with the methods used for the source category analysis described above. For these facility-wide risk analyses, the modeled source category risks were compared to the facility-wide risks to determine the portion of the facility-wide risks that could be attributed to the source category addressed in this proposal. We also specifically examined the facility that was associated with the highest estimate of risk and determined the percentage of that risk attributable to the source category of interest. The *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the Risk and Technology Review 2022 Proposed Rule,* available through the docket for this action, provides the methodology and results of the facility-wide analyses, including all facility-wide risks and the percentage of source category contribution to facility-wide risks.

7. How do we consider uncertainties in risk assessment?

Uncertainty and the potential for bias are inherent in all risk assessments, including those performed for this proposal. Although uncertainty exists, we believe that our approach, which used conservative tools and assumptions, ensures that our decisions are health and environmentally protective. A brief discussion of the uncertainties in the RTR emissions dataset, dispersion modeling, inhalation exposure estimates, and dose-response relationships follows below. Also included are those uncertainties specific to our acute screening assessments, multipathway screening assessments, and our environmental risk screening assessments. A more thorough discussion of these uncertainties is included in the *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the Risk and Technology Review 2022 Proposed Rule,* which is available in the docket for this action. If a multipathway site-specific assessment was performed for this source category, a full discussion of the uncertainties associated with that assessment can be found in Appendix 11 of that document, *Site-Specific Human Health Multipathway Residual Risk Assessment Report.*

a. Uncertainties in the RTR Emissions Dataset

Although the development of the RTR emissions dataset involved quality assurance/quality control processes, the accuracy of emissions values will vary depending on the source of the data, the degree to which data are incomplete or missing, the degree to which assumptions made to complete the datasets are accurate, errors in emission estimates, and other factors. The emission estimates considered in this analysis generally are annual totals for certain years, and they do not reflect short-term fluctuations during the course of a year or variations from year to year. The estimates of peak hourly emission rates for the acute effects screening assessment were based on an emission adjustment factor applied to the average annual hourly emission rates, which are intended to account for emission fluctuations due to normal facility operations.

b. Uncertainties in Dispersion Modeling

We recognize there is uncertainty in ambient concentration estimates associated with any model, including the EPA's recommended regulatory dispersion model, AERMOD. In using a model to estimate ambient pollutant concentrations, the user chooses certain options to apply. For RTR assessments, we select some model options that have the potential to overestimate ambient air concentrations (*e.g.,* not including plume depletion or pollutant transformation). We select other model options that have the potential to underestimate ambient impacts. Other options that we select have the potential to either under- or overestimate ambient levels (*e.g.,* meteorology and receptor locations). On balance, considering the directional nature of the uncertainties commonly present in ambient concentrations estimated by dispersion models, the approach we apply in the RTR assessments should yield unbiased estimates of ambient HAP concentrations. We also note that the selection of meteorology dataset location could have an impact on the risk estimates. As we continue to update and expand our library of meteorological station data used in our risk assessments, we expect to reduce this variability.

c. Uncertainties in Inhalation Exposure Assessment

Although every effort is made to identify all of the relevant facilities and emission points, as well as to develop accurate estimates of the annual emission rates for all relevant HAP, the uncertainties in our emission inventory likely dominate the uncertainties in the exposure assessment. Some uncertainties in our exposure assessment include human mobility, using the centroid of each census block, assuming lifetime exposure, and assuming only outdoor exposures. For most of these factors, there is neither an under- nor overestimate when looking at the maximum individual risk or the incidence, but the shape of the distribution of risks may be affected. With respect to outdoor exposures, actual exposures may not be as high if people spend time indoors, especially for very reactive pollutants or larger particles. For all factors, we reduce uncertainty when possible. For example, with respect to census-block centroids, we analyze large blocks using aerial imagery and adjust locations of the block centroids to better represent the population in the blocks. We also add additional receptor locations where the population of a block is not well represented by a single location.

d. Uncertainties in Dose-Response Relationships

There are uncertainties inherent in the development of the dose-response values used in our risk assessments for cancer effects from chronic exposures and noncancer effects from both chronic and acute exposures. Some uncertainties are generally expressed quantitatively, and others are generally expressed in qualitative terms. We note, as a preface to this discussion, a point on dose-response uncertainty that is stated in the EPA's 2005 Guidelines for Carcinogen Risk Assessment; namely, that ''the primary goal of EPA actions is protection of human health; accordingly, as an Agency policy, risk assessment procedures, including default options that are used in the absence of scientific data to the contrary, should be health protective'' (the EPA's 2005 Guidelines for Carcinogen Risk Assessment, page 1–7). This is the approach followed here as summarized in the next paragraphs.

Cancer UREs used in our risk assessments are those that have been developed to generally provide an upper bound estimate of risk. That is, they represent a ''plausible upper limit to the true value of a quantity'' (although this is usually not a true statistical confidence limit). In some circumstances, the true risk could be as low as zero; however, in other circumstances the risk could be greater. Chronic noncancer RfC and reference dose values represent chronic exposure levels that are intended to be health-protective levels. To derive dose-response values that are intended to be ''without appreciable risk,'' the methodology relies upon an uncertainty factor (UF) approach, which considers uncertainty, variability, and gaps in the available data. The UFs are applied to derive dose-response values that are intended to protect against appreciable risk of deleterious effects.

Many of the UFs used to account for variability and uncertainty in the development of acute dose-response values are quite similar to those developed for chronic durations. Additional adjustments are often applied to account for uncertainty in extrapolation from observations at one exposure duration (*e.g.,* 4 hours) to derive an acute dose-response value at another exposure duration (*e.g.,* 1 hour). Not all acute dose-response values are developed for the same purpose, and care must be taken when interpreting the results of an acute assessment of human health effects relative to the dose-response value or values being exceeded. Where relevant to the estimated exposures, the lack of acute dose-response values at different levels of severity should be factored into the risk characterization as potential uncertainties.

Uncertainty also exists in the selection of ecological benchmarks for the environmental risk screening assessment. We established a hierarchy of preferred benchmark sources to allow selection of benchmarks for each environmental HAP at each ecological assessment endpoint. We searched for benchmarks for three effect levels (*i.e.,* no-effects level, threshold-effect level, and probable effect level), but not all combinations of ecological assessment/environmental HAP had benchmarks for all three effect levels. Where multiple effect levels were available for a particular HAP and assessment endpoint, we used all of the available effect levels to help us determine whether risk exists and whether the risk could be considered significant and widespread.

Although we make every effort to identify appropriate human health effect dose-response values for all pollutants emitted by the sources in this risk assessment, some HAP emitted by this source category are lacking dose-response assessments. Accordingly, these pollutants cannot be included in the quantitative risk assessment, which could result in quantitative estimates understating HAP risk. To help to alleviate this potential underestimate, where we conclude similarity with a HAP for which a dose-response value is available, we use that value as a surrogate for the assessment of the HAP for which no value is available. To the extent use of surrogates indicates appreciable risk, we may identify a need to increase priority for an IRIS assessment for that substance. We additionally note that, generally speaking, HAP of greatest concern due to environmental exposures and hazard are those for which dose-response assessments have been performed, reducing the likelihood of understating risk. Further, HAP not included in the quantitative assessment are assessed qualitatively and considered in the risk characterization that informs the risk management decisions, including consideration of HAP reductions achieved by various control options.

For a group of compounds that are unspeciated (*e.g.,* glycol ethers), we conservatively use the most protective dose-response value of an individual compound in that group to estimate risk. Similarly, for an individual compound in a group (*e.g.,* ethylene glycol diethyl ether) that does not have a specified dose-response value, we also apply the most protective dose-response value from the other compounds in the group to estimate risk.

e. Uncertainties in Acute Inhalation Screening Assessments

In addition to the uncertainties highlighted above, there are several factors specific to the acute exposure assessment that the EPA conducts as part of the risk review under section 112 of the CAA. The accuracy of an acute inhalation exposure assessment depends on the simultaneous occurrence of independent factors that may vary greatly, such as hourly emissions rates, meteorology, and the presence of a person. In the acute screening assessment that we conduct under the RTR program, we assume that peak emissions from the source category and reasonable worst-case air dispersion conditions (*i.e.,* 99th percentile) co-occur. We then include the additional assumption that a person is located at this point at the same time. Together, these assumptions represent a reasonable worst-case actual exposure scenario. In most cases, it is unlikely that a person would be located at the point of maximum exposure during the time when peak emissions and reasonable worst-case air dispersion conditions occur simultaneously.

f. Uncertainties in the Multipathway and Environmental Risk Screening Assessments

For each source category, we generally rely on site-specific levels of PB–HAP or environmental HAP emissions to determine whether a refined assessment of the impacts from multipathway exposures is necessary or whether it is necessary to perform an environmental screening assessment. This determination is based on the results of a three-tiered screening assessment that relies on the outputs from models—TRIM.FaTE and American Meteorological Society (AMS)/Environmental Protection Agency (EPA) Regulatory Model (AERMOD)—that estimate environmental pollutant concentrations and human exposures for five PB–HAP (dioxins/furans, POM, mercury (both inorganic and methyl mercury), cadmium, and arsenic) and two acid gases (HF and HCl). For lead, the other PB–HAP, we use AERMOD to determine ambient air concentrations, which are then compared to the secondary National Ambient Air Quality Standards standard for lead. Two important types of uncertainty associated with the use of these models in RTR risk assessments and inherent to any assessment that relies on environmental modeling are model uncertainty and input uncertainty.

Model uncertainty concerns whether the model adequately represents the actual processes that might occur in the environment, such as the movement of a pollutant through soil or accumulation of the pollutant over time. This type of uncertainty is difficult to quantify. However, based on feedback received from previous EPA SAB reviews and other reviews, we are confident that the models used in the screening assessments are appropriate and state-of-the-art for the multipathway and environmental screening risk assessments conducted in support of RTRs.

Input uncertainty is concerned with how accurately the models have been configured and parameterized for the assessment at hand. For Tier 1 of the multipathway and environmental screening assessments, we configured the models to avoid underestimating exposure and risk. This was accomplished by selecting upper-end values from nationally representative datasets for the more influential parameters in the environmental model, including selection and spatial configuration of the area of interest, lake location and size, meteorology, surface water, soil characteristics, and structure of the aquatic food web. We also assume an ingestion exposure scenario and values for human exposure factors that represent reasonable maximum exposures.

In Tier 2 of the multipathway and environmental screening assessments, we refine the model inputs to account for meteorological patterns in the vicinity of the facility versus using upper-end national values, and we identify the actual location of lakes near the facility rather than the default lake location that we apply in Tier 1. By refining the screening approach in Tier 2 to account for local geographical and meteorological data, we decrease the likelihood that concentrations in environmental media are overestimated, thereby increasing the usefulness of the screening assessment. In Tier 3 of the screening assessments, we refine the model inputs again to account for hour-by-hour plume-rise and the height of the mixing layer. We can also use those hour-by-hour meteorological data in a TRIM.FaTE run using the screening configuration corresponding to the lake location. These refinements produce a more accurate estimate of chemical concentrations in the media of interest, thereby reducing the uncertainty with those estimates. The assumptions and the associated uncertainties regarding the selected ingestion exposure scenario are the same for all three tiers.

For the environmental screening assessment for acid gases, we employ a single-tiered approach. We use the modeled air concentrations and compare those with ecological benchmarks.

For all tiers of the multipathway and environmental screening assessments, our approach to addressing model input uncertainty adopts conservative assumptions that are intended to be protective of public health. We choose model inputs from the upper end of the range of possible values for the influential parameters used in the models, and we assume that the exposed individual exhibits ingestion behavior that would lead to a high total exposure. This approach reduces the likelihood of not identifying high risks for adverse impacts.

Despite the uncertainties, when individual pollutants or facilities do not exceed screening threshold emission rates (*i.e.,* screen out), we are confident that the potential for adverse multipathway impacts on human health is very low. On the other hand, when individual pollutants or facilities do exceed screening threshold emission rates, it does not mean that impacts are significant, only that we cannot rule out that possibility and that a refined assessment for the site might be necessary to obtain a more accurate risk characterization for the source category.

The EPA evaluates the following HAP in the multipathway and/or environmental risk screening assessments, where applicable: arsenic, cadmium, dioxins/furans, lead, mercury (both inorganic and methyl mercury), POM, HCl, and HF. These HAP represent pollutants that can cause adverse impacts either through direct exposure to HAP in the air or through exposure to HAP that are deposited from the air onto soils and surface waters and then through the environment into the food web. These HAP represent those HAP for which we can conduct a meaningful multipathway or environmental screening risk assessment. For other HAP not included in our screening assessments, the model has not been parameterized such that it can be used for that purpose. In some cases, depending on the HAP, we may not have appropriate multipathway models that allow us to predict the concentration of that pollutant. The EPA acknowledges that other HAP beyond these that we are evaluating may have the potential to cause adverse effects and, therefore, the EPA may evaluate other relevant HAP in the future, as modeling science and resources allow.

III. Analytical Results and Proposed Decisions

In this section, we describe the analyses performed to support the proposed decisions for establishing standards for previously unregulated processes and pollutants, the residual risk assessment, the technology review, and other issues addressed in this proposal. We also describe the proposed standards that result from this series of analyses. To develop the proposed standards, we first determined the proposed standards for previously unregulated emission sources under CAA section 112(d)(2)–(3) (MACT) or 112(d)(5) (GACT). Next, we assessed the remaining risks, taking into account the current standards and the proposed standards we developed under the first analysis for the currently unregulated sources. Based on the risk assessment, we identified additional control options to ensure that risks are acceptable and provide an ample margin of safety to protect public health. Based on those analyses, we are proposing risk-based standards for certain sources under CAA section 112(f). We also conducted a technology review, under CAA section 112(d)(6). Finally, we evaluated the startup, shutdown, and malfunction (SSM) provisions; monitoring, recordkeeping, and reporting; and

performance testing requirements in the current rule, and we are proposing amendments to ensure consistency with the EPA's current approaches related to these provisions.

A. How are we proposing to define affected sources?

We are proposing to specifically define affected sources in subpart O for the reasons explained below. The current subpart O does not contain definitions for affected sources, which means the definition of an ''affected source'' at 40 CFR 63.2 currently applies. 40 CFR 63.2 defines an affected source as ''the collection of equipment, activities, or both within a single contiguous area and under common control that is included in a section 112(c) source category or subcategory for which a section 112(d) standard or other relevant standard is established pursuant to section 112 of the Act.'' Accordingly, an affected source under the current subpart O, as defined under 40 CFR 63.2, includes all SCVs and ARVs at a currently regulated EtO commercial sterilization facility, and the applicable standard is based on the facility's annual EtO usage amount. It is not clear that EPA had intended to apply the ''affected source'' definition at 40 CFR 63.2 to subpart O as we did not find specific discussions on this topic in the prior rulemakings for subpart O. In any event, we evaluated this issue for purposes of the present rulemaking. For point source emissions (*i.e.,* SCVs, ARVs, and CEVs), we do not believe that the ''affected source'' definition at 40 CFR 63.2 is appropriate because a facility may not route all emissions from a particular type of point source (*e.g.,* emissions from all SCVs at a facility) to the same emission control system, thus making compliance demonstration with the standards difficult. Therefore, for point sources, we are proposing to define an affected source as each individual SCV, ARV or CEV at a facility.[16]

For room air emissions, which are currently unregulated, we are proposing to define Group 1 and Group 2 room air emissions as a collection of emissions. *Group 1 room air emissions* would be defined as emissions from indoor EtO storage, EtO dispensing, vacuum pump operations, and pre-aeration handling of sterilized material. *Group 2 room air emissions* would be defined as emissions from post-aeration handling of sterilized material.

Unlike point sources, the collection of Group 1 and Group 2 emissions described above are commonly routed to the same emission control and, therefore, it seems logical to define affected sources for room air emissions by the groupings described above. Also, the equipment and processes that contribute to these emissions (*e.g.,* drums, pumps, sterilized material) are so numerous that defining each of these emissions individually as an affected source would be impractical and an implementation burden.

For the reasons explained above, we are proposing to add definitions for affected sources to 40 CFR 63.360. Specifically, for SCVs, ARVs, and CEVs, we are proposing to define the affected source as the individual vent. For Group 1 and Group 2 room air emissions, we are proposing to define the affected source as the collection of all room air emissions for each group as described above at any sterilization facility. We are soliciting comment on these proposed definitions (Comment C–1).

B. What actions are we taking pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5)?

In our review of the EtO Commercial Sterilization NESHAP, we identified emission sources of EtO that are currently unregulated and developed emission standards under sections 112(d)(2)–(3) or (d)(5), as appropriate. In addition to room air emission sources, certain point source emissions are also currently unregulated, including the following: SCVs, ARVs, and CEVs at facilities where EtO use is less than 1 tpy; ARVs and CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy; and CEVs at facilities where EtO use is at least 10 tpy. Emission standards are being proposed for these sources under CAA sections 112(d)(2)–(3) or (d)(5), as appropriate. We are required under CAA section 112(d)(3) to establish MACT standards for major sources. For new sources, the MACT floor cannot be less stringent than the emission control that is achieved in practice by the best controlled similar source. For existing sources, the MACT floor cannot be less stringent than the average emission limitation achieved by the best performing 12 percent of existing sources for which data are available for source categories with 30 or more sources, or the best performing 5 sources for source categories with fewer than 30 sources. For area source facilities, CAA section 112(d)(5) gives EPA discretion to set standards based on GACT for those facilities in lieu of MACT standards. Unlike MACT, there is no prescription in CAA section 112(d)(5) that standards for existing sources must, at a minimum, be set at the level of emission reduction achieved by the best performing 12 percent of existing sources, or that standards for new sources be set at the level of emission reduction achieved in practice by the best controlled similar source. The legislative history suggests that standards under CAA section 112(d)(5) should ''[reflect] application of generally available control technology that is, methods, practices, and techniques which are commercially available and appropriate for application by the sources in the category considering economic impacts and the technical capabilities of the firms to operate and maintain the emissions control systems.'' SEN. REP. NO. 101–228, at 171 (1989). Thus, in contrast to MACT, CAA section 112(d)(5) allows us to consider various factors in determining the appropriate standard for a given area source category.

We are proposing to set EtO standards for unregulated emissions at new and existing major and area sources as authorized by the CAA.[17] In deciding how to regulate currently unregulated emissions from existing area source facilities, we are proposing that, in all cases, setting GACT standards would be appropriate because (1) a significant portion of the area source facilities are owned by small entities, (2) companies could experience significant economic burden (*i.e.,* cost-to-sales ratio exceeding 5 percent) if MACT standards are imposed, (3) we are trying to minimize disruptions to the supply of medical devices and thereby avoid creating a potential health concern, and (4) as discussed in more detail below in section III.D, we are proposing revision to the standards, including those being proposed under CAA section 112(d)(5) for certain currently unregulated emission sources, based on our assessment of the post-control risks under CAA section 112(f)(2) in this proposed rulemaking.

CAA section 112(a) defines a major source as ''any stationary source or group of stationary sources located within a contiguous area and under

[16] The proposed definition, if finalized, would not apply retroactively and, therefore, would not be used to determine compliance with subpart O for periods prior to the final rule amending subpart O.

[17] Some facilities also use propylene oxide (PpO) when conducting sterilization operations. The only facilities that reported PpO emissions were area source facilities. PpO is not one of the 30 urban HAP listed for regulation under CAA section 112(c)(3)/(k)(3)(B), an obligation that EPA completed in 2011 (76 FR 15308). Further, as mentioned earlier, area sources of commercial sterilizers were listed for regulation under CAA section 112(c)(3) based on a finding of threat of adverse effects from commercial sterilizers using EtO. We are therefore not proposing standards for PpO.

common control that emits or has the potential to emit considering controls, in the aggregate, 10 tpy or more of any HAP or 25 tpy or more of any combination of HAPs. . .''. It further defines an area source as ''any stationary source of HAPs that is not a major source''. A synthetic area source facility is one that otherwise has the potential to emit HAPs in amounts that are at or above those for major sources of HAP, but that have taken a restriction so that its potential to emit is less than such amounts for major sources. For the facilities within this source category, EtO sterilization tends to be either the primary or only activity and source of HAP emissions. In addition, most of the EtO used at these facilities is released through the SCV and ARV. As discussed in more detail below, the current subpart O contains standards for certain point sources at facilities where EtO use is at least 10 tpy. Some state and local governments also regulate EtO emissions from these facilities. Based on these facts, as well as our review of the permits, we believe that all facilities that use more than 10 tpy are synthetic area source facilities, and all but one facility where EtO use is less than 10 tpy are true area source facilities. We have only identified one facility where EtO use is less than 10 tpy that is a major source due to other HAP emissions, which are regulated under other section 112 NESHAP.[18]

1. SCVs at Facilities Where EtO Use Is Less Than 1 Tpy

a. Existing Sources

The current subpart O does not contain emission standards for SCVs at facilities where EtO use is less than 1 tpy. There are 20 facilities where EtO use is less than 1 tpy, all of which have SCVs. Of these 20 facilities, 19 are currently controlling their SCV emissions. Fourteen of these facilities use catalytic oxidizers, five use gas/solid reactors, and one uses an acid-water scrubber and gas/solid reactor in series. Note that this does not sum up to 19 because one facility is using two different types of control systems to reduce SCV emissions. Performance tests are available for SCVs at three facilities where EtO use is less than 1 tpy; two of these facilities use catalytic oxidizers, and one uses a gas/solid reactor. We reviewed all these performance tests, and the reported emission reductions range from 98.6 to 99.9 percent.

For existing sources, we considered two potential GACT options for reducing EtO emissions from this group: the first option considers setting an emission standard that reflects the use of emission controls on the SCVs, and the second option considers applying a best management practice (BMP) to reduce EtO use per sterilization cycle (*i.e.,* pollution prevention). With respect to the first option, because 19 out of 20 facilities with SCVs and EtO usage less than 1 tpy are already using controls to reduce SCV emissions, we consider emission controls to be generally available for SCVs. We considered a standard of 99 percent emission reduction, which is the current subpart O standard for SCVs at facilities where EtO use is at least 1 tpy. We find this standard to be reasonable for existing SCVs at facilities using less than 1 tpy EtO because it is comparable to the emission reductions shown in the performance tests from facilities within this group.

The second potential GACT option we considered was a management practice that would require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with International Organization for Standardization (ISO) 11135:2014 and ISO 11138–1:2017. ISO 11135:2014 describes these two approaches. Currently, ISO 11135:2014 is a voluntary consensus standard for EtO sterilization that is recognized by FDA.[19] ISO 11135:2014 ''describes requirements that, if met, will provide an EtO sterilization process intended to sterilize medical devices, which has appropriate microbicidal activity.'' [20] ISO 11138–1:2017 ''specifies general requirements for production, labelling, test methods and performance characteristics of biological indicators, including inoculated carriers and suspensions, and their components, to be used in the validation and routine monitoring of sterilization processes''.[21] The EPA has learned, through conversations with industry stakeholders, that current EtO use is based on very conservative estimates of the amount of EtO needed to achieve sterility and that current EtO use could be reduced by as much as 50 percent while still meeting sterility standards.[22] We therefore project that this BMP, which would require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance ISO 11135:2014 and ISO 11138–1:2017, would achieve those 50 percent reductions. We consider this option to be generally available because facilities already must configure sterilization cycles in accordance with ISO 11135:2014 and ISO 11138–1:2017. Option 2 would simply require that they follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to meet sterility assurance according to the ISO standards. These methods can use 50 percent less EtO than the most conservative method, Half Cycle Approach, which is currently the common industry practice.

The impacts of the two potential GACT options are presented in Table 5.

TABLE 5—NATIONWIDE EMISSIONS REDUCTIONS AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR EXISTING SCVS AT FACILITIES WHERE ETO USE IS LESS THAN 1 TPY

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$92,211	$21,762	3.3E–2	$654,578

[18] This facility is also subject to 40 CFR part 63, subparts Q, JJJJ, and ZZZZ.

[19] FDA also recognizes ISO 11138–1:2017, which remains current per ISO. See *https://www.iso.org/standard/66442.html.*

[20] ISO 11135:2014, Sterilization of health-care products—Ethylene oxide—Requirements for the development, validation and routine control of a sterilization process for medical devices, July 2014.

[21] ISO 11138–1:2017, Sterilization of health care products—Biological indicators—Part 1: General Requirements, March 2017.

[22] *See* memorandum, *Meeting Minutes for Discussion with Representative of STERIS,* located at Docket ID No. EPA–HQ–OAR–2019–0178. September 18, 2019.

TABLE 5—NATIONWIDE EMISSIONS REDUCTIONS AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR EXISTING SCVS AT FACILITIES WHERE ETO USE IS LESS THAN 1 TPY—Continued

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
2	BMP (estimated 50 percent emission reduction).	0	870,000 (one-time annual cost) [1]	0.24	3,678,138

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO 11138–1:2017, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, we find both options to be cost effective. While the cost-effectiveness number for Option 2 may seem high, EtO is a highly potent carcinogen, and the cost-effectiveness of Option 2 is within the range of the values that we have determined to be cost-effective for highly toxic HAPs. This includes hexavalent chromium, where we finalized a requirement with a cost-effectiveness of $15,000/lb ($30,000,000/ton) for existing small hard chromium electroplating to provide an ample margin of safety (taking into account cost among other factors) (77 FR 58227–8, 58239). While both options are considered generally available under CAA section 112(d)(5), Option 1 would ensure that facilities that are currently reducing emissions from SCVs using emission controls would continue to do so, whereas Option 2 would allow these facilities to remove their existing controls and potentially increase their emissions from SCVs. As mentioned earlier, 19 out of 20 facilities where EtO use is less than 1 tpy are currently controlling their SCV emissions. Therefore, the EtO emission reductions that occur because of Option 1 are relatively small. However, if 99 percent emission reduction were applied to uncontrolled emissions, the EtO emission reductions would be 7.4 tpy. In addition, Option 1 would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing Option 1 for existing SCVs at facilities where EtO use is less than 1 tpy. Specifically, we are proposing to require these facilities to continuously reduce emissions from existing SCVs by 99 percent. We solicit comment on the proposed standard (Comment C–2).

We solicit comment on whether to also adopt an alternative emission limit that reflects 99 percent emission reduction from SCVs for the following reason. There may be a point where the amount of EtO usage is so low that it may become difficult to demonstrate compliance with the proposed 99 percent emission reduction standard if available measurement instruments are not low enough to detect the resulting emissions post-control. To alleviate this problem, we considered establishing an alternative standard in a pounds per hour (lb/hr) emission rate format but recognized that the same detection issue may exist with such alternative standard for some facilities, as explained in section III.B.5 of this preamble. We solicit comment on whether to include such an alternative equivalent standard because we think sources most likely can demonstrate compliance with one or the other standard (Comment C–3). We also solicit comment on how to establish such an equivalent emission limit. We calculated the emission rate by first assuming that all of these facilities are achieving the emission reduction standard (*i.e.,* 99 percent reduction). The emission rate at each facility is dependent on EtO usage, the portion of EtO usage that is emitted from the SCVs, and the performance of the control device, if used. We then calculated the sum of SCV emissions at facilities where EtO use is less than 1 tpy by the total number of SCVs at these facilities, and rounded to two significant figures, which resulted in 2.5E–4 lb/hr. We solicit comment on whether 2.5E–4 lb/hr is equivalent to 99 percent reduction and whether the method described above used to calculate this lb/hr limit is appropriate for calculating an emission limit equivalent to a percentage emission reduction standard (Comment C–4).

We are aware that requiring facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017 may reduce the number of products that can be sterilized simultaneously. This may result in lower EtO emission reductions, bottlenecks in the medical device supply chain, and facilities having to invest in additional chambers and staff. In addition, the revalidation of sterilization cycles is a time-intensive process and could also worsen potential bottlenecks in the medical device supply chain. We also understand that this requirement may interfere with the ongoing FDA Innovation Challenges, which are aimed at producing EtO alternatives [23] and reducing overall EtO use in sterilization.[24] Therefore, we solicit comment on several aspects of this requirement, including the true effectiveness of this requirement on reducing EtO emissions, any capital and annual costs that we did not account for, the time that is needed to comply with this requirement, and any other potential barriers to or impacts of imposing this requirement (Comment C–5). We are also aware of other BMPs that may reduce EtO emissions, including a limit on EtO concentration within each sterilization chamber, as well as restrictions on packaging and pallet material. Based on responses to the December 2019 questionnaire and September 2021 ICR (OMB Control No. 2060–0733), we understand that the average EtO concentration within the chamber during sterilization is 600 milligrams per liter (mg/L). Considering the number of cycles that are conducted in each chamber per year, as well as the volume of the chambers themselves, we believe that limiting the EtO concentration within each sterilization chamber to 290 mg/L would reduce EtO emissions by 50 percent. We solicit comment on the effectiveness of limiting the EtO concentration within each sterilization chamber on EtO emissions, what that limit might be, the decision criteria for determining that limit, any capital and annual costs associated with that limit, the time needed to comply with that limit, and any other potential barriers to or consequences of imposing that limit (Comment C–6). Our understanding of the impact of packaging and pallet material on EtO emissions is mostly

[23] *https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-1-identify-new-sterilization-methods-and-technologies.*

[24] *https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-2-reduce-ethylene-oxide-emissions.*

limited to one study conducted by a commercial EtO sterilizer.[25] However, the study did conclude that packaging and pallet materials do have an impact on EtO retention and, by extension, emissions. In addition, it is our understanding that reducing paper packaging (and replacing with electronic barcodes) may aid in the reduction of EtO emissions. We solicit comment on the effectiveness of limiting packaging and pallet materials on EtO emissions, what those limits might be, the decision criteria for determining those limits, any capital and annual costs associated with those limits, the time needed to comply with those limits, and any other potential barriers to or consequences of imposing those limits (Comment C–7).

We note that, as part of the pesticide registration review required under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the EPA is concurrently issuing Proposed Interim Decision (PID) for EtO that includes use rate reduction. While the proposed CAA NESHAP and the FIFRA PID are based on different statutory authorities and mandates, they complement each other in their shared objective of preventing overuse of EtO in achieving sterility. The proposed actions are also complementary in that they are intended to reduce public health risks from EtO exposure. The proposed CAA rulemaking focuses on reducing EtO emissions to outside air from commercial sterilization facilities, in order to reduce risk to people living near those facilities (called ''residential bystanders'' in FIFRA). The FIFRA PID would also reduce EtO risk to people outside sterilization facilities, including residential and non-residential bystanders (*i.e.,* those who go to work or school near facilities), as well as risks to workers exposed to EtO inside sterilization facilities.

b. New Sources

For new SCVs at facilities where EtO use is less than 1 tpy, we considered two potential GACT options similar to those evaluated for existing SCVs at facilities where EtO use is less than 1 tpy for the same reasons explained above. The first potential GACT option would require achieving 99 percent emission reduction. The second potential GACT option we considered is a BMP described in section III.B.1.a of this preamble, which would require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017. The impacts of these options, which are presented in Table 6 of this preamble, are based on a model plant for new SCVs at a facility using less than 1 tpy EtO with the following assumptions reflecting the average of each of the parameters at existing facilities using less than 1 tpy EtO:

- Number of SCVs: 5.
- Annual EtO use: 0.39 tpy.
- Annual operating hours: 6,000.
- Portion of EtO going to SCVs: 97.47 percent.
- SCV flow rate: 30 cubic feet per second (cfs).
- Number of unique cycles: 1.

TABLE 6—MODEL PLANT EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR NEW SCVS AT FACILITIES WHERE ETO USE IS LESS THAN 1 TPY

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$92,211	$60,056	0.37	$161,105
2	BMP (estimated 50 percent emission reduction).	0	30,000 (one-time annual cost) [1]	0.19	159,344

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO 11138–1:2017, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, we find both options to be cost-effective. While both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reductions than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing to establish a standard for new SCVs at facilities where EtO use is less than 1 tpy under CAA section 112(d)(5). Specifically, we are proposing to require these facilities to continuously reduce emissions from existing SCVs by 99 percent. We are soliciting comment on this proposed standard (Comment C–8). In addition, for the same reason discussed in section III.B.1.a of this preamble, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for new SCVs at facilities using less than 1 tpy and whether 2.5E–4 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for new SCVs at facilities using less than 1 tpy (Comment C–9).

2. ARV at Facilities Where EtO Use Is at Least 10 Tpy

We first note that, unlike the other point sources discussed in this section of the preamble, ARV at facilities where EtO use is at least 10 tpy are currently regulated in subpart O. See 40 CFR 63.362(d). However, we are proposing corrections to this standard because we believe, for the following reasons, that the current standard is inconsistent with the requirements of CAA section 112. The current standard, 40 CFR 63.362(d), is a MACT standard applicable to facilities where EtO use is at least 10 tpy, which include major sources of HAP (59 FR 10597). It requires these facilities to either achieve 99 percent emission reduction or limit the outlet concentration to a maximum of 1 part-per-million by volume (ppmv), ''whichever is less stringent, from each aeration room vent.'' While a MACT standard may be expressed in multiple formats so long as they are equivalent, the phrase ''whichever is less stringent'' in 40 CFR 63.362(d) suggests that these two formats are not equivalent. Further, a MACT standard cannot allow compliance with a less stringent alternative standard, which in this case is the 1 ppmv limit. As explained

[25] See memorandum, *Engineering Studies Report,* located at Docket ID No. EPA–HQ–OAR–2019–0178. April 30, 2020.

below, we determined that the equivalent outlet concentration to a 99 percent emission reduction is 0.5 ppmv. To determine the equivalent ARV outlet EtO concentration, the EPA reviewed all available facility information for ARVs at facilities where EtO use is at least 10 tpy. We calculated the outlet EtO concentration that is equivalent to 99 percent removal efficiency for ARVs at facilities where EtO use is at least 10 tpy by first assuming that all of these facilities are achieving the removal efficiency standard. The outlet EtO concentration at each facility is dependent on EtO usage, the portion of EtO usage that is emitted from the ARVs, and the flowrate and temperature of the ARV. We then calculated the ARV outlet EtO concentration at each facility, calculated the average value of the ARV outlet EtO concentrations across all facilities, and rounded to one significant figure, which resulted in 0.5 ppmv.

In light of the above, we are proposing to remove the less stringent 1 ppmv concentration alternative for ARVs at facilities where EtO use is at least 10 tpy. We solicit comment on removing this alternative concentration standard for ARVs at facilities where EtO use is at least 10 tpy (Comment C–10).

3. ARV at Facilities Where EtO Use Is at Least 1 Tpy But Less Than 10 Tpy

a. Existing Sources

The current subpart O does not contain emission standards for ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. There are 18 facilities where EtO use is at least 1 tpy but less than 10 tpy, 10 of which have ARVs. Of these 10 facilities, nine are currently controlling their ARV emissions. Five of these facilities use catalytic oxidizers, two use gas/solid reactors, one uses a wet scrubber, and one uses a gas/solid reactor and catalytic oxidizer in series. Performance tests are available for ARVs at four facilities where EtO use is at least 1 tpy but less than 10 tpy. Two of these facilities use catalytic oxidizers, and two use gas/solid reactors. We reviewed all these performance tests, and the reported emission reductions ranged from 99.1 to 99.99 percent.

For existing sources, we considered two potential GACT options for reducing EtO emissions from this group: the first option reflects the use of emission controls on the ARVs, and the second option reflects applying a BMP to reduce EtO use per sterilization cycle (*i.e.,* pollution prevention). With respect to the first option, because nine out of 10 facilities with ARVs and EtO usage at least 1 tpy but less than 10 tpy are already using controls to reduce ARV emissions, we consider emission controls to be generally available for existing ARVs. We considered a standard of 99 percent emission reduction, which is the current subpart O standard for ARVs at facilities where EtO use is at least 10 tpy. We find this standard to be reasonable for existing ARVs at facilities using at least 1 tpy but less than 10 tpy EtO because it is comparable to the emission reductions shown in the performance tests from facilities within this group. The second potential GACT option we considered was the same management practice discussed in section III.B.1.a, which would require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017. During the sterilization process, EtO becomes trapped within the material and continues to off-gas after the sterilization process is complete. Therefore, if less EtO is used during the sterilization process, this can lead to a reduction in post-sterilization EtO emissions.

The impacts of the potential GACT options are presented in Table 7.

TABLE 7—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR EXISTING ARVS AT FACILITIES WHERE ETO USE IS AT LEAST 1 TPY BUT LESS THAN 10 TPY

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$1,290,957	$327,530	0.13	$2,597,271
2	BMP (estimated 50 percent emission reduction).	0	840,000 (one-time annual cost) [1]	7.2E–2	11,633,666

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO 11138–1:2017, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, we find both options to be cost effective. While these cost-effectiveness numbers may seem high, EtO is a highly potent carcinogen, and the cost-effectiveness numbers of these options are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. We are proposing Option 1 for the following reasons. First, while both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve much greater emission reduction than Option 2. Second, Option 1 would ensure that facilities that are currently reducing emissions from ARVs using emission controls would continue to do so, whereas Option 2 would allow these facilities to remove their existing controls and potentially increase their emissions from ARVs. Third, Option 1 would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing Option 1 for existing ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. Specifically, we are proposing to require these facilities to continuously reduce emissions from existing ARVs by 99 percent. We solicit comment on these proposed standards. In addition, we solicit comment on several aspects of this requirement, including the true effectiveness of this requirement on reducing EtO emissions, any capital and annual costs that we did not account for, the time that is needed to comply with this requirement, and any other potential barriers to or impacts of imposing this requirement (Comment C–11). In addition, for the same reason discussed above in section III.B.1.a, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for existing ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy and whether 2.1E–4 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for existing

ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy (Comment C–12).

b. New Sources

For new ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, we considered two potential GACT options similar to those evaluated for existing ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy for the same reasons explained above. The first potential GACT option would require achieving 99 percent emission reduction. The second potential GACT option we considered is a BMP described in section III.B.1.a of this preamble, which would require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017. The impacts of these options, which are presented in Table 8 of this preamble, are based on a model plant for new ARVs at a new facility using at least 1 tpy but less than 10 tpy EtO with the following assumptions reflecting the average of each of the parameters at existing facilities where both ARVs are present and EtO use is at least 1 tpy but less than 10 tpy:

- Number of ARVs: four.
- Annual EtO use: 6 tpy.
- Annual operating hours: 6,000.
- Portion of EtO going to ARVs: 3.23 percent.
- ARV flow rate: 63 cfs.
- Number of unique cycles: three.

TABLE 8—MODEL PLANT EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR NEW ARVS AT FACILITIES WHERE ETO USE IS AT LEAST 1 TPY BUT LESS THAN 10 TPY

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$184,422	$64,530	0.19	$336,823
2	BMP (estimated 50 percent emission reduction).	0	90,000 (one-time annual cost) [1]	9.7E–2	930,144

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO 11138–1:2017, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, we find both options to be cost effective. While both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reductions and would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing to establish standards for new ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy under CAA section 112(d)(5). Specifically, we are proposing to require these facilities to continuously reduce emissions from existing ARVs by 99 percent. We are soliciting comment on this proposed standard. In addition, we solicit comment on several aspects of this requirement, including the true effectiveness of this requirement on reducing EtO emissions, any capital and annual costs that we did not account for, the time that is needed to comply with this requirement, and any other potential barriers to or impacts of imposing this requirement (Comment C–13). In addition, for the same reason discussed in section III.B.1.a of this preamble, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for new ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy and whether 1.6E–4 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for new ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy (Comment C–14).

4. ARV at Facilities Where EtO Use Is Less Than 1 Tpy

a. Existing Sources

The current subpart O does not contain emission standards for ARVs at facilities where EtO use is less than 1 tpy. There are 20 facilities where EtO use is less than 1 tpy, four of which have ARVs. Of these four facilities, two are currently controlling their ARV emissions. Both of these facilities use catalytic oxidizers. There are no performance tests are available for ARVs at facilities where EtO use is less than 1 tpy.

For existing sources, we considered two potential GACT options for reducing EtO emissions from this group: the first option considers setting an emission standard that reflects the use of emission controls on the ARVs, and the second option considers applying the BMP described in section III.B.1.a to reduce EtO use per sterilization cycle. With respect to the first option, because control of ARV emissions is common at facilities using 1 or more tpy of EtO as explained above, and two out of four facilities with ARVs and EtO usage less than 1 tpy are already using controls to reduce ARV emissions, we consider emission controls to be generally available for existing ARVs at facilities with less than 1 tpy EtO usage. We don't have reason to believe that the remaining two facilities cannot use control to reduce their ARV emissions. We considered a standard of 99 percent emission reduction, which is the current subpart O standard for ARVs at facilities where EtO use is at least 10 tpy. While there are no performance test data from the four facilities with ARV and EtO usage less than 1 tpy, available performance data from other facilities with ARVs all indicate that controls can reduce ARV emissions by 99 percent, as described above. The second potential GACT option we considered was the management practice described in section III.B.1.a, which would require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017.

The impacts of the two options are presented in Table 9.

TABLE 9—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTION CONSIDERED UNDER CAA SECTION 112(d)(5) FOR EXISTING ARVS AT FACILITIES WHERE ETO USE IS LESS THAN 1 TPY

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$184,422	$72,633	2.3E–2	$3,094,182
2	BMP (estimated 50 percent emission reduction).	0	210,000 (one-time annual cost) [1]	1.2E–2	17,541,860

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO 11138–1:2017, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, we find both options to be cost effective. While these cost-effectiveness numbers may seem high, EtO is a highly potent carcinogen, and the cost-effectiveness numbers of these options are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. We are proposing Option 1 for the following reasons. First, while both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reduction than Option 2. Second, Option 1 would ensure that facilities that are currently reducing emissions from ARVs using emission controls would continue to do so, whereas Option 2 would allow these facilities to remove their existing controls and potentially increase their emissions from ARVs. Third, Option 1 would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing Option 1 for existing ARVs at facilities where EtO use is less than 1 tpy. Specifically, we are proposing to require these facilities to continuously reduce emissions from existing ARVs by 99 percent. We solicit comment on this proposed standard. In addition, we solicit comment on several aspects of this requirement, including the true effectiveness of this requirement on reducing EtO emissions, any capital and annual costs that we did not account for, the time that is needed to comply with this requirement, and any other potential barriers to or impacts of imposing this requirement (Comment C–15). In addition, for the same reason discussed in section III.B.1.a of this preamble, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for existing ARVs at facilities where EtO use is less than 1 tpy and whether 5.6E–6 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for existing ARVs at facilities where EtO use is less than 1 tpy (Comment C–16).

b. New Sources

For new ARVs at facilities where EtO use is less than 1 tpy, we considered two potential GACT options similar to those evaluated for existing ARVs at facilities where EtO use is less than 1 tpy for the same reasons explained above. The first potential GACT option would require achieving 99 percent emission reduction. The second potential GACT option we considered is the BMP described in section III.B.1.a, which would require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017. The impacts of these options, which are presented in Table 10 of this preamble, are based on a model plant for new ARVs at a new facility using less than 1 tpy EtO with the following assumptions reflecting the average of each of the parameters at existing facilities where both ARVs are present and EtO use is less than 1 tpy EtO:

- Number of ARVs: eight.
- Annual EtO use: 0.34 tpy.
- Annual operating hours: 6,800.
- Portion of EtO going to ARVs: 4 percent.
- ARV flow rate: 4 cfs.
- Number of unique cycles: two.

TABLE 10—MODEL PLANT EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR NEW ARVS AT FACILITIES WHERE ETO USE IS LESS THAN 1 TPY

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$92,211	$37,829	1.5E–2	$2,549,177
2	BMP (estimated 50 percent emission reduction).	0	60,000 (one-time annual cost) [1]	7.5E–3	8,005,582

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO 11138–1:2017, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, we find both options to be cost effective. While these cost-effectiveness numbers may seem high, EtO is a highly potent carcinogen, and the cost-effectiveness numbers of these options are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. While both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reductions and would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing to establish standards for new ARVs at facilities where EtO use is at less than 1 tpy under CAA section 112(d)(5). Specifically, we are proposing to require these facilities to continuously reduce emissions from existing ARVs by 99

percent. We are soliciting comment on this proposed standard for new ARVs at facilities where EtO use is less than 1 tpy. In addition, we solicit comment on several aspects of this requirement, including the true effectiveness of this requirement on reducing EtO emissions, any capital and annual costs that we did not account for, the time that is needed to comply with this requirement, and any other potential barriers to or impacts of imposing this requirement (Comment C–17). In addition, for the same reason discussed in section III.B.1.a of this preamble, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for new ARVs at facilities where EtO use is less than 1 tpy and whether 5.5E–6 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for new ARVs at facilities where EtO use is less than 1 tpy (Comment C–18).

5. CEV at Facilities Where EtO Use Is at Least 10 Tpy

On December 6, 1994 (59 FR 62585), we promulgated MACT standards for point sources, including CEVs, at commercial sterilization facilities where EtO use is at least 10 tpy. Emissions from CEVs occur following sterilization, as explained below. After the sterilization cycle in the sterilization chamber is completed and the chamber is vented to the SCV (*i.e.,* after most of the EtO gas is removed and after the inert nitrogen (N_2) washes and air washes are completed), the sterilized product and packaging remain in the sterilization chamber along with a small amount of EtO. CEVs evacuate EtO-laden air from the sterilization chamber after the chamber door is opened for product unloading following the completion of sterilization and associated gas washes. The CEV reduces the amount of EtO that workers are exposed to while those workers remove sterilized material from the chamber. This contributes to a facility's ability to meet U.S. Occupational Safety and Health Administration (OSHA) workplace exposure standards.[26] Following promulgation of the original rule, the EPA suspended certain compliance deadlines and ultimately removed the standards for CEVs due to safety concerns. In the late 1990s, there were multiple explosions at commercial sterilization facilities that were initially suspected to be related to the EtO Commercial Sterilization NESHAP requirements. In response, the EPA suspended compliance with the rule for one year pending the investigation of the explosions (62 FR 64736, December 9, 1997). In 1998, the suspension of the compliance dates was extended for the ARVs and the CEVs but not for SCVs (63 FR 66990, December 4, 1998). It was also later determined that EtO emissions from aeration rooms could be safely controlled, and the suspensions for the ARVs NESHAP standards were not further extended past December 2000 (64 FR 67789, December 3, 1999). For CEVs, it was determined that the primary contributing issue leading to the explosions was that EtO concentrations were above the lower explosive limit (LEL) within the CEV gas streams, and the EPA extended the suspension of the rule requirements for CEVs. The LEL is the minimum concentration of a vapor in air below which propagation of a flame does not occur in the presence of an ignition source.[27] An explosion risk occurs if the concentration of EtO exceeds the LEL. The EPA could not conclude, at the time, that the CEVs could be safely controlled, so the standards for CEVs were removed in 2001 (66 FR 55577, November 2, 2001).

Following the removal of the CEV regulatory requirement, many EtO sterilization facilities ceased operating controls for EtO emissions from the CEV. The safety issues that prevented earlier control techniques from being applied were linked to EtO concentrations in the sterilization chamber that exceeded the LEL for EtO. Since the late 1990s and early 2000s, however, facilities have begun revising their operating procedures related to the CEV to address the explosion issue. Specifically, facilities that control their CEV emissions have made process changes to avoid exceeding 10 to 25 percent of the LEL. Such process changes include (1) Reducing the EtO concentration in the sterilization chamber before opening the chamber door and (2) using an automated lock on the sterilizer chamber door. As part of these process changes, facilities are using additional final air washes in the sterilization cycle to further reduce the EtO concentration in the sterilization chamber prior to opening the chamber door and venting the CEV to the control system. In addition, the automated lock on the sterilization chamber door prohibits the door from opening until a non-explosive EtO concentration level is achieved in the chamber. Today there are 40 facilities that have CEVs, 34 of which are controlling their CEV emissions. The last known explosion involving CEVs happened in 2004, and safety incidents involving CEVs have not occurred since. For these reasons, we have determined that CEVs can be safely controlled.

The previous CEV standard required facilities where EtO use is at least 10 tpy to either (1) Combine their emissions from their CEVs (*i.e.,* to manifold their emissions) and send the combined emissions to a control device that was used to comply with the SCV or ARV standard or (2) achieve 99 percent emission reduction for their CEVs. At the time the rule was promulgated, there were no facilities that were controlling their CEVs with a dedicated control device. Rather, CEVs were routed to a control device used to control emissions from other vents (59 FR 62585, 62587). Therefore, no facility was demonstrating 99 percent emission reduction for their CEVs. Today, however, multiple facilities, where EtO use is at least 10 tpy, are routing CEV emissions to dedicated control devices and demonstrating the 99 percent emission reduction. There are 34 facilities where EtO use is at least 10 tpy and that also have CEVs, and 31 of these facilities are controlling their CEV emissions. Of these 31 facilities, 13 use a catalytic oxidizer, ten use a gas/solid reactor, three use an acid-water scrubber, three use an acid-water scrubber and gas/solid reactor in series, and two use a thermal oxidizer. There are 12 facilities that have performance and engineering tests available for CEVs; six of these facilities conducted emissions testing when one CEV was venting and most of these contained a single test run for each CEV unit. Of those six facilities, two are controlling their CEV emissions using catalytic oxidizers, two are using gas/solid reactors, one is using an acid-water scrubber, and one is using an acid-water scrubber and gas/solid reactor in series.

Because facilities are currently routing CEVs to dedicated control systems and demonstrating the emission reductions achieved, we have re-calculated the MACT floors for CEVs at facilities where EtO use is at least 10 tpy. We ranked the performance of the CEVs for which data are available. The best performing 12 percent of CEVs for which data are available consists of one CEV that is being controlled by a gas/solid reactor. We then used the upper prediction limit (UPL) approach to develop the MACT floor for existing sources. As mentioned in the EPA's Response to Remand of the Record for Commercial and Industrial Solid Waste Incineration Units, available at *https://www.regulations.gov/document/EPA-*

[26] 29 CFR 1910.1047.

[27] 29 CFR 1915.11.

HQ-OAR-2003-0119-2707, the UPL approach predicts the level of emissions that the sources upon which the floor is based are expected to meet over time, considering both the average emissions level achieved as well as emissions variability and the uncertainty that exists in the determination of emissions variability given the available, short-term data. Our practice is to use the UPL's 99th percentile, or UPL 99, as that is the level of emissions that we are 99 percent confident is achieved by the average source represented in a dataset over a long-term period based on its previous, measured performance history as reflected in short term stack test data. The UPL 99 value of the existing source MACT floor is 3.2E–4 lb/hr. The UPL 99 EtO concentration that corresponds to this emission rate is 30 ppbv. Based on our review of available EtO measurement instruments and our demonstration program, we find the in-stack detection level for EtO, given the current technology, and potential make-up of emission streams, is approximately 10 ppbv. Some EtO CEMS manufacturers claim instrument detection levels much lower than 10 ppbv. However, we believe at the current time, this is the lowest level that can be consistently demonstrated and replicated across a wide range of emission profiles. We expect that EtO CEMS manufacturers, measurement companies, and laboratories will continue to improve EtO detection levels. In the meantime, consistent with our practice regarding reducing relative measurement imprecision by applying a multiplication factor of 3 to the representative detection level (RDL), the average detection level of the best performers, or, in this case, the better performing instruments, so that measurements at or above this level have a measurement accuracy within 10 to 20 percent– similar to that contained in the American Society of Mechanical Engineers (ASME) ReMAP study,[28] we apply a multiplication factor of 3 to the RDL of 10 ppbv, which yields a workable-in-practice lower measurable value of 30 ppbv. For reference, below is the equation that relates the EtO concentration, EtO emission rate, and volumetric flow rate of the exhaust stream:

$$EtO_C = \frac{EtO_{ER} \times 385.1 \times 10^9}{Q \times 44.05}$$

Where, EtO_C is the EtO concentration (in ppbv), EtO_{ER} is the EtO emission rate (in lb/hr), Q is the volumetric flow rate (in dry standard cubic feet per hour), 44.05 is the molecular weight of EtO, and 385.1 is the conversion factor for standard temperature and pressure. Since the MACT floor of 3.2E–4 lb/hr already represents 3 × RDL, there are no more stringent (*i.e.,* beyond-the-floor) options to consider as there would be difficulty demonstrating compliance at any such lower limit. Therefore, the proposed standard for existing CEVs at facilities using at least 10 tpy EtO is 3.2E–4 lb/hr.

For new sources, CAA section 112(d)(3) requires that the standard shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source. In this case, the best controlled similar source is also the CEV that is being controlled by a gas/solid reactor and the data of which is used to determine the MACT floor for existing sources. Therefore, the new source MACT floor is equivalent to the existing source MACT floor, which is 3.2E–4 lb/hr. As explained above, because this emission limit represents the lowest level at which compliance can be demonstrated, the EPA did not consider more stringent (*i.e.,* beyond-the-floor) options. Therefore, the proposed standard for new CEVs at facilities using at least 10 tpy EtO is 3.2E–4 lb/hr.

For the reasons explained above, our proposed MACT standards under CAA sections 112(d)(2) and (3) for both new and existing CEVs at facilities where EtO use is at least 10 tpy require these facilities to limit the EtO emission rate from each new and existing CEV to 3.2E–4 lb/hr. We are soliciting comment on the proposed standards (Comment C–19).

6. CEV at Facilities Where EtO Use Is at Least 1 Tpy but Less Than 10 Tpy

a. Existing Sources

The current subpart O does not contain emission standards for CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. In the December 6, 1994 (59 FR 62585) NESHAP, we promulgated a GACT standard that required facilities, where EtO use is at least 1 tpy but less than 10 tpy, to achieve a maximum chamber EtO concentration limit of 5,300 ppm prior to activation of the chamber exhaust. Safety issues discussed in section III.B.5 of this preamble led to the removal of this CEV standard in 2001 (66 FR 55577, November 2, 2001). As explained above, the safety issues appear to have been addressed through process changes for CEV that facilities have since implemented (*i.e.,* reduce the EtO concentration in the sterilization chamber before opening the chamber door and use of an automated lock on the sterilizer chamber door). Also, as explained above, there were no dedicated controls for CEVs at the time the rule was promulgated. Today, however, facilities where EtO use is at least 1 tpy but less than 10 tpy are routing CEV emissions to control devices. Therefore, we are proposing emission CEV standards that will reflect the current status of controls.

There are 18 facilities where EtO use is at least 1 tpy but less than 10 tpy, six of which have CEVs. Of these six facilities, three are currently controlling their CEV emissions. All of these facilities use catalytic oxidizers. A performance test is available for CEVs at one facility where EtO use is at least 1 tpy but less than 10 tpy, where this facility uses a gas/solid reactor. We reviewed this performance test, and the reported percent reduction was 99.99 percent.

For existing sources, we considered two potential GACT options for reducing EtO emissions from this group: the first option reflects the use of emission controls on the CEVs, and the second option reflects applying the BMP described in section III.B.1.a, which would require facilities to configure their sterilization cycles and either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017. With respect to the first option, because 3 out of 6 facilities (50 percent) with CEVs and EtO usage of at least 1 tpy but less than 10 tpy are already using controls to reduce CEV emissions, and we have no reason to believe that the other three cannot do the same, we consider emission controls

[28] See the discussion in the MATS rule preamble at 77 FR 9370, February 16, 2012.

to be generally available for existing CEVs at these facilities. Evaluating the available information on controls, including the documented control efficiency for one unit in the category and the documented control efficiencies for the types of controls used on similar sources, the EPA determined that a control efficiency of 99 percent is generally available for existing CEVs at facilities using at least 1 tpy but less than 10 tpy of EtO.

The second potential GACT option we considered was the same management practice discussed in section III.B.1.a of this preamble, which would require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017.

The impacts of these two options are presented in Table 11.

TABLE 11—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR EXISTING CEVS AT FACILITIES WHERE ETO USE IS AT LEAST 1 TPY BUT LESS THAN 10 TPY

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$829,901	$245,764	0.11	$2,315,197
2	BMP (estimated 50 percent emission reduction).	0	570,000 (one-time annual cost) [1]	5.5E–2	10,383,471

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO 11138–1:2017, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, we find both options to be cost effective. While these cost-effectiveness numbers may seem high, EtO is a highly potent carcinogen, and the cost-effectiveness numbers of these options are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. We are proposing Option 1 for the following reasons. First, while both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reduction than Option 2. Second, Option 1 would ensure that facilities that are currently reducing emissions from CEVs using emission controls would continue to do so, whereas Option 2 would allow these facilities to remove their existing controls and potentially increase their emissions from CEVs. Third, Option 1 would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing Option 1 for existing CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. Specifically, we are proposing to require these facilities to continuously reduce emissions from existing CEVs by 99 percent. We solicit comment on this proposed standard, including whether uncontrolled sources can use controls to reduce EtO emissions. In addition, we solicit comment on several aspects of this requirement, including the true effectiveness of this requirement on reducing EtO emissions, any capital and annual costs that we did not account for, the time that is needed to comply with this requirement, and any other potential barriers to or impacts of imposing this requirement (Comment C–20). In addition, for the same reason discussed in section III.B.1.a of this preamble, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for existing CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy and whether 1.6E–4 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for existing CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy (Comment C–21).

b. New Sources

For new CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, we considered two potential GACT options similar to those evaluated for existing CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, for the same reasons explained above. The first potential GACT option would require achieving 99 percent emission reduction. The second potential GACT option we considered is a BMP described in section III.B.1.a, which would require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017. The impacts of these options, which are presented in Table 12 of this preamble, are based on a model plant for new CEVs at a new facility using at least 1 tpy but less than 10 tpy EtO with the following assumptions reflecting the average of each of the parameters at existing facilities using at least 1 tpy but less than 10 tpy EtO:

- Number of CEVs: two.
- Annual EtO use: 7 tpy.
- Annual operating hours: 6,000.
- Portion of EtO going to CEVs: 1 percent.
- CEV flow rate: 20 cfs.
- Number of unique cycles: three.

TABLE 12—MODEL PLANT EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR NEW CEVS AT FACILITIES WHERE ETO USE IS AT LEAST 1 TPY BUT LESS THAN 10 TPY

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$92,211	$46,979	6.9E–2	$677,911

TABLE 12—MODEL PLANT EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR NEW CEVS AT FACILITIES WHERE ETO USE IS AT LEAST 1 TPY BUT LESS THAN 10 TPY—Continued

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
2	BMP (estimated 50 percent emission reduction).	0	90,000 (one-time annual cost)[1]	3.5E–2	2,571,429

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO 11138–1:2017, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, we find both options to be cost effective. While these cost-effectiveness number for Option 2 may seem high, EtO is a highly potent carcinogen, and the cost-effectiveness number of Option 2 is within the range of the values that we have determined to be cost-effective for highly toxic HAPs. While both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reductions and would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing to establish standards for new CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy under CAA section 112(d)(5). Specifically, we are proposing to require these facilities to continuously reduce emissions from new CEVs by 99 percent. We are soliciting comment on this proposed standard. In addition, we solicit comment on several aspects of this requirement, including the true effectiveness of this requirement on reducing EtO emissions, any capital and annual costs that we did not account for, the time that is needed to comply with this requirement, and any other potential barriers to or impacts of imposing this requirement (Comment C–22). In addition, for the same reason discussed in section III.B.1.a of this preamble, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for new CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy and whether 1.2E–4 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for new CEVs at facilities where EtO use is at least 1 tpy but less than 1 tpy (Comment C–23).

7. CEV at Facilities Where EtO Use Is Less Than 1 Tpy

a. Existing Sources

The current subpart O does not contain emission standards for CEVs at facilities where EtO use is less than 1 tpy, nor did the EPA previously promulgate such standards. There are no facilities where EtO use is less than 1 tpy that have CEVs. It is possible, however, for a facility with existing CEVs to lower its EtO use to below 1 tpy as well as for newly constructed facilities to have CEVs with EtO usage below 1 tpy. Therefore, we are proposing CEV standards for facilities with EtO usage below 1 tpy.

For existing sources, we considered two potential GACT options for reducing EtO emissions from this group: the first option considers setting an emission standard that reflects the use of emission controls on the CEVs, and the second option considers applying the BMP discussed in section III.B.1.a of this preamble, which would require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017. With respect to the first option, any existing CEV at a facility using less than 1 tpy EtO can only be from an existing facility that is currently using more than 1 tpy of EtO but in the future lowers its EtO use to below 1 tpy. As described in section III.B.5 of this preamble, the proposed MACT standards for CEVs at facilities using at least 10 tpy of EtO reflect the use of emission controls. We also consider emission controls to be generally available for CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, as explained in section III.B.6 of this preamble. We have no reason to believe that these facilities cannot continue to control their CEV emissions should they ever reduce their EtO usage to below 1 tpy. In light of the above, we consider emission controls to also be generally available for existing CEVs at facilities with EtO usage below 1 tpy. We considered a standard of 99 percent emission reduction, which is the same standard we are proposing for existing CEVs at facilities using at least 1 tpy but less than 10 tpy of EtO. We do not have reason to believe that a facility with existing CEVs cannot meet this standard upon reducing EtO use to less than 1 tpy. The second potential GACT option we considered was the same management practice discussed in section III.B.1.a of this preamble, which would require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017.

We are proposing Option 1 for the following reasons.[29] First, Option 1 would achieve greater emission reduction than Option 2. Second, Option 1 would ensure that facilities that are currently reducing emissions from CEVs using emission controls would continue to do so upon lowering EtO use, whereas Option 2 would allow these facilities to remove their existing controls and potentially increase their emissions from CEVs. Therefore, pursuant to CAA section 112(d)(5), we are proposing Option 1 for existing CEVs at facilities where EtO use is less than 1 tpy. Specifically, we are proposing to require these facilities to continuously reduce emissions from existing CEVs by 99 percent. We solicit comment on this proposed standard. In addition, we solicit comment on several aspects of this requirement, including the true effectiveness of this requirement on reducing EtO emissions, any capital and annual costs that we did not account for, the time that is needed to comply with this requirement, and any other potential barriers to or impacts of imposing this requirement (Comment C–24). In addition, for the same reason discussed in section

[29] Unlike the other section III subsections in this preamble, which present costs impacts of the options being considered in a table format, we cannot do the same here because there are no existing CEVs at facilities using less than 1 tpy of EtO.

III.B.1.a of this preamble, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for existing CEVs at facilities where EtO use is less than 1 tpy and whether 1.6E–4 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for existing CEVs at facilities where EtO use is less than 1 tpy (Comment C–25).

b. New Sources

For new CEVs at facilities where EtO use is less than 1 tpy, we considered two potential GACT options similar to those evaluated for existing CEVs at facilities where EtO use is less than 1 tpy for the same reasons explained above. The first potential GACT option would require achieving 99 percent emission reduction. These assumptions are as follows:

- Number of CEVs: two.
- Annual EtO use: 0.99 tpy.
- Annual operating hours: 6,000.
- Portion of EtO going to CEVs: 1 percent.
- CEV flow rate: 12 cfs.
- Number of unique cycles: three.

The second potential GACT option we considered is the BMP described in section III.B.1.a, which would require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017. The impacts of these two options are presented in Table 13 of this preamble:

TABLE 13—MODEL PLANT EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR NEW CEVS AT FACILITIES WHERE ETO USE IS LESS THAN 1 TPY

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99 percent emission reduction	$92,211	$41,502	9.5E–3	$4,350,265
2	BMP (estimated 50 percent emission reduction).	0	90,000 (one-time annual cost) [1]	5.0E–3	18,181,818

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO 11138–1:2017, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, we find both options to be cost effective. While these cost-effectiveness numbers may seem high, EtO is a highly potent carcinogen, and the cost-effectiveness numbers of these options are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. While both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reductions and would incur fewer annual costs than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing to establish standards for new CEVs at facilities where EtO use is at less than 1 tpy under CAA section 112(d)(5). Specifically, we are proposing to require these facilities to continuously reduce emissions from new CEVs by 99 percent. We are soliciting comment on this proposed standard. In addition, we solicit comment on several aspects of this requirement, including the true effectiveness of this requirement on reducing EtO emissions, any capital and annual costs that we did not account for, the time that is needed to comply with this requirement, and any other potential barriers to or impacts of imposing this requirement (Comment C–26). In addition, for the same reason discussed in section III.B.1.a of this preamble, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99 percent emission reduction for new CEVs at facilities where EtO use is less than 1 tpy and whether 1.2E–4 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99 percent emission reduction standard for new CEVs at facilities where EtO use is less than 1 tpy (Comment C–27).

8. Room Air Emission Sources

The current subpart O does not regulate room air emissions. In the Commercial Sterilization Facilities source category, facilities tend to group room air emission sources together to capture and route their emissions to a common control device, rather than to control each room air emission source individually. While multiple room air emission sources at a facility are often routed to the same control system, sometimes room air emission sources are routed to different control systems, and the configurations vary from facility to facility. The configurations of room air emission sources are the following: all room air emission sources routed together; PoAHSM routed together, and all other room air emission sources routed together; and all point and room air emission sources routed together. In defining affected sources of room air emission sources for purposes of setting standards under CAA section 112, the EPA grouped room air emission sources based on process activities that occur prior to aeration and those process activities that occur after aeration of materials. This approach reflects the most common emission control configuration, which is to capture and route PoAHSM emissions to one control system and to capture and route all other room air emission sources to another control system. While room air emission sources overall tend to have higher flow rates and lower EtO concentrations compared to point sources at EtO commercial sterilization facilities, the EtO concentration and flow rate characteristics of emission streams can differ for streams prior to and after aeration. The difference in flow rates that occur for the pre- and post-aeration room air sources is important, as the post-aeration handling of sterilized material room areas (*e.g.,* quarantine, shipping, and warehouse areas) have the largest floor area and room volumes at the facility and also have the largest flow rates of any of the room air emission sources. We grouped room air emission sources into two groups. Group 1 room air emission sources include indoor EtO storage, EtO dispensing, vacuum pump operation, and pre-aeration handling of sterilized materials. Group 2 room air emission sources include post-aeration handling of sterilized material.

a. Existing Group 1 Room Air Emissions at Major Source Facilities

There are 47 facilities that use at least 10 tpy of EtO and have Group 1 room

air emissions. Based on our review of available state and local permits, as well as emissions data, we believe that all of these facilities are synthetic area sources. Of these, 24 facilities are controlling all their Group 1 emissions, while 2 are partially controlling their Group 1 room air emissions. Of the 24 facilities that are controlling all their Group 1 room air emissions, 17 use gas/solid reactors, eight use catalytic oxidizers, and five use acid-water scrubbers. Note that this does not sum to 26 because some facilities use different types of control systems for reducing Group 1 room air emissions. Of the two facilities that partially control their Group 1 room air emissions, both use gas/solid reactors.

We have calculated the MACT floor for existing Group 1 room air emissions at major source facilities. CAA section 112(d)(3)(A) requires that the MACT floor be based on the best performing 12 percent of existing sources for which data are available. We ranked the performance of the facilities with Group 1 room air emissions for which data are available. There are only three performance tests that are currently available, so the best performing 12 percent of exiting sources for which data are available consists of Group 1 room air emissions at one facility that is controlling such emissions with a gas/solid reactor. That facility reported an emission rate of 4.8E–4 lb/hr. We then used the UPL to develop the MACT floor for existing sources. The UPL 99 value of the existing source MACT floor is 7.7E–4 lb/hr. The EtO concentration (UPL 99 value) that corresponds to this emission rate is 20 ppbv. Since this is below 3 × RDL, we adjusted the MACT floor by determining the emission rate using 30 ppbv and the average volumetric flow rate of the Group 1 room air emissions stream at the facility, which is 6,202 dry standard cubic feet per minute (dscfm). This results in an adjusted MACT floor of 1.3E–3 lb/hr. Since this represents 3 × RDL, there are no more stringent (*i.e.,* beyond-the-floor) options to consider as there would be difficulty demonstrating compliance with a limit below 3 × RDL. Therefore, the proposed MACT standard for existing Group 1 room air emissions at major source facilities is 1.3E–3 lb/hr.

The proposed standards are based on complete capture of the emission from Group 1 room air emissions, which are then routed to an APCD. In recent years, state and local agencies have required EtO commercial sterilization facilities to capture room air emissions and route the emissions to an APCD. EtO commercial sterilization facilities in Illinois, Georgia, California, North Carolina, and other states have installed PTEs and add-on control systems to reduce releases of room air emissions. At most of these facilities, the PTEs meet the requirements of EPA Method 204,[30] and the enclosure is monitored continuously to demonstrate capture efficiency. EPA Method 204 (40 CFR part 51, appendix M) was promulgated on June 16, 1997 (62 FR 32500), as part of a suite of methods to support State Implementation Plans for ozone for determining capture efficiency, for the purpose of reducing volatile organic compounds. Since this time, EPA Method 204 has been incorporated into a number of NESHAP (*e.g.,* Surface Coating NESHAPs) for demonstrating compliance with PTE standards. EPA Method 204 provides the design criteria for PTEs, including (1) Criteria for the proximity of the emitting points to the natural draft openings (NDOs), (2) location of the exhaust hoods, (3) total area of all NDOs, (4) average facial velocity through the NDOs, (5) and requirements for access doors and windows that are not considered NDOs, to be closed. When all these criteria are met and verified, an affected source can assume 100 percent capture. Additionally, EPA Method 204 includes requirements to route the captured and contained EtO-laden gas for delivery to a control system. EPA Method 204 does not include procedures for demonstrating continuous compliance, however these procedures and associated standards may be defined in the affected rule and/or state permit condition. An example of this requirement can be found in 40 CFR 63.5725(f) of the NESHAP for Boat Manufacturing (40 CFR part 63, subpart VVVV), where we require either collection of the facial velocity of air through all NDOs or the pressure drop across the enclosure. The Boat Manufacturing NESHAP also requires data on facial velocity and/or pressure drop at 3-hour block averages consistent with the requirements in Method 204. It also requires maintaining the direction of air flow into the enclosure at all times. These continuous compliance requirements are also consistent with what has been applied to many of the commercial sterilizers that have installed PTEs, through permit conditions. We are therefore proposing, as a compliance assurance measure, that each major source facility operate all areas with sources of Group 1 room air emissions in accordance with the PTE requirements of Method 204 of appendix M to 40 CFR part 51. We solicit comment on these proposed standards (Comment C–28).

[30] 40 CFR part 51, appendix M, EPA Method 204—Criteria and Verification of a Permanent or Temporary Total Enclosure. U.S. EPA.

b. New Group 1 Room Air Emissions at Major Source Facilities

For new sources, CAA section 112(d)(3) requires that the standard shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source. In this case, the best controlled similar source is also the Group 1 room air emissions that are being controlled by a gas/solid reactor and the data of which is used to determine the MACT floor for existing sources. Therefore, the new source MACT floor is equivalent to the existing source MACT floor, which is 1.3E–3 lb/hr. As explained above, because this emission limit represents the lowest level at which compliance can be demonstrated, the EPA did not consider more stringent (*i.e.,* beyond-the-floor) options. Therefore, the proposed standard for new Group 1 room air emissions at major source facilities is 1.3E–3 lb/hr.

For the reasons explained above, our proposed MACT standards under CAA sections 112(d)(2) and (3) for Group 1 room air emissions at major source facilities are to require these facilities to limit the Group 1 room air EtO emission rate to 1.3E–3 lb/hr. Also, for the reasons explained in section III.B.8.a, to ensure complete capture of EtO emissions from this source and, in turn, compliance with the proposed standard, we are proposing to require each facility within this group to operate areas with Group 1 room air emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51. We solicit comment on these proposed standards (Comment C–29).

c. Existing Group 1 Room Air Emissions at Area Source Facilities

A description of existing Group 1 room air emissions at synthetic area source facilities is available in section III.B.8.a of this preamble. Of these, 24 facilities are controlling all of their Group 1 room air emissions. In addition, there are 38 area source facilities where EtO use is less than 10 tpy, 27 of which have Group 1 room air emissions. Of these, three facilities are controlling all their Group 1 emissions, while three are partially controlling its Group 1 room air emissions. Of the three facilities that are controlling all of their Group 1 room air emissions, two use catalytic oxidizers, and one uses a gas/solid reactor and catalytic oxidizer in series. Of the three facilities that partially control their Group 1 room air

emissions, two use gas/solid reactors, one uses catalytic oxidizer, and one uses a wet scrubber and gas/solid reactor in series. Note that this does not sum to three because one facility uses different types of control systems for reducing Group 1 room air emissions Performance tests are available for Group 1 room air emissions at three synthetic area source facilities, all of which use gas/solid reactors. We reviewed these performance tests, and the reported emission rates ranged from 2.0E–5 lb/hr to 4.8E–4 lb/hr.[31] As explained above in section III.B.8.a, the proposed MACT standard for existing Group 1 room air emissions at major source facilities was based on the performance test of one of these three facilities as that was the only facility within ''the best performing 12 percent of the existing sources (for which the Administrator has emission information)'' (CAA section 112(d)(3)(A)). That facility reported an emission rate of 4.8E–4 lb/hr.

For existing Group 1 room air emissions at area source facilities, we considered two potential GACT options for reducing EtO emissions from this group: the first option reflects the use of emission controls on Group 1 room air emissions, and the second option reflects applying a BMP to reduce EtO use per sterilization cycle (*i.e.,* pollution prevention). With respect to the first option, 32 out of 74 area source facilities with Group 1 room air emissions are already using controls to reduce those emissions. We considered a standard of 1.3E–3 lb/hr, which is the MACT standard for Group 1 room air emissions at major source facilities. We find this standard to be reasonable for existing Group 1 room air emissions at area source facilities because it is within an order of magnitude of the Group 1 room air emission reductions shown in the 3-run performance test for an area source facility (4.8E–4 lb/hr). The second potential GACT option we considered was the same management practice discussed in section III.B.1.a, which would require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017. During the sterilization process, EtO becomes trapped within the material and continues to off-gas after the sterilization process is complete. Therefore, if less EtO is used during the sterilization process, this can lead to a reduction in post-sterilization EtO emissions, including those from pre-aeration handling of sterilized material. In addition, a reduction in EtO use can result in less EtO needing to be stored at the facility, as well as less EtO throughput in dispensing equipment and vacuum pumps. This would, in turn, lead to a reduction in EtO emissions.

The impacts of these options are presented in Table 14.

TABLE 14—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR EXISTING GROUP 1 ROOM AIR EMISSIONS AT AREA SOURCE FACILITIES

Option	Emission rate (lb/hr)	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	1.3E–3	$100,437,729	$14,719,405	5.4	$2,733,571
2	BMP (estimated 50 percent reduction)	0	12,570,000[1] (one-time annual cost	2.8	4,445,789

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO 11138–1:2017, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, we find both options to be cost effective. While these cost-effectiveness numbers may seem high, EtO is a highly potent carcinogen, and the cost-effectiveness numbers of these options are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. We are proposing Option 1 for the following reasons. First, while both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reduction than Option 2. Second, Option 1 would ensure that facilities that are currently reducing emissions from Group 1 room air emissions using emission controls would continue to do so, whereas Option 2 would allow these facilities to remove their existing controls and potentially increase their emissions from Group 1 room air emissions. Therefore, pursuant to CAA section 112(d)(5), we are proposing Option 1 for existing Group 1 room air emissions at area source facilities. Specifically, we are proposing to require these facilities to limit the Group 1 EtO emission rate to 1.3E–3 lb/hr. Also, for the reasons explained in section III.B.8.a, to ensure complete capture of EtO emissions from this source and, in turn, compliance with the proposed standard, we are proposing to require each facility within this group to operate areas with Group 1 room air emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51. We solicit comment on these proposed standards. In addition, we solicit comment on several aspects of this requirement, including the true effectiveness of this requirement on reducing EtO emissions, any capital and annual costs that we did not account for, the time that is needed to comply with this requirement, and any other potential barriers to or impacts of imposing this requirement (Comment C–30).

d. New Group 1 Room air Emissions at Area Source Facilities.

For new Group 1 room air emissions at area sources facilities, we considered the same two potential GACT options as those evaluated for existing Group 1 room air emissions at area source facilities for the same reasons explained above. The first potential GACT option (Option 1) would require achieving an emission rate of 1.3E–3 lb/hr. The second potential GACT option we considered (Option 2) is a BMP that would require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017. The impacts of these options, which are presented in Table

[31] Two of these performance tests consist of one run each, and the other consists of three runs. Performance tests that consist of only one run tend to be less reliable than those with multiple runs because single run tests do not provide any information about source variability. The emission rate for the three-run test shows the reported rate that has not undergone a UPL or 3 × RDL adjustment.

15 of this preamble, are based on a model plant for new Group 1 room air emissions at an area source facility with the following assumptions reflecting the average of each of the parameters at area source facilities with new Group 1 room air emissions:

- EtO use: 90 tpy.
- Annual operating hours: 8,000.
- Portion of EtO going to Group 1 room air emissions: 0.4 percent.
- Group 1 room air emissions flow rate: 300 cfs.
- Number of unique cycles: six.

TABLE 15—MODEL PLANT EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR NEW GROUP 1 ROOM AIR EMISSIONS AT AREA SOURCE FACILITIES

Option	Emission standard rate (lb/hr)	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	1.3E–3	$1,106,534	$223,464	0.35	$629,830
2	BMP (estimated 50 percent emission reduction).	0	180,000[1] (one-time annual cost)	0.18	1,000,000

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO 11138–1:2017, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, we find both options to be cost effective. While both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reductions than Option 2. Therefore, pursuant to CAA section 112(d)(5), we are proposing to establish standards for new Group 1 room air emissions at area source facilities. Specifically, we are proposing to require these facilities to limit the Group 1 room air EtO emission rate to 1.3E–3 lb/hr. Also, as explained in section III.B.8.a, to ensure complete capture of EtO emissions from this source and, in turn, compliance with the proposed standard, we are proposing to require each facility within this group to operate areas with Group 1 room air emissions in accordance with the PTE requirements of Method 204 of appendix M to 40 CFR part 51. We are soliciting comment on this proposed standard (Comment C–31).

e. Existing Group 2 Room Air Emissions at Major Source Facilities

There are 47 facilities where EtO use is at least 10 tpy of EtO, all of which are both subject to subpart O and have Group 2 room air emissions. Based on our review of available state and local permits, as well as emissions data, we believe that all these facilities are synthetic area sources. 24 of these facilities are controlling all their Group 2 room air emissions, and one facility is partially controlling its Group 2 room air emission. Of these 24 facilities, 20 use gas/solid reactors, two use catalytic oxidizers, one uses acid-water scrubbers, and one uses a catalytic oxidizer and thermal oxidizer in series. The one facility that is partially controlling its room air emissions uses a gas/solid reactor.

We have calculated the MACT floor for existing Group 2 room air emissions at major source facilities. We ranked the performance of the facilities with Group 2 room air emissions for which data are available. There are only three performance tests that are currently available, so the best performing 12 percent of facilities for which data are available consists of one facility that is controlling its Group 2 room air emissions with a gas/solid reactor. That facility reported an emission rate of 8.3E–4 lb/hr. We then used the UPL to develop the MACT floor for existing sources. The UPL 99 value of the existing source MACT floor is 9.5E–4 lb/hr. The EtO concentration (UPL 99 value) that corresponds to this emission rate is 10 ppbv. Since this is below 3 × RDL, we adjusted the MACT floor by determining the emission rate using 30 ppbv and the average flow rate of the Group 2 room air emissions stream at the facility, which is 13,711 dscfm. This results in an adjusted MACT floor of 2.8E–3 lb/hr. Since this represents 3 × RDL, there are no more stringent (*i.e.,* beyond-the-floor) options to consider as there would be difficulty demonstrating compliance at any such lower limit. Therefore, the proposed standard for existing Group 2 room air emissions at major source facilities is 2.8E–3 lb/hr.

For the reasons explained above, our proposed MACT standards under CAA sections 112(d)(2) and (3) for existing Group 2 room air emissions at major source facilities are to require these facilities to limit the Group 2 room air EtO emission rate to 2.8E–3 lb/hr.[32] Also, for the reasons explained in section III.B.8.a, to ensure complete capture of EtO emissions from this source and, in turn, compliance with the proposed standard, we are proposing to require each facility within this group to operate areas with Group 2 room air emissions in accordance with the PTE requirements of Method 204 of appendix M to 40 CFR part 51. We solicit comment on these proposed standards (Comment C–32).

f. New Group 2 Room Air Emissions at Major Source Facilities

For new sources, CAA section 112(d)(3) requires that the standard shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source. In this case, the best controlled similar source is also the Group 2 room air emissions that are being controlled by a gas/solid reactor and the data of which is used to determine the MACT floor for existing sources. Therefore, the new source MACT floor is equivalent to the existing source MACT floor, which is 2.8E–3 lb/hr. As explained above, because this emission limit represents the lowest level at which compliance can be demonstrated, the EPA did not consider more stringent (*i.e.,* beyond-the-floor) options. Therefore, the proposed standard for new Group 2 room air emissions at major source facilities is 2.8E–3 lb/hr.

For the reasons explained above, our proposed MACT standards under CAA sections 112(d)(2) and (3) for new Group 2 room air emissions at major source facilities are to require these facilities to limit the Group 2 room air EtO emission rate to 2.8E–3 lb/hr. as Also, as explained in III.B.8.a, to ensure complete capture of EtO emissions from this source and, in turn, compliance with the proposed standard, we are

[32] While data from synthetic area sources are included with data from major sources in determining the MACT floor as described above, synthetic area sources, which limit their potential to emit HAP below the major source threshold, are not major sources and therefore not subject to major source standards under section 112.

proposing to require each facility within this group to operate areas with Group 2 room air emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51. We solicit comment on these proposed standards (Comment C–33).

g. Existing Group 2 Room Air Emissions at Area Source Facilities

A description of synthetic area sources with existing Group 2 room air emissions is available in section III.B.8.c of this preamble. Of these, 25 facilities are controlling all of their Group 1 room air emissions. In addition, there are 37 facilities where EtO use is less than 10 tpy that are not major sources, all of which have Group 2 room air emissions. Two of these facilities are controlling all their Group 2 room air emissions, while one is partially controlling its Group 2 room air emissions. Of the 2 facilities that are controlling all of their Group 2 room air emissions, one uses a catalytic oxidizer, and one uses a gas/solid reactor. The one facility that partially controls its Group 2 room air emissions uses both a wet scrubber and gas/solid reactor in series, as well as a stand-alone gas/solid reactor. Performance tests are available for Group 2 room air emissions at three synthetic area source facilities, all of which use gas/solid reactors. We reviewed these performance tests, and the reported emission rates ranged from 5.0E–5 lb/hr to 1.8E–2 lb/hr.[33] As explained above in section III.B.8.e, the proposed MACT standard for existing Group 2 room air emissions at major source facilities was based on the performance test of one of these three facilities as that was the only facility within ''the best performing 12 percent of the existing sources (for which the Administrator has emission information'' (CAA section 112(d)(3)(A)). That facility reported an emission rate of 8.3E–4 lb/hr.

For existing sources, we considered two potential GACT options for reducing EtO emissions from this group: the first option considers setting an emission standard that reflects the use of emission controls on Group 2 room air emissions, and the second option that reflects applying a BMP to reduce EtO use per sterilization cycle (*i.e.,* pollution prevention). With respect to the first option, 28 out of 84 area source facilities subject to subpart O are using controls to reduce Group 2 room air emissions. We considered a standard of 2.8E–3 lb/hr (Option 1), which is the MACT standard for Group 2 room air emissions at major source facilities; as discussed above, the performance test that was used to generate the MACT floor was conducted at a synthetic area source facility This limit is within an order of magnitude of the Group 2 room air emission reductions shown in the 3-run performance test for an area source facility (8.3E–4 lb/hr). The second potential GACT option we considered (Option 2) was the same management practice discussed in section III.B.1.a, which would require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014. During the sterilization process, EtO becomes trapped within the material and continues to off-gas after the sterilization process is complete. Therefore, if less EtO is used during the sterilization process, this can lead to a reduction in post-sterilization EtO emissions, including Group 2 room air emissions.

The impacts of these options are presented in Table 16.

TABLE 16—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR EXISTING GROUP 2 ROOM AIR EMISSIONS AT AREA SOURCE FACILITIES

Option	Emission standard rate (lb/hr)	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	2.8E–3	$210,007,878	$27,719,141	1.4	$19,420,188
2	BMP	0	[1] 13,050,000	0.78	16,790,792

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO 11138–1:2017, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, we find both options to be cost effective. While these cost-effectiveness numbers may seem high, EtO is a highly potent carcinogen, and the cost-effectiveness numbers of these options are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. There are multiple factors we consider in assessing the cost of the emission reductions. See NRDC v. EPA, 749 F.3d 1055, 1060 (DC Cir. April 18, 2014) (''Section 112 does not command EPA to use a particular form of cost analysis.''). These factors include, but are not limited to, total capital costs, total annual costs, cost-effectiveness, and annual costs compared to total revenue (*i.e.,* costs to sales ratios). Our established methodology for assessing economic impacts of regulations indicates that the potential for adverse economic impacts begins when the cost to sales ratio exceeds five percent. According to our estimates, the annual cost of the emission control option for most of the affected sources discussed above is well below five percent.[34] However, reducing existing Group 2 room air emissions at area source facilities using emission control devices (Option 1), would significantly impact several companies operating nine area source facilities with Group 2 room air emissions. We estimate that the annual cost of controls at the level under Option 1 would exceed five percent of revenue for these companies. Based on the available economic information, assuming market conditions remain approximately the same, we are concerned that these companies would not be able to sustain the costs associated with Option 1. In addition, EPA is aware of other facilities that, according to FDA, could impact the availability of certain medical devices, including those that are (1)

[33] Two of these performance tests consist of one run each, and the other consists of three runs. Performance tests that consist of only one run tend to be less reliable than those with multiple runs because single run tests do not provide any information about source variability. The emission rate for the three-run test shows the reported rate that has not undergone a UPL or 3 × RDL adjustment.

[34] See memorandum, *Technical Support Document for Proposed Rule—Industry Profile, Review of Unregulated Emissions, CAA Section 112(d)(6) Technology Review, and CAA Section 112(f) Risk Assessment for the Ethylene Oxide Emissions Standards for Sterilization Facilities NESHAP,* located at Docket ID No. EPA–HQ–OAR–2019–0178.

Experiencing or at risk of experiencing a shortage, (2) in high demand as a result of the COVID–19 pandemic, (3) used in pediatric services, and/or (4) sterilized exclusively at a particular facility. Therefore, pursuant to CAA section 112(d)(5), we are proposing Option 2 for existing Group 2 room air emissions at area source facilities. Specifically, we are proposing to require these facilities follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017. We solicit comment on these proposed standards. In addition, we solicit comment on several aspects of this requirement, including the true effectiveness of this requirement on reducing EtO emissions, any capital and annual costs that we did not account for, the time that is needed to comply with this requirement, and any other potential barriers to or impacts of imposing this requirement (Comment C–34).

h. New Group 2 Room Air Emissions at Area Source Facilities

For new Group 2 room air emissions at area sources facilities, we considered the same two potential GACT options as those evaluated for existing Group 2 room air emissions at area source facilities for the same reasons explained above. The first potential GACT option we considered (Option 1) would require achieving an emission rate of 2.8E–3 lb/hr. The second potential GACT option we considered (Option 2) is a BMP that would require facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017. The impacts of these options, which are presented in Table 17 of this preamble, are based on a model plant for new Group 2 room air emissions at an area source facility with the following assumptions reflecting the average of each of the parameters at area source facilities:

- EtO use: 80 tpy.
- Annual operating hours: 7,000.
- Portion of EtO going to Group 2 room air emissions: 0.2 percent.
- Group 2 room air emissions flow rate: 800 cfs.
- Number of unique cycles: five.

TABLE 17—MODEL PLANT EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(d)(5) FOR NEW GROUP 2 ROOM AIR EMISSIONS AT AREA SOURCE FACILITIES

Option	Emission standard rate (lb/hr)	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	2.8E–3	$2,120,857	$378,546	4.3E–2	$8,820,981
2	BMP (estimated 50 percent emission reduction).	0	150,000 [1] (one-time annual cost)	2.3E–2	6,562,500

[1] This includes the cost for testing to verify that the new sterilization process complies with ISO 11135:2014 and ISO 11138–1:2017, as well as re-submitting to FDA for approval. It is expected that facilities will only incur this cost once and it is assumed to be incurred in the first year of compliance, but it is treated as an annual cost for the purposes of estimating total annual costs (*i.e.,* annualized capital costs plus annual costs) in the analysis.

Based on the estimates above, we find both options to be cost effective. While these cost-effectiveness numbers may seem high, EtO is a highly potent carcinogen, and the cost-effectiveness numbers of these options are within the range of the values that we have determined to be cost-effective for highly toxic HAPs. We are proposing Option 1 for the following reasons. While both options are considered generally available under CAA section 112(d)(5), Option 1 would achieve greater emission reductions than Option 2. Also, unlike Option 1 for existing Group 2 room air emissions at area source facilities, companies constructing new source(s) of Group 2 room air emissions in the future can plan and design operations to avoid significant impact (or choose not to build). Therefore, pursuant to CAA section 112(d)(5), we are proposing to establish standards for new Group 2 room air emissions at area source facilities. Specifically, we are proposing to require these facilities to limit the Group 2 room air EtO emission rate to 2.8E–3 lb/hr. As explained in section III.B.8.a of this preamble, to ensure complete capture of EtO emissions from this source and, in turn, compliance with the proposed standard, we are proposing to require each facility within this group to operate areas with Group 2 room air emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51. We are soliciting comment on this proposed standard. In addition, we solicit comment on several aspects of this requirement, including the true effectiveness of this requirement on reducing EtO emissions, any capital and annual costs that we did not account for, the time that is needed to comply with this requirement, and any other potential barriers to or impacts of imposing this requirement (Comment C–35).

9. Summary of Baseline Standards

Pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5), we are proposing standards for a number of currently unregulated EtO emission sources at commercial sterilizes.[35] As mentioned earlier and described in more detail in sections III.C and III.D of this preamble, the EPA conducted a second section 112(f)(2) analysis for the source category. For that analysis, the EPA conducted a baseline risk assessment that took into account the current standards in subpart O as well as implementation of the proposed 112(d) standards for the currently unregulated emission sources discussed here in section III.B. Table 18 summarizes these standards.

[35] In addition, we are proposing a correction to the current standard under 112(d) for ARV at facilities where EtO use is at least 10 tpy.

TABLE 18—SUMMARY OF STANDARDS AFTER PROPOSED ACTIONS PURSUANT TO CAA SECTIONS 112(d)(2), 112(d)(3), AND 112(d)(5)

Emission source	Existing or new?	EtO use	Standards	CAA section
SCV	Existing	At least 10 tpy	99 percent emission reduction	Current standard.
		At least 1 but less than 10 tpy.	99 percent emission reduction	Current standard.
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
	New	At least 10 tpy	99 percent emission reduction	Current standard.
		At least 1 but less than 10 tpy.	99 percent emission reduction	Current standard.
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
ARV	Existing	At least 10 tpy	99 percent emission reduction	Current standard.
		At least 1 but less than 10 tpy.	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
	New	At least 10 tpy	99 percent emission reduction	Current standard.
		At least 1 but less than 10 tpy.	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction.	
CEV	Existing	At least 10 tpy	3.2E–4 lb/hr	112(d)(2) and (3)
		At least 1 but less than 10 tpy.	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
CEV	New	At least 10 tpy	3.2E–4 lb/hr	112(d)(2) and (3).
		At least 1 but less than 10 tpy.	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
Group 1 room air emissions at major sources.	Existing and new.	N/A	1.3E–3 lb/hr[1]	112(d)(2) and (3).
Group 1 room air emissions at area sources.	Existing and new.	N/A	1.3E–3 lb/hr[1]	112(d)(5).
Group 2 room air emissions at major sources.	Existing and new.	N/A	2.8E–3 lb/hr[1]	112(d)(2) and (3).
Group 2 room air emissions at area sources.	Existing	N/A	Follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 (July 15, 2014) and ISO 11138–1:2017 (March 2017)[2].	112(d)(5).
	New	N/A	2.8E–3 lb/hr[1]	112(d)(5).

[1] We are also proposing to require each facility to operate areas with these emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51.

[2] Owners and operators may also apply for an alternative means of emission limitation under CAA section 112(h)(3).

C. What are the results of the risk assessment and analyses?

We conducted a risk assessment for the Commercial Sterilization Facilities source category using the risk assessment methods described in section II.F of this preamble. We present results of the risk assessment briefly below and in more detail in the *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2022 Risk and Technology Review Proposed Rule,* which is available in Docket ID No. EPA–HQ–OAR–2019–0178. The risk assessment was conducted on the 86 facilities in the commercial sterilization source category that are currently in operation and 11 research and development facilities, for a total of 97 facilities. To exercise caution with respect to this source category, we included research facilities in our assessment because there is a lack of certainty over whether these are true research facilities, for which CAA section 112(c)(7) requires that a separate category be established. However, EtO use at these facilities tends to be very low (less than 1 tpy), and these facilities have low risk.

All baseline risk results are developed using the best estimates of actual emissions and release parameters summarized in section II.F.1. Because allowable emissions and risks would be higher than actual emissions in this case, and in light of our finding that risks are unacceptable based on actual emissions, as discussed in section III.D.2 of this preamble, a separate assessment of allowable emissions appears unnecessary.

The results of the baseline chronic inhalation cancer risk assessment using actual emissions are shown in Table 19. The MIR is estimated to be 6,000-in-1 million, driven by EtO from Group 2 room air emissions (70 percent) and sterilization chamber vents (28 percent). The total estimated cancer incidence is 0.9 excess cancer case per year, or one cancer case every 13 months. The estimated population exposed to cancer risks between 1,000-in-1 million and the maximum risk level of 6,000-in-1 million is 900 people. The total population exposed to cancer risks greater than 100-in-1 million is 18,000 people. The population exposed to cancer risks greater than or equal to 1-in-1 million living within 50 km of a facility is approximately 8.3 million (see Table 19 of this preamble). Of the 97 facilities that were assessed, 16 facilities have an estimated maximum cancer risk greater than 100-in-1 million and six of those facilities have an estimated maximum cancer risk greater than 1,000-in-1 million. The maximum chronic noncancer TOSHI for the source category is estimated to be 0.04 (for neurological effects). The acute risk screening assessment of reasonable worst-case inhalation impacts indicates

a maximum acute HQ of 0.002 for PpO based on the REL acute health reference value. For EtO, the maximum HQ is 0.0005 based on the AEGL–2 acute health reference value.[36]

TABLE 19—STERILIZATION FACILITIES SOURCE CATEGORY INHALATION RISK ASSESSMENT RESULTS BASED ON ACTUAL EMISSIONS

	Maximum individual cancer risk (in 1 million)	Estimated population at increased risk of cancer >100-in-1 million	Estimated population at increased risk of cancer ≥1-in-1 million	Estimated annual cancer incidence (cases per year)	Maximum chronic noncancer TOSHI [1]	Maximum screening acute noncancer HQ
Source Category	6,000	18,000	8,300,000	0.9	0.04 (Neurological)	0.002 (REL).

[1] The TOSHI is the sum of the chronic noncancer HQs for substances that affect the same target organ or organ system.

An assessment of facility-wide (or ''whole facility'') risks was performed to characterize the source category risk in the context of whole facility risks. Non-source category emissions were estimated using the EPA's 2017 NEI as described in section II.F.6. The facility-wide assessment showed that risks from non-source category emission sources were minimal. The MIR, populations above cancer risk thresholds, incidence, and maximum chronic noncancer TOSHI in the facility-wide risk assessment were the same as the source category risk assessment (Table 19). We also examined areas surrounding sterilization facilities for other significant emission sources of HAP. That analysis determined that the vast majority of sterilization facilities are not located nearby other significant sources of HAP as most are isolated or located within office parks.[37]

We then repeated our risk assessment for the Commercial Sterilization Facilities source category assuming emission reductions under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) as described above and summarized in Table 18, with the exception of the proposed Group 1 room air emission standards. Instead, the risk assessment was based on requiring BMP (Option 2) under section 112(d)(5) for Group 1 room air emissions, which we had initially considered proposing instead of an emission limit reflecting use of control devices (Option 1); however, following our risk assessment, we continued to review our regulatory options and determined that the emission limit reflecting use of control devices (Option 1) is a more appropriate option than the BMP for Group 1 room air emissions for the reason discussed in section III.B.8. We are therefore proposing such emission limit instead of the BMP under section 112(d)(5). While we have not reassessed risks based on this one change in a proposed section 112(d)(5) standard, we do not expect this change to affect the MIR for the source category in this scenario, as it was driven by Group 2 room air emissions and sterilization chamber vent emissions, although we anticipate that one or more of the other results presented in Table 20 may be lower (*e.g.,* populations at various risk thresholds and cancer incidence).

In the scenario assuming emission reductions under the proposed CAA sections 112(d)(2), 112(d)(3), and 112(d)(5),[38] the MIR is estimated to be 3,000-in-1 million driven by EtO from Group 2 room air emissions (70 percent) and sterilization chamber vents (28 percent). The total estimated cancer incidence is 0.3 excess cancer case per year, or one cancer case every 3.3 years. The estimated population exposed to cancer risks between 1,000-in-1 million and the maximum risk level of 3,000-in-1 million is 200 people, down from 900 people in the baseline scenario. The total population exposed to cancer risks greater than 100-in-1 million is 2,350 people, down from 18,000 people in the baseline scenario. The population exposed to cancer risks greater than or equal to 1-in-1 million living within 50 km of a facility is approximately 3.2 million, down from 8.3 million. Of the 97 facilities that were assessed, 13 facilities have an estimated maximum cancer risk greater than 100-in-1 million (down from 16) and two of those facilities have an estimated maximum cancer risk greater than 1000-in-1 million (down from six). The maximum chronic noncancer TOSHI for the source category is estimated to be 0.003 for the neurological target organ. The acute risk screening assessment of reasonable worst-case inhalation impacts indicates a maximum acute HQ of 0.001 for propylene oxide (PpO) based on the REL acute health reference value. For EtO, the maximum HQ is 0.0003 based on the AEGL 2 acute health reference value.[39]

[36] Acute RELs, ERPG–1, and AEGL–1 acute health reference values are not available for ethylene oxide.

[37] EPA Air Toxics Screening Assessment (AirToxScreen). Available at: *https://www.epa.gov/AirToxScreen.*

[38] As explained immediately above, the risk assessment assumed emission reductions from the BMP option (Option 2) for Group 1 room air emissions, and that based on further analysis following the risk assessment, we are proposing the emission limit reflecting use of control devices (Option 1) instead of the BMP option assumed in the risk assessment.

[39] RELs, ERPG–1, and AEGL–1 acute health reference values are not available for ethylene oxide.

TABLE 20—STERILIZATION FACILITIES SOURCE CATEGORY INHALATION RISK ASSESSMENT RESULTS BASED ON ACTUAL EMISSIONS AFTER EMISSION REDUCTIONS UNDER CAA SECTIONS 112(d)(2), 112(d)(3), AND 112(d)(5)

	Maximum individual cancer risk (in 1 million)	Estimated population at increased risk of cancer >100-in-1 million	Estimated population at increased risk of cancer ≥1-in-1 million	Estimated annual cancer incidence (cases per year)	Maximum chronic noncancer TOSHI [1]	Maximum screening acute noncancer HQ
Source category	3,000	[2] 2,350	[2] 3,200,000	[2] 0.3	0.003 (Neurological)	0.001 (REL).

[1] The TOSHI is the sum of the chronic noncancer HQs for substances that affect the same target organ or organ system.
[2] These values may be lower due to the proposed Group 1 room air emission standards that were not included in the risk assessment.

D. What are our proposed decisions regarding risk acceptability, ample margin of safety, and adverse environmental effect?

As noted in section II.A of this preamble, the EPA sets standards under CAA section 112(f)(2) using ''a two-step standard-setting approach, with an analytical first step to determine an 'acceptable risk' that considers all health information, including risk estimation uncertainty, and includes a presumptive limit on MIR of approximately 1-in-10 thousand'' (54 FR 38045, September 14, 1989). For this proposal, the EPA estimated baseline risks based on actual emissions from the Commercial Sterilization Facilities source category, as well as emission reductions from the proposed standards for the currently unregulated emissions sources under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) as described above and summarized in Table 18. For the purposes of risk acceptability, we considered the risks after the emission reductions under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5).

1. Determination of Risk Acceptability After Emission Reductions Under CAA Sections 112(d)(2), 112(d)(3), and 112(d)(5)

As noted in section II.D of this preamble, we weigh a wide range of health risk measures and factors in our risk acceptability determination, including the cancer MIR, the number of persons in various cancer and noncancer risk ranges, cancer incidence, the maximum noncancer TOSHI, the maximum acute noncancer HQ, the extent of noncancer risks, the distribution of cancer and noncancer risks in the exposed population, and risk estimation uncertainties (54 FR 38044, September 14, 1989).

For the Commercial Sterilization Facilities source category, the risk results indicate that the cancer risks to the individual most exposed are well above 100-in-1 million, which is the presumptive upper end of the range of acceptability. The estimated inhalation cancer risk to the individual most exposed to emissions from the source category is 3,000-in-1 million after emission reductions under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5). The estimated incidence of cancer due to inhalation exposures is 0.3 excess cancer case per year. The population estimated to be exposed to cancer risks greater than 100-in-1 million is approximately 2,350, and the population estimated to be exposed to cancer risks greater than or equal to 1-in-1 million is approximately 3.2 million. The estimated maximum chronic noncancer TOSHI from inhalation exposure for this source category is 0.003 (for neurological effects), indicating low likelihood of adverse noncancer effects from long-term inhalation exposures. The acute risk screening assessment of reasonable worst-case inhalation impacts indicates a maximum acute HQ of 0.001. Therefore, we conclude that adverse effects from acute exposure to emissions from this category are not anticipated.

Considering the health risk information and factors discussed above, particularly the high MIR for the source category, we propose to find that the risks from the Commercial Sterilization Facilities source category, taking into account emission reductions under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) as described above and summarized in Table 18, are unacceptable. As noted in section II.A of this preamble, when risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level. Therefore, pursuant to CAA section 112(f)(2), we are proposing certain standards that are more protective than those shown in Table 18 based on our proposed finding that risks from this source category remain unacceptable even after the application of revised standards under section 112(d).

a. Available Controls To Address Risks

We evaluated several control options for reducing risks. Based on the results of the risk assessment, we have identified SCVs and Group 2 room air emissions as the primary contributors to risks. Therefore, we focused our analysis of control options on SCVs and Group 2 room air emissions to reduce risk.

As mentioned above, the MIR for the source category is estimated to be 3,000-in-1 million, driven by EtO from one facility. Results from our risk assessment indicate that, for that facility with the source category MIR of 3,000-in-1 million, 28 percent of the risk is from SCVs. The remaining risk is mostly from Group 2 room air emissions (70 percent).

This facility is the only one within the source category where the emissions from SCVs contribute to the facility's MIR exceeding 100-in-1 million, and this facility currently uses 44 tpy of EtO. The current subpart O requires 99 percent emission reduction for SCVs at facilities where EtO use is at least 1 tpy. An emission reduction of 99 percent is also the proposed standard under CAA section 112(d)(5) for the currently unregulated SCVs, which are those facilities where EtO use is less than 1 tpy (see section III.B.1.a).

Our data do not identify any add-on controls beyond those we have already considered when promulgating the SCV standards in subpart O or proposing the standards for the currently unregulated SCV standards in section II.B.1. However, our evaluation of the performance data shows that these controls can achieve greater than 99 percent reduction. We therefore considered a more stringent SCV standard for facilities where EtO use is at least 40 tpy, which would include the one and only facility where the emissions from SCVs contribute to the facility's MIR exceeding 100-in-1 million. The emission limit that we evaluated is 99.94 percent reduction, which would reduce this facility's SCV emissions such that they no longer contribute to this facility's MIR exceeding 100-in-a-million.[40] We have

[40] As mentioned above, the remaining risks from this facility are from Group 2 room air emissions,

determined that this is feasible because our evaluation of performance tests indicates that 27 out of 36 facilities with SCVs and using at least 40 tpy of EtO are already exceeding this emission reduction from their SCVs. Of those 27 facilities, 14 use wet scrubbers, six use catalytic oxidizers, four use a wet scrubber and gas/solid reactor in series, two use thermal oxidizers, and one uses a wet scrubber and catalytic oxidizer in series.

As mentioned above, results from our risk assessment indicate that, for the facility with the source category MIR of 3,000-in-1 million, 70 percent of the risk is from Group 2 room air emissions. In addition to this facility, which is an area source, there are two other facilities, also area sources, where Group 2 room air emissions contribute to the facilities' MIRs exceeding 100-in-1 million.[41] Because Group 2 room air emissions are one of the two principal contributors to unacceptable risks from existing area sources in this source category, we evaluated available control options for reducing risks from Group 2 room air emissions.

As discussed in section III.B.8.g of this preamble, we are proposing a GACT standard for currently unregulated Group 2 room air emissions at existing area source facilities. Specifically, we are proposing under CAA section 112(d)(5) that facilities follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility in accordance with ISO 11135:2014 and ISO 11138–1:2017 is not exceeded.[42]

In proposing this standard, we also considered an emission rate of 2.8E–3 lb/hr that reflects the use of control devices (Option 1) but did not propose that option based on our analysis of relevant factors under section 112(d)(5). However, having proposed to determine under CAA section 112(f)(2) that the risk for the source category is unacceptable, we must determine the emissions standards necessary to reduce risk to an acceptable level without considering costs. Therefore, we are considering under section 112(f)(2) this emission rate of 2.8E–3 lb/hr for reducing risks from existing area source facilities where EtO use is at least 20 tpy, which would include all three facilities where the Group 2 room air emissions contribute to these facilities' MIRs exceeding 100-in-1 million.[43]

Another option for reducing Group 2 room air emissions is setting a work practice standard to limit both the maximum volumetric flow rate and maximum EtO concentration of the exhaust streams that contain these emissions. Based on our estimate, this work practice standard would reduce emissions below the 2.8E–3 lb/hr limit. We note that if both the volumetric flow rate and EtO concentration are restricted, there are at least two potential outcomes. One outcome is that a facility could keep the volume of the enclosure constant but restrict the number of room air changes (RACs) per hour. This could potentially result in an increase in EtO concentration within the enclosure. In order to maintain personnel safety, significant upgrades and changes may need to be made, which could require significant costs. Another outcome is that the facility could keep the number of RACs per hour constant but restrict the volume of the enclosure. Both of these outcomes could result in a reduced capacity to sterilize medical products, which is an important consideration in light of the role that sterilization facilities play in the medical supply chain.

b. Regulatory Options

We considered more stringent SCV and Group 2 room air emission standards to reduce risk from the source category to an acceptable level. To that end, we identified the following two options. Control Option 1 would require that (1) facilities where EtO use is at least 40 tpy reduce emissions from individual SCVs by 99.94 percent; and (2) area source facilities where EtO use is at least 20 tpy limit the Group 2 room air EtO emission rate to 2.8E–3 lb/hr. Control Option 2 would have the same two requirements as Option 1, except that the 2.8E–3 lb/hr limit would not apply to facilities with MIR remaining greater than 100-in-1 million even after the imposition of the requirements under Control Option 1, as determined by this risk assessment, and detailed in Appendix 10 of the document titled *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2022 Risk and Technology Review Proposed Rule,* which is available in the docket for this rulemaking. For these two facilities,[44] Option 2 would require work practice standards that would reduce Group 2 room air emissions at these two facilities to a level that would lower their MIR to 100-in-1-million, based on our estimates. Under this work practice standard, Group 2 room air emissions would be limited to a maximum volumetric flow rate of 2,900 dscfm and a maximum EtO concentration of 30 ppbv.

In considering the work practice standards described above, it is important to understand the uncertainties related to the modeled EtO emissions for the two area source facilities that would be subject to these standards. For one facility, we did not receive any room area or EtO monitoring data as part of the September 2021 ICR that could have been used to quantify Group 2 room air emissions. Therefore, we modeled emissions using our default assumption that 0.2 percent of EtO used is emitted as part of Group 2 room air emissions. In addition, we did not receive any information on how the air for areas where there are Group 2 room air emissions is leaving the facility (*i.e.,* the height, temperature, diameter, velocity, and flow rate of each release point for these areas). Therefore, Group 2 room air emissions were modeled as an area source. These factors increase the uncertainty of the MIR for this facility. For the other facility, we understand that a new approval order has recently been issued for this facility that includes limits on Group 2 room air emissions.[45] However, we do not know how the dispersion characteristics for these emissions will change upon the installation of additional controls. This increases the uncertainty of the MIR for this facility.

c. Determination of Risk Acceptability After Emission Reductions Under CAA Section 112(f)(2)

As discussed above, we consider two options for reducing risks. Control Option 1 would require (1) 99.94 percent emission reduction for each SCV at facilities using at least 40 tpy EtO and (2) 2.8E–3 lb/hr emission limit for Group 2 room air emissions at area source facilities using at least 20 tpy. Control Option 2 would require (1)

which we will address immediately below in the next subsection.

[41] As discussed earlier, the EPA has the authority to conduct an (f)(2) review of GACT standards and is exercising that authority in this action.

[42] As discussed in section III.B.8 of this preamble, we are proposing an emission rate of 2.8E–3 lb/hr for all new area source facilities, regardless of EtO use, under CAA section 112(d)(5).

[43] The EtO usage at these three facilities range from 22 to 77 tpy.

[44] As explained below in section III.D.1.c, following our risk modeling, which showed 3 facilities in this group, we conducted additional analysis that resulted in stricter proposed standards under section 112(d)(5) for Group 1 room air emissions, which in turn changed the number of facilities (from three to two) that, after taking into account emission reduction from Option 1, would still have an MIR > 100-in-a-million due to group 2 room air emissions.

[45] *https://eqedocs.utah.gov/TempEDocsFiles/142039467_142039467_AgencyInterest_10301-10400_10377%20-%20BD%20Medical-%20Medical%20Device%20Manufacturing%20Plant_New%20Source%20Review_2022_DAQ-2022-008635.pdf.*

99.94 percent emission reduction for each SCV at facilities using at least 40 tpy EtO; (2) 2.8E–3 lb/hr emission limit for Group 2 room air emissions at area source facilities using at least 20 tpy, except for 2 facilities with MIR > 100-in-1-million after imposition of the requirements under Control Option 1; and (3) for these two facilities, work practice standards that would bring their MIR to 100-in-1-million.

In Table 21, we present the risks after the implementation of Control Options 1 and 2 based on our risk assessment. The risk metrics shown in the table include the cancer MIR, population exposed to cancer risks greater than 100-in-1 million, population exposed to cancer risks greater than or equal to 1-in-1 million, and the cancer incidence.

TABLE 21—POST-CONTROL RISK ASSESSMENT RESULTS FOR THE COMMERCIAL STERILIZATION FACILITIES SOURCE CATEGORY

Control option scenario	Maximum individual cancer risk (in-1-million)	Estimated population at increased risk of cancer >100-in-1 million	Estimated population at increased risk of cancer ≥1-in-1 million	Estimated annual cancer incidence (cases per year)
Option 1	400	~33	[1] 1,290,000	[1] 0.2
Option 2	100	0	[1] 1,260,000	[1] 0.1

[1] These values may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment.

Control Option 1 reduces the MIR from 3,000-in-1 million to 400-in-1-million. The total number of facilities posing cancer risks greater than 100-in-1 million would drop from 13 facilities at baseline after emission reductions under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) to 3 facilities (two in Puerto Rico and one in Utah). We note that 1 of those 3 facilities would be subject to the proposed Group 1 room air emission standards that were not included in the risk assessment and its risks would be below 100-in-1 million (but it would not impact the source category MIR). Additionally, the baseline population exposed to risk levels greater than 100-in-1 million would be reduced from 2,350 people to approximately 33 people. The total population exposed to risk levels greater than or equal to 1-in-1 million living within 50 km of a facility would be reduced from 3.2 million people to 1.29 million people. The total estimated cancer incidence of 0.9 drops to 0.2 excess cancer cases per year in Control Option 1. We note that the populations at risk levels greater than or equal to 1-in-1 million and the cancer incidence may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment. Control Option 2 further reduces the MIR to 100-in-1million, with no facilities or populations at risk levels greater than 100-in-1 million. The total population exposed to risk levels greater than or equal to 1-in-1 million living with 50 km of a facility would be further reduced to 1.26 million people. Finally, in Control Option 2, the total estimated cancer incidence would be further reduced to 0.1 excess cancer cases per year. Again, the populations at risk levels greater than or equal to 1-in-1 million and the cancer incidence may be lower because the risk assessment did not account for the proposed Group 1 room air emission standards.

In summary, both Control Options 1 and 2 would provide significant health benefits by reducing the cancer MIR from 3,000-in-1 million in the baseline after emission reductions under CAA sections 112(d)(2), 112(d)(3), and 112(d)(5) to 400-in-1 million in Control Option 1 and to 100-in-1 million in Control Option 2. That said, as noted earlier in this section, the EPA considers an MIR of ''approximately 1-in-10 thousand'' to be the presumptive limit of acceptability (54 FR 38045, September 14, 1989). Therefore, because Control Option 2 provides an MIR at the presumptive limit of 1-in-10 thousand (or 100-in-1 million), we are proposing that Control Option 2 reduces risks to an acceptable level. We expect that 40 facilities will be affected by the proposed standards of Control Option 2, 36 of these 40 facilities will be subject to the SCV provisions, and all of these 40 facilities are expected to be subject to the provisions for Group 2 room air emissions. We solicit comment on the proposed requirements for SCVs and Group 2 room air emissions, including whether we should apply the limits on volumetric flow rate and EtO concentration at facilities where MIR is greater than 100-in-1 million after implementation of Control Option 1 to all Group 2 room air emissions at facilities where EtO use is at least 20 tpy (Comment C–36). In addition, for the same reason discussed above in section III.B.1.a, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99.94 percent emission reduction for SCVs at facilities where EtO use is at least 40 tpy and whether 3.1E–3 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99.94 percent emission reduction standard for SCVs at facilities where EtO use is at least 40 tpy (Comment C–37). We also solicit comment on whether we should determine that Control Option 1 would reduce risks to an acceptable level, because, while the MIR is 400-in-1 million, the population exposed to risk levels above 100-in-1 million is low (~33 people) and the population exposed to risks ≥1-in-1 million is similar to Control Option 2 (1,290,000 people in Control Option 1 and 1,260,000 people in Control Option 2) (Comment C–38).

2. Ample Margin of Safety

The second step in the residual risk decision framework is determination of whether the emission standards proposed to achieve an acceptable risk level would protect public health with an ample margin of safety, or whether more stringent emission standards would be required. In making this determination, we considered the estimate of health risk and other health information, along with additional factors relating to the appropriate level of control, including costs and economic impacts of controls, technological feasibility, uncertainties, and other relevant factors, consistent with the approach of the 1989 Benzene NESHAP.

As discussed in the previous section, SCVs and Group 2 room air emissions

are the primary contributors to risks. At step 1 of our review of residual risks under section 112(f), we determined that more stringent standards for SCVs at facilities with EtO usage of at least 40 tpy and Group 2 room air emissions at area source facilities with EtO usage of at least 20 tpy are necessary to reduce risks to an acceptable level. For step 2 of our review of residual risks, which requires EPA to evaluate whether more stringent standards are necessary to provide an ample margin of safety to protect public health, we considered additional options to further reduce emissions from SCVs and Group 2 room air emissions.

Table 22 of this preamble presents the summary of costs and EtO emission reductions we estimated for the control options we considered, which are described immediately following the table. For details on the assumptions and methodologies used in the costs and impacts analyses, see the technical memorandum titled *Technical Support Document for Proposed Rule—Industry Profile, Review of Unregulated Emissions, CAA Section 112(d)(6) Technology Review, and CAA Section 112(f) Risk Assessment for the Ethylene Oxide Emissions Standards for Sterilization Facilities NESHAP,* which is available in the docket for this rulemaking.

TABLE 22—NATIONWIDE EMISSION REDUCTIONS AND COST IMPACTS OF CONTROL OPTIONS CONSIDERED FOR COMMERCIAL STERILIZATION FACILITIES IN THE AMPLE MARGIN OF SAFETY ANALYSIS

Control option	Total capital investment ($)	Total annualized costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
A—99.94 percent emission reduction requirement for SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy	$737,689	$266,687	0.17	$1,531,726
B—99.6 percent emission reduction requirement for SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy (prevent backsliding)	0	0	0	N/A
C—99.8 percent emission reduction requirement for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy	92,211	34,939	1.8E–2	1,947,753
D—99.2 percent emission reduction requirement for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy (prevent backsliding)	0	0	0	N/A
E—99.3 percent emission reduction requirement for SCVs at facilities where EtO use is less than 1 tpy	368,845	92,295	3.4E–2	2,724,634
F—Limit Group 2 room air emissions to a maximum volumetric flow rate of 2,900 dscfm and a maximum EtO concentration of 30 ppbv [1]	28,542,825	2,861,119	1.52	1,883,935
G—Existing Group 2 room air emission limit of 2.8E–3 lb/hr at area source facilities where EtO use is less than 20 tpy	98,400,887	10,648,525	5.5E–2	194,111,365

[1] As discussed later in this section, these costs only include PTE and do not include the costs of upgrades and changes needed to maintain personnel safety or potential revenue losses from a reduced capacity to sterilize product.

As mentioned earlier, available performance data show controls for reducing SCV emissions have much improved. We therefore consider potential options to further reduce SCV emissions. We considered two options for SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy (Control Options A and B). Under Control Option A, we considered 99.94 percent emission reduction for SCVs at facilities where EtO use is at least than 10 tpy but less than 40 tpy. This is the same limit as that we are proposing for all facilities where EtO use is at least 40 tpy in order to bring the source category risk to an acceptable level. Under Control Option B, we considered the maximum SCV emission reduction that all facilities where EtO use is at least 10 tpy but less than 40 tpy are currently meeting. This emission reduction is 99.6 percent. We also considered two options for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy (Control Options C and D). Under Control Option C, we considered the maximum SCV emission reduction with which compliance can be demonstrated [46] at all facilities where EtO use is at least 1 tpy but less than 10 tpy considering current emission profiles. This emission reduction is 99.8 percent. Under Control Option D, we considered the maximum SCV emission reduction that all facilities where EtO use is at least 1 tpy but less than 10 tpy are currently meeting. This emission reduction is 99.2 percent. We identified one option for SCVs at facilities where EtO use is less than 1 tpy. Specifically, under Control Option E, we considered the maximum SCV emission reduction for which compliance can be demonstrated at all facilities where EtO use is less than 1 tpy considering current emission profiles. This emission reduction is 99.3 percent. The ample margin of safety analysis for these options is discussed below.

As mentioned above, Control Options A and B address SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy. For Control Option A, which would require 99.94 percent emission reduction for SCVs at all facilities where EtO use is at least 10 tpy but less than 40 tpy, we found a total capital cost of $737,689 and a total annualized cost of $266,687. The estimated EtO emissions reductions are 0.17 tpy with a cost effectiveness of $1,531,726 per ton of EtO. While we do not know what the full extent of risk reductions would be, we expect that some risk reduction would occur as a result of reduced EtO emissions.

Control Option B would require 99.6 percent emission reduction (reflecting the maximum reduction that all facilities within this EtO usage amount are meeting). While there would be no costs, there would also be no further reductions in emissions and in turn no further reductions in risks; at best Option B would simply prevent backsliding in the performance of current SCV emission controls at these facilities. In light of the above, we believe that Option A would be a better choice than Option B for further reducing emissions from SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy.

[46] *i.e.,* Based on facility characteristics, there is no compliance demonstration issue because the required EtO concentration to meet this limit would be at or above 30 ppbv (3 × RDL).

Control Options C and D address SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. For Control Option C, which would require 99.8 percent emission reduction (reflecting the maximum reduction with which compliance can be demonstrated at all facilities where EtO use is at least 1 tpy but less than 10 tpy), we determined a total capital cost of $92,211 and a total annualized cost of $34,939. The estimated EtO emissions reductions are 1.8E–2 tpy with a cost effectiveness of $1,947,753 per ton of EtO. While we do not know what the full extent of risk reductions would be, we expect that some risk reduction would occur as a result of reduced EtO emissions.

Control Option D would require 99.2 percent emission reduction (reflecting the maximum reduction that all facilities within this EtO usage amount are meeting). While there would be no costs, there would also be no reductions in emissions and in turn no reductions in risks; at best Option D would simply prevent backsliding in the performance of current SCV emission controls at these facilities. In light of the above, we believe that Option C would be a better choice than Option D for further reducing emissions from SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy.

Control Option E addresses SCVs at facilities where EtO use is less than 1 tpy. Specifically, Control Option E would require that these facilities reduce emissions from each SCV by 99.3 percent (the maximum emission reduction with which compliance can be demonstrated at all facilities using less than 1 tpy). We expect that some risk reduction would occur as a result of reduced EtO emissions but do not know what the full extent of risk reductions would be. The costs were found to be a $368,845 total capital investment and a $92,295total annualized cost. The estimated EtO emissions reductions are 3.4E–2 tpy with a cost effectiveness of $2,724,634 per ton of EtO. Our established methodology for assessing economic impacts of regulations indicates that the potential for adverse economic impacts begins when the cost to sales ratio exceeds five percent. Considering Control Option E, along with the standards that we have proposed up to this point, the cost to sales ratio for one company operating a facility where EtO use is less than 1 tpy would be 11 percent, far exceeding our estimated five percent at which point the potential for adverse economic impacts begins. Based on the available economic information, assuming market conditions remain approximately the same, we are concerned that this company would not be able to sustain the costs associated with any additional control requirements.

We consider two potential options to further reduce Group 2 room air emissions (Control Options F and G). Under Control Option F, Group 2 room air emissions would be limited to a maximum volumetric flow rate of 2,900 dscfm and a maximum EtO concentration of 30 ppbv at all facilities. These are the same limits as that we are proposing for facilities where MIR is greater than 100-in-1 million after implementation of Control Option 1 in order to bring the source category risk to an acceptable level.[47] Under Control Option G, existing Group 2 room air emissions would be limited to 2.8E–3 lb/hr at area source facilities where EtO use is less than 20 tpy. This is the same limit as that we are proposing for all facilities where EtO use is at least 20 tpy (except for facilities where MIR is greater than 100-in-1 million after implementation of Control Option 1) to bring the source category risk to an acceptable level. The ample margin of safety analysis for these options is discussed below.

Under Control Option F, which would require that Group 2 room air emissions be limited to a maximum volumetric flow rate of 2,900 dscfm and a maximum EtO concentration of 30 ppbv at all facilities, we were unable to fully estimate costs because it is unknown how this would affect operations. As discussed in section III.C.1.a, if both the volumetric flow rate and EtO concentration are restricted, there are at least two potential outcomes. One outcome is that a facility could keep the volume of the enclosure constant but restrict the number of RACs per hour. This could potentially result in an increase in EtO concentration within the enclosure. In order to maintain personnel safety, significant upgrades and changes may need to be made, which could require significant costs. Another outcome is that the facility could keep the number of RACs per hour constant but restrict the volume of the enclosure. While both outcomes could result in potential costs savings from reduced air handling, this may be offset by a loss a revenue from a reduced capacity to sterilize product. This could also impact the supply of medical devices. We did not consider this a viable option in light of the potentially adverse safety, production capacity, and cost implications of this option as described above.

Under Control Option G, which would limit Group 2 room air emission to 2.8E–3 lb/hr at area source facilities where EtO use is less than 20 tpy[48] costs were found to be a $98,400,887 total capital investment and a $10,648,525 total annualized cost. The estimated EtO emissions reductions are 5.5E–2 tpy with a cost effectiveness of $194,111,365 per ton of EtO. While we do not know what the full extent of risk reductions would be, we expect that some risk reduction would occur as a result of reduced EtO emissions. However, the cost to sales ratio for three companies operating three facilities where EtO use is less than 20 tpy would range from 17 to 56 percent, far exceeding our estimated five percent at which point the potential for adverse economic impacts begins. Based on the available economic information, assuming market conditions remain approximately the same, we are concerned that these companies would not be able to sustain the costs associated with any additional control requirements.

Based on our ample margin of safety analysis, including all health information and the associated cost and feasibility as discussed above, we propose that requiring the standards that based on our analysis would bring risks to an acceptable level, along with Control Options A and C here in the present analysis, would provide an ample margin of safety to protect public health. These standards, which we are proposing under the AMOS analysis, consist of 99.94 percent reduction for SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy, as well as 99.8 percent emission reduction for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. We are soliciting comment on our proposed determination, including whether Control Options B, D, E, F, or G would provide an ample margin of safety to protect public health. (Comment C–39). In addition, for the same reason discussed above in section III.B.1.a, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99.94 percent emission reduction for SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy, and whether 1.2E–3 lb/hr for existing sources and 1.0E–3 lb/hr for new sources, which we calculated using

[47] As explained in section III.C.1, reducing the source category risk to an acceptable level would require a separate and more stringent standard for these two facilities.

[48] This is the proposed MACT standard for Group 2 room air emissions at major sources; it is also our proposed standard for Group 2 room air emissions at area source facilities where EtO usage is at least 20 tpy.

the method described in section III.B.1.a, are appropriate alternative standards that are equivalent to the proposed 99.94 percent emission reduction standard for SCVs at facilities where EtO use is at least 10 tpy but less than 40 tpy. Similarly, we solicit comment on whether to include alternative lb/hr limits that are equivalent to 99.8 percent emission reduction for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, and whether 7.2E–4 lb/hr for existing sources and 5.5E–4 lb/hr for new sources, which we calculated using the method described in section III.B.1.a, are appropriate alternative standards that are equivalent to the proposed 99.8 percent emission reduction standard for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy (Comment C–40).

3. Environmental Effects

The emissions data indicate that no environmental HAP are emitted by sources within this source category. In addition, we are unaware of any adverse environmental effects caused by HAP emitted by this source category. Therefore, we do not expect there to be an adverse environmental effect as a result of HAP emissions from this source category and we are proposing that it is not necessary to set a more stringent standard to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

4. Summary of Proposed Standards

Pursuant to CAA sections 112(d)(2), 112(d)(3), and 112(d)(5), we are proposing standards for a number of currently unregulated EtO emission sources at commercial sterilizers.[49] The EPA also conducted a section 112(f)(2) analysis. For that analysis, the EPA conducted a baseline risk assessment that took into account the implementation of the current standards in subpart O as well as the proposed 112(d) standards for the currently unregulated emission sources discussed here in section III.B. Having proposed to determine that the risk is unacceptable for the source category, the EPA is proposing under section 112(f)(2) standards, including tightening certain proposed section 112(d) standards, to bring the risk from this source category to an acceptable level and provide ample margin of safety to protect public health. Table 23 summarizes the proposed section 112(d) and 112(f)(2) standards.

TABLE 23—SUMMARY OF STANDARDS AFTER TAKING ACTIONS PURSUANT TO CAA SECTIONS 112(d)(2), 112(d)(3), 112(d)(5), and 112(f)(2)

Emission source	Existing or new?	EtO use	Standards	CAA section
SCV	Existing	At least 40 tpy	99.94 percent emission reduction	112(f)(2).
		At least 10 tpy but less than 40 tpy	99.94 percent emission reduction	112(f)(2).
		At least 1 but less than 10 tpy	99.8 percent emission reduction	112(f)(2).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
	New	At least 40 tpy	99.94 percent emission reduction	112(f)(2).
		At least 10 tpy but less than 40 tpy	99.94 percent emission reduction	112(f)(2).
		At least 1 but less than 10 tpy	99.8 percent emission reduction	112(f)(2).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
ARV	Existing	At least 10 tpy	99 percent emission reduction	112(f)(2).
		At least 1 but less than 10 tpy	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
	New	At least 10 tpy	99 percent emission reduction	112(f)(2).
		At least 1 but less than 10 tpy	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction.	
CEV	Existing	At least 10 tpy	3.2E–4 lb/hr	112(d)(2) and (3).
		At least 1 but less than 10 tpy	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
	New	At least 10 tpy	3.2E–4 lb/hr	112(d)(2) and (3).
		At least 1 but less than 10 tpy	99 percent emission reduction	112(d)(5).
		Less than 1 tpy	99 percent emission reduction	112(d)(5).
Group 1 room air emissions at major sources.	Existing and new.	N/A	1.3E–3 lb/hr [1]	112(d)(2) and (3).
Group 1 room air emissions at area sources.	Existing and new.	N/A	1.3E–3 lb/hr [1]	112(d)(5).
Group 2 room air emissions at major sources.	Existing and new.	N/A	2.8E–3 lb/hr [1]	112(d)(2) and (3).
Group 2 room air emissions at area sources.	Existing	At least 20 tpy	2.8E–3 lb/hr [1 2]	112(f)(2).
		Less than 20 tpy	Follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 (July 15, 2014) and ISO 11138–1:2017 (March 2017) [3].	112(d)(5).
	New	N/A	2.8E–3 lb/hr [1]	112(d)(5).

[1] We are also proposing to require each facility to operate areas with these emissions in accordance with the PTE requirements of EPA Method 204 of appendix M to 40 CFR part 51.

[49] In addition, we are proposing a correction to the current standard under 112(d) for ARV at facilities with EtO usage ≥10 tpy.

[2] Facilities where MIR is greater than 100-in-1 million after implementation of Control Option 1 must instead limit the total volumetric flow rate of exhaust streams that contain Group 2 room air emissions to a maximum of 2,900 dscfm at each facility, and the EtO concentration of these streams must not exceed 30 ppbv.

[3] Owners and operators may also apply for an alternative means of emission limitation under CAA section 112(h)(3).

E. What environmental justice analysis did we conduct?

Consistent with the EPA's commitment to integrating EJ in the Agency's actions, and following the directives set forth in multiple Executive orders, the Agency has carefully considered the impacts of this action on communities with EJ concerns. Overall, the results of the proximity demographic analysis (see first three columns of Table 24) indicate that the percent of the population living within 10 km of the 97 facilities that is Hispanic or Latino is substantially higher than the national average (34 percent versus 19 percent), driven largely by the seven facilities in Puerto Rico. The baseline proximity analysis indicates that the proportion of other demographic groups living within 10 km of commercial sterilizers is closer to the national average. The baseline risk-based demographic analysis (see ''baseline'' column in Tables 24 to 26), which focuses on those specific locations that are expected to have higher cancer risks (greater than or equal to 1-in-1 million, greater than or equal to 50-in-1 million, and greater than 100-in-1 million), suggests that African Americans are disproportionally represented at the higher risk levels. The post-control risk-based demographic analysis focuses on how the options considered in this proposed regulatory action would affect the distribution of risks within the population identified in the baseline. The CAA section 112(d)(2), (3), and (5) post-control scenario is shown in Tables 24 to 26 and the residual risk post-control options are shown in Tables 27 to 29. The post-control options show a substantial reduction in the number of individuals at each risk level, as well as a significant reduction in the proportion of African Americans that experience higher risk levels from facilities in this source category. EPA projects that a majority of the individuals that would remain at risk after implementation of the proposed standards is Hispanic or Latino, driven largely by the facilities in Puerto Rico. These three distinct but complementary analyses indicate the potential for EJ concerns associated with this source category in the baseline, as well as the substantial benefits these proposed standards would have in reducing EtO emissions and associated health risks in communities with EJ concerns. For more details see the remainder of this section.

Executive Order 12898 directs EPA to identify the populations of concern who are most likely to experience unequal burdens from environmental harms, which are specifically minority populations (people of color), low-income populations, and indigenous peoples (59 FR 7629, February 16, 1994). Additionally, Executive Order 13985 is intended to advance racial equity and support underserved communities through Federal Government actions (86 FR 7009, January 20, 2021). The EPA defines EJ as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income, with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' [50] The EPA further defines fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.'' In recognizing that people of color and low-income populations often bear an unequal burden of environmental harms and risks, the EPA continues to consider ways of protecting them from adverse public health and environmental effects of air pollution. For purposes of analyzing regulatory impacts, the EPA relies upon its June 2016 ''Technical Guidance for Assessing Environmental Justice in Regulatory Analysis,'' [51] which provides recommendations that encourage analysts to conduct the highest quality analysis feasible, recognizing that data limitations, time, resource constraints, and analytical challenges will vary by media and circumstance. The Technical Guidance states that a regulatory action may involve potential EJ concerns if it could: (1) Create new disproportionate impacts on minority populations, low-income populations, and/or Indigenous peoples; (2) exacerbate existing disproportionate impacts on minority populations, low-income populations, and/or Indigenous peoples; or (3) present opportunities to address existing disproportionate impacts on minority populations, low-income populations, and/or Indigenous peoples through this action under development.

For this proposal, the EPA examined the potential for the 97 facilities that were assessed to pose concerns to EJ communities both in the baseline and under the control options considered in this proposal. Specifically, the EPA analyzed how demographics and risk are distributed both pre- and post-control, enabling us to address the core questions that are posed in the EPA's 2016 Technical Guidance for Assessing Environmental Justice in Regulatory Analysis. In conducting this analysis, we considered key variables highlighted in the guidance including ''minority populations (people of color and Hispanic or Latino), low-income populations, and/or indigenous peoples''. The methodology and detailed results of the demographic analysis are presented in a technical report, *Analysis of Demographic Factors for Populations Living Near Ethylene Oxide Commercial Sterilization and Fumigation Operations,* available in the docket for this action.

To examine the potential for EJ concerns in the pre-control baseline, the EPA conducted two baseline demographic analyses, a proximity analysis and a risk-based analysis. The baseline proximity demographic analysis is an assessment of individual demographic groups in the total population living within 10 kilometers (km) and 50 km of the facilities. In this preamble, we focus on the 10 km radius for the demographic analysis because it encompasses all the facility MIR locations and captures 100 percent of the population with risks greater than 100-in-1 million. The results of the proximity analysis for populations living within 50 km are included in the technical report included in the docket for this proposed rule.

The baseline risk-based demographic analysis is an assessment of risks to individual demographic groups in the population living within the 10 km and 50 km radii around the facilities prior to the implementation of any controls proposed by this action (''baseline''). Again, in this preamble, we focus on the results for populations living within 10 km of facilities. Results for populations living within 50 km are included in the technical report included in the docket for this proposed rule.

[50] *https://www.epa.gov/environmentaljustice.*

[51] See *https://www.epa.gov/environmentaljustice/technical-guidance-assessing-environmental-justice-regulatory-analysis.*

1. Demographics

The first three columns of Tables 24, 25, and 26 of this document show the total population, population percentages, and population count for each demographic group for the nationwide population and the total population living within 10 km of EtO sterilization facilities. A total of 19.4 million people live within 10 km of the 97 facilities that were assessed. The results of the proximity demographic analysis indicate that the percent of the population that is Hispanic or Latino is substantially higher than the national average (34 percent versus 19 percent), driven by the seven facilities in Puerto Rico, where an average of 99 percent of the 658,000 people living within 10 km of the facilities are Hispanic or Latino. The percent of the population that is ''Other and multiracial'' (13 percent) is higher than the national average (8 percent). The percentages of the population that are African American (13 percent) or Native American (0.3 percent) are similar to or less than the national averages (12 percent and 0.7 percent, respectively). The percent of people living below the poverty level (14 percent) and those over the age of 25 without a high school diploma (15 percent) are higher than the national averages (13 percent and 12 percent, respectively). The percent of people living in linguistic isolation is double the national average (10 percent versus 5 percent).[52] However, we note that this estimate of linguistic isolation is largely driven by the facilities in Puerto Rico, where an average of 67 percent of the population is in linguistic isolation in comparison to the national average.

In summary, the baseline proximity analysis indicates that the percent of Hispanic or Latino populations living near commercial sterilizers (within 10 km) is higher than what would be expected based on the national average distribution. This is largely driven by the seven facilities located in Puerto Rico where, on average, the population of 658,000 people living within 10 km of these seven facilities is 99 percent Hispanic or Latino. In addition, the population around the facilities in Puerto Rico has 67 percent living in linguistic isolation, 45 percent living below the poverty level, and 24 percent over 25 without a high school diploma.

[52] Linguistic Isolation is defined in the U.S. Census Bureau's American Community Survey as ''a household in which all members age 14 years and over speak a non-English language and also speak English less than ''very well'' (have difficulty with English).''

2. Baseline Risk-Based Demographics

The baseline risk-based demographic analysis results are shown in the ''baseline'' column of Tables 24, 25, and 26. This analysis focused on the populations living within 10 km of the facilities with estimated cancer risks greater than or equal to 1-in-1 million (Table 24), greater than or equal to 50-in-1 million (Table 25), and greater than 100-in-1 million (Table 26). The risk analysis indicated that emissions from the source category, prior to the reductions we are proposing, expose a total of 5.3 million people to a cancer risk greater than or equal to 1-in-1 million around 78 facilities, 119,000 people to a cancer risk greater than or equal to 50-in-1 million around 42 facilities, and 18,000 people to a cancer risk greater than 100-in-1 million around 16 facilities. The demographics of the baseline population with estimated cancer risks greater than or equal to 1-in-1 million are very similar to the total population within 10 km. Specifically, the percent of the population that is Hispanic or Latino is significantly above the national average (38 percent versus 19 percent), the percent below the poverty level is above national average (16 percent versus 13 percent), the percent over 25 without a high school diploma is above the national average (18 percent versus 12 percent), and the percent linguistic isolation is two times the national average (11 percent versus 5 percent). In contrast, the smaller populations with baseline cancer risk greater than or equal to 50-in-1 million (119,000 people) and >100-in-1 million (18,000 people) are predominantly made up of African Americans (45 and 34 percent versus 12 percent nationally), have a higher percentage of the population below the poverty level (22 and 23 percent versus 13 percent nationally), the percent over 25 without a high school diploma is above the national average (17 and 16 percent versus 12 percent) and linguistic isolation is above the national average (7 and 10 percent versus 5 percent). This shows that risks tend to be higher where more African American residents reside and where poverty is higher than in the rest of the area within 10 km. It should be noted that, the higher percentage African American population with baseline cancer risk greater than or equal to 50-in-1 million is driven largely by seven facilities that have African American populations that are between two and eight times the national average. The higher percentage African American population with baseline cancer risk greater than 100-in-1 million is driven largely by three facilities that are located in communities where the proportion of African American residents is between 2.5 and 8 times the national average. The population with higher baseline cancer risks living within 10 km of the facilities consists of a substantially smaller percentage of Hispanic or Latino (18 and 19 percent) than the total population living within 10 km (34 percent Hispanic or Latino) and is near the national average (19 percent).

In summary, the baseline risk-based demographic analysis, which focuses on those specific locations that are expected to have higher cancer risks, suggests that African Americans are the one demographic group disproportionally represented where risk is highest. The population with risks greater than 100-in-1 million living within 10 km of a commercial sterilizer has a significantly higher proportion of African Americans (34 percent) than the national average (12 percent).

3. Risk-Based Demographics Considering Standards Under CAA Sections 112(d)(2), (3), and (5)

This analysis focused on the populations living within 10 km of the facilities with estimated cancer risks greater than or equal to 1-in-1 million (Table 24), greater than or equal to 50-in-1 million (Table 25), and greater than 100-in-1 million (Table 26) after implementation of standards that we are proposing under CAA sections 112(d)(2), (3), and (5). The results of our analysis of risk-based demographics considering standards under CAA sections 112(d)(2), (3), and (5) are shown in the last column of Tables 24, 25, and 26 titled ''Baseline and CAA Section 112(d)(2), (3), and (5).'' In this analysis we evaluated how the proposed CAA sections 112(d)(2), (3), and (5) emission reductions in this proposed regulatory action affect the distribution of risks identified in the baseline. This enables us to characterize the post-control risks and to evaluate whether the proposed action creates or mitigates potential EJ concerns as compared to the baseline. Note that as described in section III.C, the risk results in this scenario were based on requiring BMP (Option 2) under section 112(d)(5) for Group 1 room air emissions, instead of the proposed emission limit reflecting use of control devices (Option 1). Therefore, the populations at the various risk levels may be lower than reported here (and the demographics slightly different).

The risk analysis indicated that the emissions from the source category, after implementation of the emissions reductions we are proposing under CAA

section 112(d), reduces the number of people living within 10 km of a facility and with a cancer risk greater than or equal to 1-in-1 million from 5.3 million people around 78 facilities to 2.6 million people around 73 facilities, reduces the number of people living within 10 km of a facility and with a cancer risk greater than or equal to 50-in-1 million from 119,000 people around 42 facilities to 19,000 people around 20 facilities, and reduces the number of people living within 10 km of a facility and with a cancer risk greater than 100-in-1 million from 18,000 people around 16 facilities to 2,350 people around 13 facilities.

The demographics of the population with estimated cancer risks greater than or equal to 1-in-1 million considering the standards we are proposing under CAA section 112(d) are very similar to both the total population within 10 km and to the baseline population with risks greater than or equal to 1-in-1 million. Specifically, the percent of the population that is Hispanic or Latino is significantly above the national average (32 percent versus 19 percent), the percent below the poverty level is above national average (16 percent versus 13 percent), the percent over 25 without a high school diploma is above the national average (16 percent versus 12 percent), and the percent linguistic isolation is two times the national average (10 percent versus 5 percent).

After implementation of the standards we are proposing under CAA section 112(d), the percentage and number of African Americans at cancer risks greater than or equal to 50-in-1 million and greater than 100-in-1 million is significantly reduced. For example, African Americans exposed to risks greater than 100-in-1 million went from 34 percent or 6,000 people in the baseline to 11 percent or 300 people after implementation of the proposed technology review emissions reductions. It should be noted that, the percentage of the population that is Hispanic or Latino exposed to risks greater than 100-in-1 million went up from 18 percent in the baseline to 51 percent after the proposed technology review emissions reductions. However, the number of Hispanic or Latino people with risks greater than 100-in-1 million was reduced from 3,000 to 1,200 people. Similarly, the percentage of the population that are below the poverty level or are linguistically isolated with a cancer risk greater than 100-in-1 million went up from the baseline, but the number of people in these demographics decreased significantly. For example, the proportion of the population with risks greater than 100-in-1 million that were below the poverty level was much higher than the baseline (34 percent versus 23 percent), but the number of people was reduced from 4,000 people to 800 people.

In summary, the proposed CAA section 112(d) standards significantly reduced the number of people in all demographic groups that are exposed to risks greater than or equal to 1-in-1 million, greater than and equal to 50-in-1 million, and greater than 100-in-1 million. Specifically, the percent of the population that is African American who are at a cancer risk greater than or equal to 50-in-1 million and greater than 100-in-1 million was reduced from about 40 percent in the baseline to about 15 percent after the technology review controls. The percentage of Hispanic or Latino people increased as the higher risk facilities in Puerto Rico make-up an increasing portion of the remaining populations with higher cancer risks.

TABLE 24—COMPARISON OF BASELINE AND CAA SECTION 112(d)(2), (3), AND (5) POST-CONTROL DEMOGRAPHICS OF POPULATIONS WITH CANCER RISK GREATER THAN OR EQUAL TO 1-IN-1 MILLION LIVING WITHIN 10 km OF FACILITIES THAT WERE ASSESSED

Demographic group	Nationwide	Total population living within 10 km of EtO facilities	Cancer risk ≥1-in-1 million	
			Baseline	Post-control
Total Population	328M	19.4M	5.3M	[1] 2.6M
Number of Facilities	.....	97	78	[1] 73
Race and Ethnicity by Percent [Number of People]				
White	60 [197M]	40 [7.7M]	40 [2.1M]	[1] 43 [1M]
African American	12 [40M]	13 [2.5M]	15 [780K]	[1] 19 [480K]
Native American	0.7 [2M]	0.3 [56K]	0.3 [16K]	[1] 0.3 [7K]
Hispanic or Latino (includes white and nonwhite)	19 [62M]	34 [6.5M]	38 [2M]	[1] 32 [840K]
Other and Multiracial	8 [27M]	13 [2.6M]	7 [360K]	[1] 6 [150K]
Income by Percent [Number of People]				
Below Poverty Level	13 [44M]	14 [2.8M]	16 [800K]	[1] 16 [400K]
Above Poverty Level	87 [284M]	86 [16.6M]	84 [4.5M]	[1] 84 [2.2M]
Education by Percent [Number of People]				
Over 25 and without a High School Diploma	12 [40M]	15 [3M]	18 [900K]	[1] 16 [400K]
Over 25 and with a High School Diploma	88 [288M]	85 [16.4M]	82 [4.4M]	[1] 84 [2.2M]
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 [18M]	10 [2M]	11 [600K]	[1] 10 [300K]

[1] These values may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment.

Notes:

• Nationwide population and demographic percentages are based on the Census Bureau's (Census) 2015–2019 American Community Survey (ACS) 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.

• To avoid double counting, the "Hispanic or Latino" category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.
• The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.
• The sum of individual populations with a demographic category may not add up to total due to rounding.

TABLE 25—COMPARISON OF BASELINE AND CAA SECTION 112(d)(2), (3), AND (5) POST-CONTROL DEMOGRAPHICS OF POPULATIONS WITH CANCER RISK GREATER THAN OR EQUAL TO 50-IN-1 MILLION LIVING WITHIN 10 km OF FACILITIES THAT WERE ASSESSED

Demographic group	Nationwide	Total population living within 10 km of EtO facilities	Cancer risk ≥50-in-1 million	
			Baseline	Post-control
Total Population	328M	19.4M	119,000	[1] 19,000
Number of Facilities	.....	97	42	[1] 20
Race and Ethnicity by Percent [Number of People]				
White	60 [197M]	40 [7.7M]	33 [39K]	[1] 54 [10K]
African American	12 [40M]	13 [2.5M]	45 [54K]	[1] 19 [4K]
Native American	0.7 [2M]	0.3 [56K]	0.1 [200]	[1] 0.1 [<100]
Hispanic or Latino (includes white and nonwhite)	19 [62M]	34 [6.5M]	19 [23K]	[1] 25 [5K]
Other and Multiracial	8 [27M]	13 [2.6M]	3 [4K]	[1] 2 [400]
Income by Percent [Number of People]				
Below Poverty Level	13 [44M]	14 [2.8M]	22 [26K]	[1] 23 [4K]
Above Poverty Level	87 [284M]	86 [16.6M]	78 [93K]	[1] 77 [15K]
Education by Percent [Number of People]				
Over 25 and without a High School Diploma	12 [40M]	15 [3M]	17 [8K]	[1] 15 [2K]
Over 25 and with a High School Diploma	88 [288M]	85 [16.4M]	83 [111K]	[1] 85 [17K]
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 [18M]	10 [2M]	7 [54K]	[1] 13 [4K]

[1]These values may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment.

Notes:
• Nationwide population and demographic percentages are based on Census' 2015–2019 ACS 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.
• To avoid double counting, the "Hispanic or Latino" category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.
• The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.
• The sum of individual populations with a demographic category may not add up to total due to rounding.
• To account for the uncertainty of demographics estimates in smaller populations, any population values of 100 persons or less have been shown simply as "<100."

TABLE 26—COMPARISON OF BASELINE AND CAA SECTION 112(d)(2), (3), AND (5) POST-CONTROL DEMOGRAPHICS OF POPULATIONS WITH CANCER RISK GREATER THAN 100-IN-1 MILLION LIVING WITHIN 10 km OF FACILITIES THAT WERE ASSESSED

Demographic group	Nationwide	Total population living within 10 km of EtO facilities	Cancer risk ≥100-in-1 million	
			Baseline	Post-control
Total Population	328M	19.4M	18,000	[1] 2,350
Number of Facilities	.....	97	16	[1] 13
Race and Ethnicity by Percent [Number of People]				
White	60 [197M]	40 [7.7M]	45 [8K]	[1] 37 [900]
African American	12 [40M]	13 [2.5M]	34 [6K]	[1] 11 [300]
Native American	0.7 [2M]	0.3 [56K]	0.1 [<100]	0 [0]
Hispanic or Latino (includes white and nonwhite)	19 [62M]	34 [6.5M]	18 [3K]	[1] 51 [1.2K]
Other and Multiracial	8 [27M]	13 [2.6M]	3 [500]	[1] 1 [<100]

TABLE 26—COMPARISON OF BASELINE AND CAA SECTION 112(d)(2), (3), AND (5) POST-CONTROL DEMOGRAPHICS OF POPULATIONS WITH CANCER RISK GREATER THAN 100-IN-1 MILLION LIVING WITHIN 10 km OF FACILITIES THAT WERE ASSESSED—Continued

Demographic group	Nationwide	Total population living within 10 km of EtO facilities	Cancer risk ≥100-in-1 million	
			Baseline	Post-control
Income by Percent [Number of People]				
Below Poverty Level	13 [44M]	14 [2.8M]	23 [4K]	[1] 34 [800]
Above Poverty Level	87 [284M]	86 [16.6M]	77 [14K]	[1] 66 [1.55K]
Education by Percent [Number of People]				
Over 25 and without a High School Diploma	12 [40M]	15 [3M]	16 [2K]	[1] 17 [700]
Over 25 and with a High School Diploma	88 [288M]	85 [16.4M]	84 [15K]	[1] 83 [1.65K]
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 [18M]	10 [2M]	10 [6K]	[1] 31 [300]

[1] These values may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment.

Notes:

- Nationwide population and demographic percentages are based on Census' 2015–2019 ACS 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.
- To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.
- The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.
- The sum of individual populations with a demographic category may not add up to total due to rounding.
- To account for the uncertainty of demographics estimates in smaller populations, any population values of 100 persons or less have been shown simply as ''<100.''

4. Residual Risk Post-Control Risk-Based Demographics

This analysis focused on the populations living within 10 km of the facilities with estimated cancer risks greater than or equal to 1-in-1 million (Table 27), greater than or equal to 50-in-1 million (Table 28), and greater than 100-in-1 million (Table 29) after implementation of the control options investigated under the residual risks analysis as described in section III.D of this preamble. The demographic results for the control options are in the columns titled ''Control Option 1'' and ''Control Option 2.'' One of these control options would be implemented in addition to the CAA section 112(d)(2), (3), and (5) post-control emissions reductions. Therefore, in this analysis, we evaluated how all of the proposed controls and emission reductions described in this action affect the distribution of risks. This enables us to characterize the post-control risks and to evaluate whether the proposed action creates or mitigates potential EJ concerns as compared to the baseline. Again, as described in section III.C, the risk results in this scenario were based on requiring BMP (Option 2) under section 112(d)(5) for Group 1 room air emissions, instead of the proposed emission limit reflecting use of control devices (Option 1). Therefore, the populations at the various risk levels may be lower than reported here (and the demographics slightly different).

The risk analysis indicated that the number of people exposed to risks greater than or equal to 1-in-1 million within 10 km of a facility (Table 27) is reduced from 2.6 million people after implementation of the CAA section 112(d)(2), (3), and (5) controls to approximately 1.15 million people after implementation of one of the residual risk control options. This represents a significant reduction (about 60 percent reduction) in the size of the populations at risk for each of the three residual risk control options investigated when compared to the populations after implementation of the technology review controls. The populations with a cancer risk greater than or equal to 1-in-1 million are located around 73 facilities for both post-control options.

The demographics of the post-control population living within 10 km of a facility and with an estimated cancer risks greater than or equal to 1-in-1 million for control options 1 and 2 (Table 27) are very similar to the CAA section 112(d)(2), (3), and (5) post-control population with risks greater than or equal to 1-in-1 million. Specifically, the percent of the population that is Hispanic or Latino is significantly above the national average (37 percent versus 19 percent), the percent below poverty is above national average (16 percent versus 13 percent), the percent over 25 without a high school diploma is above the national average (16 percent versus 12 percent), and the percent linguistic isolation is almost two times the national average (9 percent versus 5 percent).

The risk analysis indicated that the number of people living within 10 km of a facility and exposed to risks greater than or equal to 50-in-1 million (Table 28) is reduced from 19,000 people after implementation of the CAA section 112(d)(2), (3), and (5) controls to 1,400 to 2,000 people after implementation of one of the residual risk control options. This represents a 90 percent reduction in the size of the populations at risk for each of the three residual risk control options investigated when compared to the populations after implementation of the CAA section 112(d)(2), (3), and (5) controls. The populations living within 10 km of a facility and with a cancer risk greater than or equal to 50-in-1 million are located around 11 facilities for both post-control options.

The demographics of the post-control population living within 10 km of a facility and with estimated cancer risks greater than or equal to 50-in-1 million for control options 1 and 2 (Table 28)

are significantly different from the population after implementation of the CAA section 112(d)(2), (3), and (5) controls. Specifically, the percent of the population that is Hispanic or Latino is significantly higher at 79 percent and 72 percent for control options 1 and 2, respectively. This higher percentage is driven by three facilities in Puerto Rico and one in Texas, for which the population is over 95 percent Hispanic or Latino. However, the number of Hispanic or Latino people with risks greater than or equal to 50-in-1 million was reduced by about 80 percent from 5,000 people to 1,600 and 1,000 people for Option 1 and 2, respectively. Similarly, the percentage of the population that is below the poverty level or linguistically isolated went up from the CAA section 112(d)(2), (3), and (5) post-control population, but the number of people in these demographics decreased significantly.

The risk analysis indicated that the number of people living with 10 km of a facility and exposed to risks greater than 100-in-1 million (Table 29) is reduced from 2,350 people after implementation of the CAA section 112(d)(2), (3), and (5) controls to 33 people for Option 1 and to zero people for Option 2. For control Option 1, there are three facilities with risks greater than 100-in-1 million. Two of these facilities are located in Puerto Rico and one is in Utah.[53] The demographics in Table 29 are for one of the facilities in Puerto Rico. For the other two facilities, the MIR was located at individual residences closest to the facilities and not at a census block centroid. Therefore, we were unable to estimate the risk-based population and risk-based demographics for those facilities. However, the proximity analysis indicated that the demographics for all people living within 10 km of the other Puerto Rico facility are almost identical to the one shown in Table 29. The proximity analysis shows that the population of all people living within 10 km of the Utah facility is 80 percent white with the percent Hispanic or Latino, African American, below the poverty level, over 25 without a high school education, and linguistic isolation all below the national average.

For control Option 2, there are no facilities or people with risks greater than 100-in-1 million. Therefore, there are no greater than 100-in-1 million demographics to discuss.

In summary, as shown in the residual risk post-control risk-based demographic analysis, the options under consideration in this proposal would reduce the number of people and facilities expected to have cancer risks greater than or equal to 1-in-1 million, greater than or equal to 50-in-1 million, and greater than 100-in-1 million significantly. Under Option 1, the percentage of population that is Hispanic or Latino, below the poverty level, over 25 without a high school diploma, and in linguistic isolation increases as the cancer risk increases. This trend is driven largely by the higher risk facilities in Puerto Rico. Under Option 1, the number of Hispanic or Latino people that are exposed to risks greater than or equal to 1-in-1 million is reduced by 50 percent, the number of Hispanic or Latino people that are exposed to risks greater than or equal to 50-in-1 million is reduced by 70 percent, and the number of Hispanic or Latino people that are exposed to risks greater than 100-in-1 million is reduced by 97 percent. The three facilities remaining above 100-in-1 million for Option 1 are located in Puerto Rico (two facilities) and Utah. The two facilities in Puerto Rico have Hispanic or Latino populations of greater than 99 percent and the population around the facility in Utah is 80 percent white.

Under Option 2, the number of Hispanic or Latino people that are exposed to risks greater than or equal to 1-in-1 million is reduced by 50 percent, the number of Hispanic or Latino people that are exposed to risks greater than or equal to 50-in-1 million is reduced by 80 percent, and the number of Hispanic or Latino people that are exposed to risks greater than 100-in-1 million is reduced by 100 percent. We note that, primarily driven by the higher risk facilities in Puerto Rico, the percentage of population that is Hispanic or Latino, below the poverty level, over 25 without a high school diploma, and in linguistic isolation increases as the cancer risk increases from greater than or equal to 1-in-1 million to greater than 50-in-1 million. Under Option 2, there are no facilities or people with risks greater than 100-in-1 million.

TABLE 27—COMPARISON OF POST-CONTROL DEMOGRAPHICS FOR POPULATIONS WITH CANCER RISK GREATER THAN OR EQUAL TO 1-IN-1 MILLION LIVING WITHIN 10 KM OF STERILIZER FACILITIES FOR VARIOUS CONTROL OPTIONS

Demographic group	Nationwide	Cancer risk ≥1-in-1 million		
		Post-control CAA section 112(d)(2), (3), and (5)	Control option 1	Control option 2
Total Population	328M	2.6M [1]	1.2M [1]	1.1M [1]
Number of Facilities with Pop. Above Cancer Level.		73 [1]	73 [1]	73 [1]
Race and Ethnicity by Percent [number of people]				
White	60 percent [197M]	43 percent [1M] [1]	38 percent [447K] [1]	38 percent [429K] [1]
African American	12 percent [40M]	19 percent [480K] [1]	18 percent [209K] [1]	18 percent [208K] [1]
Native American	0.7 percent [2M]	0.3 percent [7K] [1]	0.4 percent [5K] [1]	0.4 percent [4.5K] [1]
Hispanic or Latino (includes white and nonwhite).	19 percent [62M]	32 percent [840K] [1]	37 percent [431K] [1]	37 percent [419K] [1]
Other and Multiracial	8 percent [27M]	6 percent [150K] [1]	7 percent [76K] [1]	7 percent [74K] [1]
Income by Percent [Number of People]				
Below Poverty Level	13 percent [44M]	16 percent [400K] [1]	16 percent [182K] [1]	16 percent [177K] [1]
Above Poverty Level	87 percent [284M]	84 percent [2.2M] [1]	84 percent [1M] [1]	84 percent [900K] [1]

[53] As described in section III.D.1.c, we expect the risks at one of the facilities in Puerto Rico to be below 100-in-1 million after accounting for the proposed Group 1 room air emission reductions.

TABLE 27—COMPARISON OF POST-CONTROL DEMOGRAPHICS FOR POPULATIONS WITH CANCER RISK GREATER THAN OR EQUAL TO 1-IN-1 MILLION LIVING WITHIN 10 KM OF STERILIZER FACILITIES FOR VARIOUS CONTROL OPTIONS—Continued

Demographic group	Nationwide	Cancer risk ≥1-in-1 million		
		Post-control CAA section 112(d)(2), (3), and (5)	Control option 1	Control option 2
Education by Percent [Number of People]				
> 25 w/o a HS Diploma	12 percent [40M]	16 percent [400K] [1]	16 percent [186K] [1]	16 percent [181K] [1]
> 25 w/HS Diploma	88 percent [288M]	84 percent [2.2M] [1]	84 percent [1M] [1]	84 percent [900K] [1]
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 percent [18M]	10 percent [300K] [1]	9 percent [105K] [1]	9 percent [100K] [1]

[1] These values may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment

Notes:

• Nationwide population and demographic percentages are based on Census' 2015–2019 ACS 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.

• To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.

• The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.

• The sum of individual populations with a demographic category may not add up to total due to rounding.

TABLE 28—COMPARISON OF POST-CONTROL DEMOGRAPHICS FOR POPULATIONS WITH CANCER RISK GREATER THAN OR EQUAL TO 50-IN-1 MILLION LIVING WITHIN 10 KM OF STERILIZER FACILITIES FOR VARIOUS CONTROL OPTIONS

Demographic group	Nationwide	Cancer risk ≥ 50-in-1 million		
		CAA section 112(d)(2), (3), and (5) post-control	Control option 1	Control option 2
Total Population	328M	19,000 [1]	1,985 [1]	1,368 [1]
Number of Facilities with Pop. Above Cancer Level.		20 [1]	11 [1]	11 [1]
Race and Ethnicity by Percent [number of people]				
White	60 percent [197M]	54 percent [10K] [1]	12 percent [200] [1]	15 percent [200] [1]
African American	12 percent [40M]	19 percent [4K] [1]	7 percent [100] [1]	10 percent [100] [1]
Native American	0.7 percent [2M]	0.1 percent [<100] [1]	0.2 percent [<100] [1]	0.3 percent [<100] [1]
Hispanic or Latino (includes white and nonwhite).	19 percent [62M]	25 percent [5K] [1]	79 percent [1,600] [1]	72 percent [1000] [1]
Other and Multiracial	8 percent [27M]	2 percent [400] [1]	2 percent [<100] [1]	3 percent [<100] [1]
Income by Percent [Number of People]				
Below Poverty Level	13 percent [44M]	23 percent [4K] [1]	35 percent [700] [1]	26 percent [400] [1]
Above Poverty Level	87 percent [284M]	77 percent [15K] [1]	65 percent [1,300] [1]	74 percent [1K] [1]
Education by Percent [Number of People]				
> 25 w/o a HS Diploma	12 percent [40M]	15 percent [2K] [1]	20 percent [400] [1]	20 percent [300] [1]
> 25 w/HS Diploma	88 percent [288M]	85 percent [17K] [1]	80 percent [1,600] [1]	80 percent [1K] [1]
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 percent [18M]	13 percent [4K] [1]	34 percent [700] [1]	21 percent [300] [1]

[1] These values may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment

Notes:

• Nationwide population and demographic percentages are based on Census' 2015–2019 ACS 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.

• To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.

• The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.

• The sum of individual populations with a demographic category may not add up to total due to rounding.

• To account for the uncertainty of demographics estimates in smaller populations, any population values of 100 persons or less have been shown simply as ''<100''.

TABLE 29—COMPARISON OF POST-CONTROL DEMOGRAPHICS FOR POPULATIONS WITH CANCER RISK GREATER THAN 100-IN-1 MILLION LIVING WITHIN 10 KM OF STERILIZER FACILITIES FOR VARIOUS CONTROL OPTIONS

Demographic group	Nationwide	Cancer risk >100-in-1 million		
		CAA section 112(d)(2), (3), and (5) post-control	Control option 1	Control option 2
Total Population	328M	2,350 [1]	33	0
Number of Facilities with Pop. Above Cancer Level		13 [1]	3 [1]	0
Race and Ethnicity by Percent [number of people]				
White	60 percent [197M]	37 percent [900] [1]	0.9 percent [0]	
African American	12 percent [40M]	11 percent [300] [1]	0.1 percent [0]	
Native American	0.7 percent [2M]	0 percent [0]	0 percent [0]	
Hispanic or Latino (includes white and nonwhite)	19 percent [62M]	51 percent [1.2K] [1]	99 percent [<100]	
Other and Multiracial	8 percent [27M]	1 percent [<100] [1]	0.1 percent [0]	
Income by Percent [Number of People]				
Below Poverty Level	13 percent [44M]	34 percent [800] [1]	61 percent [<100]	
Above Poverty Level	87 percent [284M]	66 percent [1.55K] [1]	39 percent [<100]	
Education by Percent [Number of People]				
> 25 w/o a HS Diploma	12 percent [40M]	17 percent [700] [1]	27 percent [<100]	
> 25 w/HS Diploma	88 percent [288M]	83 percent [1.65K] [1]	73 percent [<100]	
Linguistically Isolated by Percent [Number of People]				
Linguistically Isolated	5 percent [18M]	31 percent [300] [1]	84 percent [<100]	

[1] These values may be lower because the proposed Group 1 room air emission standards were not applied or accounted for in the risk assessment

Notes:

- Nationwide population and demographic percentages are based on Census' 2015–2019 ACS 5-year block group averages. Total population count within 10 km is based on 2010 Decennial Census block population.
- To avoid double counting, the "Hispanic or Latino" category is treated as a distinct demographic category. A person who identifies as Hispanic or Latino is counted as Hispanic or Latino, regardless of race.
- The number of facilities represents facilities with a cancer MIR above level indicated. When the MIR was located at a user assigned receptor at an individual residence and not at a census block centroid, we were unable to estimate population and demographics for that facility.
- The sum of individual populations with a demographic category may not add up to total due to rounding.
- To account for the uncertainty of demographics estimates in smaller populations, any population values of 100 persons or less have been shown simply as "<100".

F. What are the results and proposed decisions based on our technology review, and what is the rationale for those decisions?

1. SCV At Facilities Where EtO Use Is at Least 10 Tpy

The current subpart O contains emission standards for SCVs at facilities where EtO use is at least 10 tpy. There are 47 facilities where EtO use is at least 10 tpy, all of which have SCVs. Of these facilities, 26 currently use wet scrubbers to control their SCV emissions, 11 use catalytic oxidizers, and six use a wet scrubber and gas/solid reactor in series, four use thermal oxidizers, and one uses a wet scrubber and catalytic oxidizer in series. Performance tests are available for SCVs at all facilities where EtO use is at least 10 tpy. We reviewed these performance tests, and the reported emission reductions ranged from 99.6 percent to 99.999996 percent.

We considered two potential options as part of the technology review. The first option we considered (Option 1) is 99.94 percent emission reduction. The second option we considered (Option 2) is the maximum SCV emission reduction that all facilities where EtO use is at least 10 tpy are currently meeting, which is 99.6 percent. We considered these standards as part of the analysis pursuant to CAA section 112(f)(2) as discussed in section III.C. Under Option 1, costs were found to be $3,596,236 total capital investment and a $1,178,927 total annualized cost. The estimated EtO emissions reductions are 1.5 tpy with a cost effectiveness of $783,816 per ton of EtO. There are no cost or emission impacts for Option 2.

As discussed in section III.C.2, 99.94 percent emission reduction (Option 1) reflects the current developments in processes and technology by this industry (*i.e.,* well performing air pollution control). While Option 2 would prevent backsliding, it does not achieve additional emission reduction.

Therefore, pursuant to CAA section 112(d)(6), we are proposing to revise the standard for SCVs at facilities where EtO use is at least 10 tpy. Specifically, we are proposing to require facilities where EtO use is at least 10 tpy to reduce their emissions from new and existing SCVs by 99.94 percent. This is the same standard that was proposed pursuant to CAA section 112(f)(2) as discussed in section III.C. We solicit comment on this proposed standard (Comment C–41).

2. SCV at Facilities Where EtO Use Is at Least 1 Tpy but Less Than 10 Tpy

The current subpart O contains emission standards for SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. There are 18 facilities where EtO use is at least 1 tpy but less than 10 tpy, all of which have SCVs. Of these facilities, 10 currently use catalytic oxidizers to control their SCV emissions, three use gas/solid reactors, three use wet scrubbers, one uses a wet scrubber and catalytic oxidizer in series, and one uses a wet scrubber and gas/solid reactor in series. Performance tests are available for SCVs at 10 facilities where EtO use is at least 1 tpy but less than 10 tpy; seven of these facilities use catalytic oxidizers, and three use wet scrubbers. We reviewed these performance tests, and the reported emission reductions ranged from 99.2 percent to 99.9999 percent.

We considered two potential options as part of the technology review. The first option we considered (Option 1) is maximum SCV emission reduction with which compliance can be demonstrated at all facilities where EtO use is at least 1 tpy but less than 10 tpy considering current emission profiles. This emission reduction is 99.8 percent. The second option we considered (Option 2) is the maximum SCV emission reduction that all facilities where EtO use is at least 1 tpy but less than 10 tpy are currently meeting, which is 99.2 percent. These standards were considered as part of the analysis pursuant CAA section 112(f)(2) as discussed in section III.C.2. The impacts of Option 1 are presented in Table 22 as Control Option C. There are no cost or emission impacts for Option 2.

As discussed in section III.C.2, the emission reduction requirements under Option 1 reflect the current developments in processes and technology by this industry (*i.e.,* well performing air pollution control). While Option 2 would prevent backsliding, it does not achieve additional emission reduction. Therefore, pursuant to CAA section 112(d)(6), we are proposing to revise the standard for new and existing SCVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. Specifically, we are proposing to require facilities where EtO use is at least 1 tpy but less than 10 tpy to reduce their SCV emissions by 99.8 percent. This is the same standard that was proposed pursuant to CAA section 112(f)(2) as discussed in section III.C. We solicit comment on these proposed standards (Comment C–42).

3. ARV at Facilities Where EtO Use Is at Least 10 Tpy

a. Existing Sources

The current subpart O contains emission standards for ARVs at facilities where EtO use is at least 1 tpy but less than 10 tpy. As discussed in section III.B.2 of this preamble, we are proposing to remove the 1 ppmv alternative for ARVs at facilities where EtO use is at least 10 tpy. There are 47 facilities where EtO use is at least 10 tpy, 41 of which have ARVs. Of these facilities, 22 currently use catalytic oxidizers, seven use gas/solid reactors, four use wet scrubbers, three use thermal oxidizers, three use a wet scrubber and gas/solid reactor in series, two use a catalytic oxidizer and gas/solid reactor in series, and one uses a catalytic oxidizer and thermal oxidizer in series. Performance tests are available for 32 ARVs at all facilities where EtO use is at least 10 tpy; 19 currently use catalytic oxidizers, four use gas/solid reactors, two use wet scrubbers, two use a wet scrubber and gas/solid reactor in series, four use thermal oxidizers, and one uses a catalytic oxidizer and gas/solid reactor in series. We reviewed these performance tests, and the reported emission reductions ranged from 95.7 percent to 99.998 percent.

For existing ARVs at facilities where EtO use is at least 10 tpy, we considered two potential options as part of the technology review. The first option we considered (Option 1) is the emission reduction that has been demonstrated in 75 percent of all available performance tests, which is 99.6 percent. The second option we considered (Option 2) is the emission reduction that has been demonstrated in 50 percent of all available performance tests, which is 99.9 percent.

The impacts of these options are presented in Table 30:

TABLE 30—NATIONWIDE EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(D)(6) FOR EXISTING ARVS AT FACILITIES WHERE ETO USE IS AT LEAST 10 TPY

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99.6 percent emission reduction	$5,348,248	$1,389,805	1.89	$734,581
2	99.9 percent emission reduction	20,563,093	4,504,268	2.96	1,521,440

We are proposing Option 1 because Option 1 would be more cost-effective. Therefore, pursuant to CAA section 112(d)(6), we are proposing to revise the standard for existing ARVs at facilities where EtO use is at least 10 tpy under CAA section 112(d)(6). Specifically, we are proposing to require these facilities to continuously reduce emissions from existing ARVs by 99.6 percent. We are soliciting comment on our proposed revision to this standard (Comment C–43). In addition, for the same reason discussed above in section III.B.1.a, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99.6 percent emission reduction for existing ARVs at facilities where EtO use is at least 10 tpy and whether 9.8E–4 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99.6 percent emission reduction standard for existing ARVs at facilities where EtO use is at least 10 tpy (Comment C–44).

b. New Sources

The current subpart O contains emission standards for new ARVs at facilities where EtO use is at least 10 tpy. As discussed in section III.B.2 of this preamble, we are proposing to remove the 1 ppmv alternative for ARVs at facilities where EtO use is at least 10 tpy. For new ARVs at facilities where EtO use is at least 10 tpy, we considered the same two potential options as those

evaluated for existing ARVs at facilities where EtO use is at least 10 tpy for the same reasons explained above. The first potential option (Option 1) would require achieving 99.6 percent emission reduction, and the second potential option (Option 2) would require achieving 99.9 percent emission reduction. The impacts of these options, which are presented in Table 31 of this preamble, are based on a model plant for new ARVs at a facility using at least 10 tpy EtO with the following assumptions reflecting the average of each of the parameters at existing facilities at least 10 tpy EtO:

- Number of ARVs: 6.
- Annual EtO use: 150 tpy.
- Annual operating hours: 8,400.
- Portion of EtO going to ARVs: 3.90 percent.
- ARV flow rate: 300 cfs.

TABLE 31—MODEL PLANT EMISSIONS REDUCTION AND COST IMPACTS OF OPTIONS CONSIDERED UNDER CAA SECTION 112(D)(6) FOR NEW ARVS AT FACILITIES WHERE ETO USE IS AT LEAST 10 TPY

Option	Proposed standard	Total capital investment ($)	Total annual costs ($/yr)	EtO emission reductions (tpy)	Cost effectiveness ($/ton EtO)
1	99.6 percent emission reduction	$272,825	$90,990	3.5E–2	$2,592,644
2	99.9 percent emission reduction	400,076	115,974	5.3E–2	2,203,031

We are proposing Option 2 because Option 2 would achieve greater emission reductions than Option 1, and Option 2 would be more cost-effective. Therefore, pursuant to CAA section 112(d)(6), we are proposing to revise the standard for new ARVs at facilities where EtO use is at least 10 tpy under CAA section 112(d)(6). Specifically, we are proposing to require these facilities to continuously reduce emissions from new ARVs by 99.9 percent. We are soliciting comment on our proposed revision to this standard (Comment C–45). In addition, for the same reason discussed in section III.B.1.a of this preamble, we solicit comment on whether to include an alternative lb/hr limit that is equivalent to 99.9 percent emission reduction for new ARVs at facilities where EtO use is at least 10 tpy and whether 2.3E–4 lb/hr, which we calculated using the method described in section III.B.1.a, is an appropriate alternative standard that is equivalent to the proposed 99.9 percent emission reduction standard for new ARVs at facilities where EtO use is at least 10 tpy (Comment C–46).

G. What other actions are we proposing, and what is the rationale for those actions?

In addition to the proposed actions described above, we are proposing additional revisions to the NESHAP. We are proposing revisions to the SSM provisions of the NESHAP in order to ensure that they are consistent with the decision in *Sierra Club* v. *EPA,* 551 F. 3d 1019 (DC Cir. 2008), in which the court vacated two provisions that exempted sources from the requirement to comply with otherwise applicable CAA section 112(d) emission standards during periods of SSM. We also are proposing revisions to performance test procedures and methods; revisions to monitoring, recordkeeping, and reporting requirements, including requirements for electronic reporting of emissions test results and reports; and making clarifications related to single-item sterilization processes. Our analyses and proposed changes related to these issues are discussed below.

1. SSM Requirements

In its 2008 decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), the court vacated portions of two provisions in the EPA's CAA section 112 regulations governing the emissions of HAP during periods of SSM. Specifically, the court vacated the SSM exemption contained in 40 CFR 63.6(f)(1) and (h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some CAA section 112 standards apply continuously.

We are proposing the elimination of the SSM exemption in this rule that appears at 40 CFR 63.363(f). We are also proposing to eliminate the malfunction exemption in this rule that appears at 40 CFR 63.362(b) and instead require compliance with the standards at all times. Consistent with *Sierra Club* v. *EPA,* we are proposing standards in this rule that apply at all times. We are also proposing several revisions to Table 7 (the General Provisions Applicability Table) as explained in more detail below. For example, we are proposing to eliminate and revise certain recordkeeping requirements related to the SSM exemption as further described below.

The EPA has attempted to ensure that the provisions we are proposing to eliminate are inappropriate, unnecessary, or redundant in the absence of the SSM exemption. We are specifically seeking comment on whether we have successfully done so (Comment C–47).

In proposing the standards in this rule, the EPA has taken into account startup and shutdown periods and, for the reasons explained below, has not proposed alternate standards for those periods. Emission reductions for SCV, ARV, CEV, and room air emission sources are typically achieved by routing vapors to an APCD such as a wet scrubber, catalytic oxidizer, and dry bed scrubber. It is common practice in this source category to start an APCD prior to startup of the emissions source it is controlling, so the APCD would be operating before emissions are routed to it. We expect APCDs would be operating during startup and shutdown events in a manner consistent with normal operating periods, and that these APCDs will be operated to maintain and meet the monitoring parameter operating limits set during the performance test. We have no reason to believe that emissions are different during startup and shutdown. Therefore, we are proposing that emissions from startup and shutdown activities be included when determining if all the standards are being attained. As currently proposed in 40 CFR 63.362(b), compliance with the emission limitations (including operating limits) in this subpart is required ''at all times.'' We solicit comment on whether facilities in the Commercial Sterilization Facilities source category will be able to comply with the standards during these times (Comment C–48).

Periods of startup, normal operations, and shutdown are all predictable and routine aspects of a source's operations. Malfunctions, in contrast, are neither predictable nor routine. Instead, they are, by definition, sudden, infrequent, and not reasonably preventable failures of emissions control, process, or monitoring equipment (40 CFR 63.2)

(Definition of malfunction). The EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards and this reading has been upheld as reasonable by the court in *U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579, 606–610 (2016).

a. 40 CFR 63.362(j) General Duty

We are proposing to add general duty regulatory text at 40 CFR 63.362(j) that reflects the general duty to minimize emissions while not including any reference to periods covered by an SSM exemption. In the absence of the SSM exemption, there is no need to differentiate between normal operations, startup and shutdown, and malfunction events in describing the general duty.

b. Compliance With Standards

We are proposing to revise 40 CFR 63.632 to reflect the court order and correct the CFR to remove any exemptions from compliance during an SSM event. Revisions will clarify and remove any language that is premised on the existence of an exemption and is inappropriate in the absence of the exemption. Thus, we require compliance with standards at all times through additions to the regulatory text at 40 CFR 63.362(j).

c. 40 CFR 63.365 Performance Testing

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.7(e) by adding separate rows for 40 CFR 63.7(e)(1) through (4) and by changing the ''yes'' for 40 CFR 63.7(e)(1) to a ''no.'' Section 63.7(e)(1) describes performance testing requirements. The EPA is instead proposing to modify the performance testing requirements at 40 CFR 63.365(d). The performance testing requirements that we are proposing to modify differ from the General Provisions performance testing provisions in several respects. The regulatory text does not include the language in 40 CFR 63.7(e)(1) that restated the SSM exemption and language that precluded startup and shutdown periods from being considered ''representative'' for purposes of performance testing. The proposed performance testing provisions will exclude periods of startup or shutdown as representative conditions for conducting performance testing. As in 40 CFR 63.7(e)(1), performance tests conducted under this subpart should not be conducted during malfunctions because conditions during malfunctions are often not representative of normal operating conditions. The EPA is proposing to add language that requires the facility to record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Section 63.7(e) requires that the facility make available to the Administrator upon request such records ''as may be necessary to determine the condition of the performance test,'' but does not specifically require the information to be recorded. The regulatory text the EPA is proposing to add to this provision builds on that requirement and makes explicit the requirement to record the information.

d. Monitoring

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.8(c)(1)(iii) by changing the ''yes'' to a ''no.'' The cross-references to the SSM plan requirements in that paragraph are not necessary in light of other requirements of 40 CFR 63.8 that require good air pollution control practices (40 CFR 63.8(c)(1)) and that set out the requirements of a quality control program for monitoring equipment (40 CFR 63.8(d)).

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.8(d) by adding separate rows for 40 CFR 63.8(d)(1) through (3) and changing the ''yes'' to a ''no'' for 40 CFR 63.8(d)(3). The final sentence in 40 CFR 63.8(d)(3) refers to the General Provisions' SSM plan requirement which is no longer applicable. The EPA is proposing to add to the rule at 40 CFR 63.367 text that is identical to 40 CFR 63.8(d)(3) except that the final sentence is replaced with the following sentence: ''The program of corrective action should be included in the plan required under 40 CFR 63.8(d)(2).''

e. 40 CFR 63.367 SSM-Related Recordkeeping

The regulations in 40 CFR 63.10(b)(2)(i) describe the recordkeeping requirements during startup and shutdown. It will continue to be important to know when such startup and shutdown periods begin and end in order to determine compliance with the appropriate standard for normal operations or any separate standard for startup and shutdown. We are proposing to add recordkeeping requirements to 40 CFR 63.367 that require recordkeeping of startup, shutdown events and require reporting related to all exceedances.

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.10(b)(2)(ii) by changing the ''yes'' to a ''no.'' Section 63.10(b)(2)(ii) describes the recordkeeping requirements for malfunction. We are instead proposing to add recordkeeping requirements that require reporting of malfunction events and require reporting related to all exceedances. The EPA is proposing that this requirement apply to all malfunction events requiring that the source record the date, time, cause, and duration of the malfunction and report any failure to meet the standard. The EPA is also proposing to add to 40 CFR 63.367 a requirement that sources keep records that includes the affected source or equipment, whether the failure occurred during a period of startup, shutdown or malfunction, actions taken to minimize emissions, an estimate of the quantity of each regulated pollutant emitted over the standard for which the source failed to meet the standard, and a description of the method used to estimate the emissions. Examples of such methods would include product-loss calculations, mass balance calculations, measurements when available, or engineering judgment based on known process parameters. The EPA is proposing to require that sources keep records of this information to ensure that there is adequate information to allow the EPA to determine the severity of any failure to meet a standard, and to provide data that may document how the source met the general duty to minimize emissions when the source has failed to meet an applicable standard.

f. 40 CFR 63.366 SSM-Related Reporting

When applicable, 40 CFR 63.10(b)(2)(iv)(B) requires sources to record actions taken during SSM events when actions were inconsistent with their SSM plan. The requirement is no longer appropriate because SSM plans will no longer be required. The requirement under 40 CFR 63.10(b)(2)(iv)(B) to record actions to minimize emissions and record corrective actions is now applicable by reference to 40 CFR 63.367(g).

We are proposing to add reporting requirements to 40 CFR 63.366 that would require sources that fail to meet an applicable standard at any time to report the information concerning such events in the compliance report that we are also co-proposing in this action. We are proposing that the report must contain the number, date, time, duration, and the cause of such events (including unknown cause, if applicable), a list of the affected source or equipment, an estimate of the

quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions.

Examples of such methods would include product-loss calculations, mass balance calculations, measurements when available, or engineering judgment based on known process parameters. The EPA is proposing this requirement to ensure that there is adequate information to determine compliance, to allow the EPA to determine the severity of the failure to meet an applicable standard, and to provide data that may document how the source met the general duty to minimize emissions during a failure to meet an applicable standard.

2. Monitoring, Recordkeeping, Reporting and Testing Requirements

a. Monitoring and Testing

Currently, the rule requires that compliance be demonstrated though an initial performance test and continuous parametric monitoring, with additional work practice standards for catalytic oxidizers. We do not believe that this is sufficient to ensure continuous compliance with the emissions limitations. We are proposing to instead require facilities to demonstrate continuous compliance through either an annual compliance demonstration and operating limits or by using EtO CEMS. We solicit comment on this proposed change (Comment C–49).

The rule currently requires facilities to conduct initial performance testing within 180 days of the compliance date for an emission source. We are considering reducing the amount of time allowed between the compliance date and when the initial performance test is required in order to provide more timely assurance to affected communities that emission limits are being met. We solicit comment on what might be a more appropriate timeframe for requiring the initial performance test (Comment C–50).

Due to the increasingly complex nature of control systems, we are also proposing to significantly revise the test methods and procedures requirements (40 CFR 63.365). The revised structure would be laid out as follows:

- Paragraph (b), currently the efficiency at the SCV, would be dedicated to the approved test methods used to determine the mass of EtO entering and exiting a control system or stack,
- Paragraph (c), currently the concentration determination, would provide an alternative method for determining the mass of EtO entering a control system if demonstrating compliance with a removal efficiency standard for a stream that only includes sterilization chamber vents,
- Paragraph (d), currently the efficiency determination at the aeration room vent (not manifolded), would lay out the procedures for determining either the removal efficiency of a control system or the emission rate,
- Paragraph (e), currently the determination of baseline parameters for acid-water scrubbers, would lay out the procedures for establishing the operating limit(s) for parameter monitoring for control devices that are used to comply with an emission limit,
- Paragraph (f) would lay out the procedures for establishing operating limit(s) for a process parameter where a control system is not used to comply with an emission limit, and
- Paragraph (g) would lay out the procedures for demonstrating compliance with EPA Method 204 and establishing an operating limit for PTE.

We are proposing to remove EPA Test Methods 2D, 18, and 25A, as well as California Air Resources Board (CARB) Method 431, from the list of approved methods within the rule. For EPA Method 2D, we are unaware of any facilities currently using Roots type meters to determine flow rate. EPA Methods 18 and 25A, as well as CARB Method 431, are currently required for SCV in the subpart O rule. EPA Method 25A uses a flame ionization detector to count carbon atoms, and EPA Method 18 typically uses flame ionization detector or a photoionization detector (with a column that separates the hydrocarbons to speciate the compounds. CARB Method 431 has a lower detection limit of roughly 0.2 ppmv, and EPA Method 18 also uses techniques that allow detection of EtO concentrations to 0.2 ppmv (or 200 ppbv). Based on our proposed changes to the emissions standard, facilities will likely have to achieve much lower EtO concentration levels from commercial sterilization processes and control systems, and a more robust measurement technology is needed. Some states already require EtO emissions to be reduced to lower levels at 99.9 percent or greater or 0.2 ppmv (Illinois 2019). If the outlet from the control system is, for example 30 ppbv, the current test methods included in subpart O, such as Method 18, may not reliably detect this level of concentration. There are many performance tests in this source category conducted with Method 18, CARB Method 431, and Method 25A that report outlet concentrations as non-detect (and provide the detection level value as the lowest possible concentration detected). With non-detect concentrations at the outlet, facilities may not be able to demonstrate compliance with the removal efficiency standard or the emission rate standards. We solicit comment on the removal of these approved test methods (Comment C–51).

We are also proposing to add EPA Test Methods 1 [54] and 320 [55] to the list of approved methods within the rule. Method 1 would be used for determining the location of sampling ports. EPA Method 320 for Fourier Transform Infrared Spectroscopy (FTIR) uses the absorption of the infrared (IR) spectrum to identify compounds, where each compound produces a unique absorption pattern or spectrum. The sensitivity of this approach is often reliant on the complexity of the emission stream and the presence of potential spectral interferences. For EtO commercial sterilization, the emission streams are not very complex and the primary spectral interferences (*i.e.,* water and carbon dioxide) are minimal. Furthermore, EPA Method 320 using an optically enhanced FTIR is capable of measuring in-stack EtO concentration to approximately 10 ppbv which is consistent with the proposal emission standards. We solicit comment on the addition of these test methods as well as solicit comment on other techniques or methods with detection levels in the range of EPA Method 320 (Comment C–52).

Currently, the performance test that is required to be conducted to determine the control efficiency for the SCV is conducted on a single chamber that contains no product, and it is only conducted on the first evacuation of the sterilization chamber. In addition, facilities are required to perform three 1-hour test runs. In assessing the performance testing procedures for the source category, the EPA followed the *Clean Air Act National Stack Testing Guidance* issued in 2009. The intent of the 2009 stack testing guidance was to improve uniformity on how stack tests are conducted to demonstrate compliance for NESHAP (40 CFR parts 61 and 63) programs (and also New Source Performance Standards in 40 CFR part 60).[56] In the *Stack Testing*

[54] See Sample/Velocity Traverses, available at *https://www.epa.gov/emc/method-1-samplevelocity-traverses.*

[55] Measurement of Vapor Phase Organic and Inorganic Emissions by Extractive Fourier Transform Infrared Spectroscopy.

[56] The 2009 *Clean Air Act National Stack Testing Guidance* document, available at *https://www.epa.gov/sites/default/files/2013-09/*

Continued

Guidance document, the EPA recommends that performance tests be performed under representative (normal) conditions that:

—represent the range of combined process and control measure conditions under which the facility expects to operate (regardless of the frequency of the conditions); and

—are likely to most challenge the emissions control measures of the facility with regard to meeting the applicable emission standards, but without creating an unsafe condition. (EPA 2009)

Concerns with the current testing procedures in subpart O include that testing is conducted on a single sterilizer chamber while no product is present, and testing is conducted for the first evacuation only, neither of which may be representative of actual nor normal operations. Each sterilization cycle is conducted on product and packaging in the sterilizer chamber, with a set charge of EtO and a defined number of nitrogen and air washes. To incorporate the 2009 stack testing guidance, the performance testing should be conducted during normal sterilizer chamber conditions. This change to the performance testing procedure would provide an emission reduction percentage from the performance test that more closely reflects the emission reduction achieved during normal operation. To address both the maximum capacity and the low emissions loading criteria in the 2009 *Stack Testing Guidance,* the full series of nitrogen and air washes of the sterilization cycle could be included in the performance test period. For the first nitrogen wash, the maximum capacity of the EtO concentration would be addressed, and with each additional nitrogen wash and air wash of the sterilization cycle, the EtO concentration inlet to the control system will decline and further challenge the emission removal efficiency of the control system. Because multiple emission sources may be vented to the APCD at one time, the performance testing procedure should also include the normal, simultaneous routing of emissions sources to an APCD typically seen during operation.

The EPA has determined that the current performance testing procedures in subpart O do not reflect normal operations as discussed in the 2009 *Stack Testing Guidance.* A more encompassing performance test procedure for SCVs that includes normal operation of the sterilizer chamber with product present, covers all evacuations, *i.e.,* all venting and washes, and also includes the number of sterilizer chambers (or other emission sources) that typically vent simultaneously would provide a more representative control level actually achieved by the control system. A longer test run period would provide a better indication of the emission reduction achieved by the APCD over time with multiple normal processes routing to the device. For CEV and ARV emission sources, a longer test run period would provide the time-averaged emission reduction achieved by the APCD with multiple, normally operating processes routing to the device.

The EPA is proposing a 24-hour test run across all emission source types, SCV, CEV, ARV, and room air for facilities where EtO use is at least 10 tpy. We are proposing that the performance testing be conducted under normal operating conditions and each test run be conducted for 24 hours. For facilities where EtO use is less than 10 tpy, the EPA is proposing that each test run within the test may instead be conducted for a 1-hour period.

When determining the volumetric flow rate during performance testing, we currently require that ''the flowrate must be constant during time (t).'' We are unsure of whether this is feasible or necessary, and we request comment on whether this language should be modified and, if so, how (Comment C–53).

In addition, we believe that the current language surrounding standard volume is unclear, and we are proposing to revise our description of standard volume to read as follows: ''24.05 liters per gram-mole (L/g-mole) at 20 °C and 101.325 kilopascals (kPa) (385.1 standard cubic feet (scf) per pound-mole (scf/lb-mole) at 68 °F and 1 atmosphere). We solicit comment on our proposed revisions to language regarding standard volume (Comment C–54).

The APCD and process parameters that are selected for monitoring should be key indicators that confirm the control system or process is operating properly and that the emission limit(s) is being met. The operating limits that are set for these parameters are important as they help to ensure that conditions are similar to those that occurred during the most recent compliance demonstration with the emissions standards. Monitoring these APCD and process parameters ensures that ongoing operations are within the range of values that occurred during the compliance demonstration. Maintaining the APCD and process parameters within the operating limits established during the performance test helps ensure the emission standard is being met. Note that APCD and process operating parameters need to be collected during each periodic performance test and perhaps revised because of the performance test. Moreover, when substantial process changes occur or control devices change, performance testing along with concurrent parameter data collection must occur, and the operating limit for the parameter be adjusted or reaffirmed, as required.

During the initial and annual performance testing, the operating limits for APCD and process parameters are determined. For the most part, the APCD parameters required in the EtO Commercial Sterilization NESHAP are appropriate and will continue to be monitored, however more explicit procedures for establishing the operating limits are needed in the rule. The current procedure for determining operating limits typically includes measuring and recording the parameter value every 15 minutes over three test runs and calculating the average parameter value for each test run. The average value from the test runs will be the minimum or maximum operating limit, depending on the parameter, for the APCD.

We are proposing several changes to how operating limits are established during and monitored between compliance demonstrations. The parameters selected for ongoing monitoring of control devices are generally related to the key operating principles for the type of control device.

For acid-water scrubbers, the current operating limits that are allowed in the rule include the maximum ethylene glycol (EG) concentration in the scrubber liquor and the maximum height of scrubber liquor in the recirculation tank(s). We are not proposing any changes to how the maximum EG concentration is established. We are, however, proposing to add requirements regarding how the maximum scrubber liquor tank level is established. Currently, the rule states that ''For determining the scrubber liquor tank level, the sterilization facility shall establish the maximum liquor tank level based on a single measurement of the liquor tank level during one test run.'' We believe that a single measurement at an unspecified time during the performance test will

documents/stacktesting1.pdf, addresses the timeframe for conducting stack tests (*i.e.,* granting an extension), stack test waivers, stack notifications to the delegated agency, observation of stack tests by the delegated agency, representative testing conditions, stopping a stack test once started, postponement of a stack test, and information to include in the test report.

not provide a representative operating limit that would ensure compliance with the emission limit between performance tests. We are proposing to instead require facilities that chose to establish a maximum scrubber liquor tank level(s) as their operating limit for acid-water scrubbers to monitor and record the maximum scrubber liquor tank level once during each of the three test runs. We would further require them to use the data collected during the most recent performance test to calculate the average scrubber liquor tank level measured during the performance test. This scrubber liquor tank level would be the maximum operating limit for the scrubber liquor tank. This procedure would be conducted for every scrubber liquor tank that is included in the performance test. We are soliciting comment on these proposed changes to how the maximum scrubber liquor tank level is established (Comment C–55).

We are also proposing to allow facilities with acid-water scrubbers to establish a maximum scrubber liquor pH as an alternative to a maximum EG concentration or scrubber liquor tank level. The pH of the scrubber liquor is a good indicator of performance and has been implemented in other rules that we have promulgated (*e.g.,* the New Source Performance Standards for Commercial and Industrial Solid Waste Incineration Units at 40 CFR part 60, subpart CCCC). In addition, based on responses to our data collection efforts, at least 12 facilities are already monitoring this parameter in addition to what we currently require. This limit would be established in a similar manner to our proposed changes for establishing the scrubber liquor tank level in that facilities would be required to monitor and record the scrubber liquor pH at least once every 15 minutes during each of the three test runs. They would then use the data collected during the most recent performance test to calculate the average scrubber liquor pH measured during the performance test. This scrubber liquor pH would be the maximum operating limit for the acid-water scrubber, and these procedures would be conducted for every acid-water scrubber that is included in the performance test. We would also require that the instrumentation used for monitoring the scrubber liquor pH meet the following requirements.

- The pH sensor must be installed in a position that provides a representative measurement of scrubber liquor pH;
- The facility must ensure the sample is properly mixed and representative of the fluid to be measured;
- A performance evaluation of the pH monitoring system must be conducted in accordance with the facility's monitoring plan at least once each process operating day; and
- The facility must conduct a performance evaluation (including a two-point calibration with one of the two buffer solutions having a pH within 1 of the pH of the operating limit) of the pH monitoring system in accordance with the facility's monitoring plan at the time of each performance test but no less frequently than quarterly.

We solicit comment on allowing facilities with acid-water scrubbers to establish a maximum scrubber liquor pH and our proposed requirements for instrumentation and establishing the operating limit (Comment C–56).

In 1994, we promulgated requirements for facilities to establish a minimum operating temperature for their catalytic or thermal oxidation units during the performance test if they were used to comply with an emission limitation. In 2001, this requirement was removed, and the operating limit consisted of the manufacturer's recommended minimum operating temperature. This change was made under the old testing paradigm of the rule where, for SCVs, the performance test was only conducted for one empty chamber during one phase of the cycle (evacuation). Control systems are much more complex, with multiple sterilizer chambers at different phases exhausting to the same control system simultaneously, often with other emission source types. Therefore, establishing a minimum operating temperature during the performance test is appropriate. Temperature as the operating parameter for thermal oxidizers will be maintained in the rule. We are proposing that the current use of manufacturer recommended minimum oxidation temperatures for catalytic and thermal oxidizers be replaced with site-specific temperatures determined during the performance test.

For thermal oxidizers, we are proposing that facilities would measure and record the temperature every 15 minutes over three test runs, calculate the average temperature for each test run, and the average of the three test runs would be calculated and would be the minimum operating limit. For catalytic oxidizers, the average of the three test runs would be calculated for both the inlet temperature to the catalyst bed and the temperature difference across the catalyst bed, where these values would be the minimum operating limits. For temperature measurement, we are proposing that the facility install, calibrate, operate, and maintain a temperature monitor with a minimum accuracy of ±1 percent over the normal range of the temperature measured, expressed in degrees Celsius, or 2.8 degrees Celsius, whichever is greater. We are also proposing that the accuracy of the temperature monitor be verified twice each calendar year with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested. As an alternative, the accuracy of the temperature monitor may be verified in a calibrated oven (traceable to NIST standards). We are soliciting comment on the changes to establishing the operating limits for temperature and verifying the instrument two times per year (Comment C–57).

Gas-solid reactors (*i.e.,* dry bed scrubbers) are now commonly used at commercial sterilization facilities. We are aware of certain operating parameters for this type of control device, including pressure drop and temperature across the dry bed packing. However, we believe that these are not viable parameters to monitor as indicators of EtO removal because neither indicate that the reaction is occurring on the media bed nor the remaining activity of the dry bed media, and that the only way to ensure continuous compliance is using an EtO CEMS. Therefore, we are proposing that, for control systems where a gas-solid reactor is present, facilities must demonstrate continuous compliance with the appropriate emission rate standard using an EtO CEMS. We solicit comment on (1) The viability of pressure drop and temperature across the solid packing for parametric monitoring as indicators of EtO removal or EtO concentration level, along with data demonstrating the viability for continuous compliance purposes, (2) other parameters for which an operating limit could be established, along with data demonstrating the viability of such parameters for continuous compliance purposes, and (3) requiring the use of an EtO CEMS for control systems where a gas-solid reactor is present (Comment C–58).

It is possible to demonstrate compliance with an emission rate standard without the use of a control system. However, operating limits must still be established and monitored to confirm that operation of the process stays within the range(s) established

during the most recent compliance demonstration. Typical process parameters for EtO commercial sterilization could include the mass of EtO charged to the sterilizer chamber cycle and the EtO concentration of the room or vent. We are proposing that if any portion of the SCV(s) at a facility is neither routed to a control system nor monitored using an EtO CEMS, the facility must establish as an operating limit and monitor the maximum daily amount of EtO charged to the sterilization chamber(s). We are also proposing that if the ARV(s), Group 1 room air emissions, or Group 2 room air emissions at a facility are subject to an emissions limitation and if the emissions are neither routed to a control system nor monitored using an EtO CEMS, the facility must establish as an operating limit the maximum EtO concentration for each aeration room and area where there are Group 1 or Group 2 room air emissions, as applicable. We are further proposing that the facility monitor and record every 15 minutes the EtO concentration within each of these areas and compute three-hour rolling averages that must be maintained below the appropriate operating limits. We are also proposing that an affected facility must develop a site-specific monitoring plan for the operation of the measurement systems used to monitor room air EtO concentration, and we are also proposing a set of requirements for these monitoring plans in 40 CFR 63.364(c)(5) of the proposed rule. We are soliciting comment on these proposed changes for process parameter monitoring when no control system or EtO CEMS is present (Comment C–59).

For facilities where a PTE is required (as discussed in sections III.B.8 and III.D.1 of this preamble), we are proposing to give facilities the option to either establish a minimum volumetric flow rate through the exhaust duct(s) or stack(s) or install, operate, calibrate, and maintain a continuous pressure differential monitoring system to verify the presence of PTE. If a facility chooses to use a continuous differential pressure monitoring system, a monitor must be installed within each room that is included in the PTE, and the pressure differential must be maintained above 0.007 inches of water. Regardless of whether a facility chooses to establish a minimum volumetric flow rate(s) or monitor pressure differential, we are also proposing that facilities continuously verify the direction of air flow through daily inspections of each natural draft opening (NDO), which may be done through a smoke test or using streamers. We are soliciting comment on the continuous compliance requirements for facilities implementing a PTE (Comment C–60).

b. EtO CEMS

The use of CEMS is an option in the current rule for the measurement of EtO from the exhaust of catalytic or thermal oxidation controls for the purpose of parametric monitoring of those control options. The current rule includes two options for CEMS, one reliant on gas chromatography (GC) systems for the direct measurements of EtO (Performance Specification 9 of 40 CFR part 60, appendix B) and another which uses an appropriate detector to determine a surrogate, volatile organic compound value as EtO (Performance Specification 8 of 40 CFR part 60, appendix B). The current rule requires these systems to be capable of measuring and recording once per hour and that the facility record a 24-hour average of the EtO measurements. These recordkeeping requirements are unique to subpart O but are inconsistent with the requirements in the general provisions 40 CFR 63.8(c)(4)(ii) which require systems to be capable of measuring once each 15-minutes. While the current requirements in the rule may be appropriate for parametric monitoring, the use of speciated EtO CEMS for compliance purposes is warranted and therefore we are proposing (1) to remove Performance Specification 8 as an option for continuous monitoring because it is not selective to EtO and (2) that systems be capable of completing a collection, transport, and analysis cycle at least once each 15-minutes to be consistent with the General Provisions. Note that source facilities may choose to time-share their CEMS among different measuring points, provided that the measurement points are approximately equidistant from the CEMS, the sampling time at each measurement point is at least 3 times as long as the response time for that point, and that each measurement point has at least one complete cycle within 15 minutes. Of course, we propose that a complete description of the time-shared CEMS must be provided in the facility's monitoring plan. As an example, consider an EtO CEMS with a response time of 60 seconds and a cycling time of 75 seconds. Could it be used for time-sharing purposes, and if so, how many points could be sampled? Three times the response time would be 180 seconds, which when added to twice the response time (from the CEMS to the measurement point and back), or 120 seconds, would be 300 seconds, so the EtO CEMS could be used. Fifteen minutes divided by 300 seconds would yield three measurement points, so a facility could sample from up to three points for this case. Note that daily calibration checks would need to be provided for each measurement point and that a facility may choose to provide fewer than the maximum number of measurement points on an EtO CEMS in order to have more data from which to calculate an hourly average. Also, a fewer number of measurement points per EtO CEMS could mean fewer numbers of excess emissions, for should the CEMS malfunction or become out-of-control, each shared measurement point would also be subject to a malfunction or would be out-of-control until corrections were made. We are soliciting comment on the removal of PS 8, the requirement to monitor every 15 minutes, and allowing time-share use of an EtO CEMS (Comment C–61). The techniques for measuring EtO in stationary sources have significantly improved since the risk and technology review (71 FR 17712, April 7, 2006), and to account for these changes the EPA is proposing a new set of standards for the operation of these measurement techniques as CEMS. EPA is aware of at least two optical based technologies (*e.g.,* FTIR and Cavity Ringdown Spectroscopy) being applied to continuous measurements of EtO in commercial sterilizer sector. In order to provide a pathway for these technology in the rule, EPA is also proposing a new Performance Specification (PS) 19 in 40 CFR part 60, appendix B, to allow for the use of these and other EtO CEMS sampling and analytical technologies as long as the required performance criteria set out in the performance specification are met. Initial minimum requirements for instruments are contained in the PS, while ongoing quality assurance (QA) and quality control procedures are found in QA Procedures. To that end, we are also proposing QA Procedure 7 in 40 CFR part 60, appendix F, to establish consistent requirements for ensuring and assessing the quality of data measured by a EtO CEMS on an ongoing basis. These requirements will ensure that the EtO CEMS have the ability to make appropriate measurements and continue to make these measurements appropriately, as well as to demonstrate compliance with the emission limits. These proposed procedures are based on techniques found in the recently promulgated Performance Specification 18 (PS–18) in CFR part 60, appendix B, and QA Procedure 6 in CFR part 60,

appendix F, relying on a performance-based approach used for HCl CEMS in PS–18 and on adherence to the continual QA Procedure for their operation. However, the PS and QA Procedures proposed in this rule contain criteria specifically devised for operation at EtO commercial sterilizers. We believe performance-based techniques, along with their associated QA procedures, offer a viable path for introducing and using new measurement approaches quickly. We solicit comment on the use of performance-based approaches and on the proposed PS and QA Procedures (Comment C–62). In addition, we are proposing that CEMS data be reported daily so that results can be shared with the public on a daily basis. We are soliciting comment on the frequency of CEMS data reporting, as well as the period that the reported CEMS data are to be shared with the public (Comment C–63).

This proposed PS–19 and associated QA procedures represent a significant adjustment in how the Agency uses CEMS for organic HAPS, specifically the application of CEMS for sub ppmv-level measurements. With these levels of measurements, there is a need to be more prescriptive as to the data quality objectives in the PS, specifically as to how the systems are initially certified and continually quality assured. For those reasons we are proposing to remove PS–9 as an option for continuous monitoring from the rule because (1) The data quality objectives of this PS are not equivalent with what is found in proposed PS–19 and (2) the underlying technology in PS–9 (GC) would fit within the performance-based structure in proposed PS–19. We solicit comment on the removal of PS–9 as an option from the rule for continuous monitoring and on whether there were any concerns that a GC based system could meet the requirements of proposed PS–19 (Comment C–64). Also, we are aware there are currently EtO CEMS in place that use FTIR technology at commercial sterilizers that have been successfully certified according to Performance Specification 15 (PS–15) of 40 CFR part 60, appendix B as part of existing state rules, and therefore we have considered its use in the proposed rule. However, we consider the proposed PS–19 is more appropriate for low-level standards and the underlying technology fits within the performance-based structure in proposed PS–19. We are soliciting comment on whether PS–15 should be an option from the rule for continuous monitoring, and if so, how could the lower-level measurements be addressed (Comment C–65).

In addition, if a facility chooses to demonstrate continuous compliance with an emission rate standard using an EtO CEMS, we are proposing that the facility may comply with the applicable emission rate standard on a 30-day rolling average basis, where each valid hourly average is determined from the EtO CEMS; the sum of those valid hourly averages is determined for each day; and the 30-day rolling average is determined from the sum of that day's average plus the previous 29 daily averages divided by 30. We are soliciting comment on allowing facilities to comply with a 30-day rolling average emission rate if an EtO CEMS is used to demonstrate continuous compliance, as well as the 30-day rolling average calculation procedure (Comment C–66).

In the absence of NIST traceable reference gases for EtO and in an effort to improve the accuracy and reliability of continuous measurements, both for performance testing and CEMS application, in PS–19 we are also proposing to include an appendix B for the preparation of certification of EtO Cylinder Gas Standards consistent with the procedures used in Broadly Applicable Approved Alternative Methods (Alt) 114 [57] for HCl standards and Alt 118 [58] for mercury standards. We are soliciting comment on PS–19 appendix B for preparation of gas standards (Comment C–52). Finally, we are soliciting comment on whether certain facilities or groups of facilities should be required to use CEMS to comply (Comment C–67).

c. Fenceline Monitoring

The EPA has previously employed fenceline monitoring (for benzene as a surrogate for HAP emissions from fugitive sources) as part of a work practice standard for petroleum refineries, promulgated as part of the technology review for the source category (40 CFR part 63, subpart CC), to monitor and manage fugitive emissions as well as aiding in the monitoring of the sector's ground-level emission points (*e.g.,* storage tanks, wastewater collection systems, equipment leaks, etc.). This type of monitoring is performed at multiple points located at the edge of a facility's property line, commonly known as the ''fenceline,'' and the results of this monitoring are used to calculate a long-term average (*e.g.,* annual rolling average) of a pollutant concentration at the boundary. If this long-term average exceeds an ''action-level,'' then a facility is required to conduct the associated work practices (*i.e.,* root cause and corrective action) to identify and mitigate the source of the excess emissions. The ''action-level'' was set at a level reflecting full compliance with the emissions standards for the emission points described above and at a concentration in which there was a robust measurement method (*i.e.,* EPA Method 325B) for measuring benzene at and well below the action-level. This level was based on the highest modeled impact from the refinery sector at the fenceline using the emission inventories and dispersion modeling.

EPA gave close consideration to the feasibility and utility of adopting a similar fenceline monitoring requirement as part of this proposed rule, in response to a substantial number of comments from front-line communities supporting the use of fenceline measurements to address potential room air emissions from Commercial Sterilization Facilities. EPA notes that room air release points from this source category differ from fugitive emission at refineries in important respects. First, the boundaries for a commercial sterilization facility are often the building itself or very small easements, making boundary line measurements problematic because these locations are unlikely to be representative of emissions from the release points. Typically for this type of monitoring, we require the fenceline monitor to be at least 50 meters from the source of emissions to the property boundary [59] to allow for some dispersion. Second, in contrast to the large number of dispersed and difficult-to-monitor emission points at a refinery, current room air releases at commercial sterilization facilities are typically at ground-level and consist of uncontrolled building emissions through doorways, loading points, and ventilation exhausts, all of which can be captured while inside the building and routed through a vent to a control device. Moreover, the proposed PTE design criteria, proposed room air emission standards, and associated parametric monitoring discussed in section III.B.8 will effectively and continuously ensure these previously uncontrolled emissions are captured and routed to exhaust points that are subject to removal or emission rate standards. As a result, EPA does not believe that a fenceline monitor would

[57] See *https://www.epa.gov/sites/default/files/2020-08/documents/alt114.pdf.*

[58] See *https://www.epa.gov/sites/default/files/2020-08/documents/alt118.pdf.*

[59] EPA Method 325A, section 8.2.1.1.

measure a significant quantity of residual EtO emissions, or identify a compliance issue that has not already been detected through the continuous monitoring requirements included in this proposal.

Given the feasibility to capture room air emissions from this sector through the requirements to install PTEs and continuous parametric monitoring of these capture systems, as well as control systems being proposed, we consider fenceline monitoring and the associated work practice requirements to be unnecessary. In addition, as described above, we believe fenceline monitoring could be technically challenging to implement for this source category given the physical configurations of these facilities. We solicit comment on (1) Whether fenceline monitoring should be required regardless of the proposed PTE design criteria, proposed room air emission standards, and continuous parametric monitoring; (2) the technical feasibility of fenceline monitoring and available technology able to measure at any potential action level; and (3) the potential cost of continuous fenceline monitoring and associated work practices if implemented (Comment C–68).

The EPA is also considering the application of beyond the fenceline measurements (*i.e.,* ambient monitoring) as part of a work practice standard where the proposed standards in this action are in such format, or as an additional measure to assure additional compliance assurance where the proposed standards are numeric. The EPA is interested in and is therefore soliciting comment on how ambient monitoring could be used to screen for elevated concentrations of ethylene oxide above the ambient baseline and how this information could be used to trigger a root cause analysis to identify potential source(s) of emission and to perform corrective action, if a potential source of the emissions was part of an affected source under this commercial sterilization proposed rule. We also solicit comment on (1) The feasibility of other types of air monitoring that could be applied to this sector for compliance assurance and the costs associated with this type of monitoring, (2) how frequently this monitoring should occur, (3) the recordkeeping and reporting requirements for this type of monitoring, and (4) how should any action-level be defined (Comment C–69).

d. Initial Summary Report

We are proposing that facilities record and report the following information in the initial summary report to aid us in determining compliance with the proposed requirements:

- EtO use and operating hours of the facility over the previous 12 months

If a sterilization facility is demonstrating continuous compliance through periodic performance testing, the EPA is proposing that the following information be included in the initial summary report:

- Control system identification (ID); [60]
- Control device ID;
- Control device type; and
- Recirculation tank ID if an acid-water scrubber is used to meet the emission limitation and if an election is made to comply with the maximum scrubber liquor height limit.

The EPA is proposing that the following information be included in the initial summary report for each sterilization chamber at the facility:

- The sterilization chamber ID;
- The ID of the control system that the SCV was routed to, if applicable;
- The portion of SCV exhaust that was routed to the control system, if applicable;
- The ID of the control system that the CEV was routed to, if applicable; and
- The portion of CEV exhaust that was routed to the control system, if applicable.

If emissions from any room in the facility are subject to an emission limitation (*e.g.,* aeration room or rooms where Group 1 or Group 2 room air emissions are present), the EPA is proposing that the following information be included in the initial summary report for each room where there are EtO emissions:

- Room ID;
- The ID of the control system that the room air was routed to, if applicable;
- The portion of room air that was routed to the control system, if applicable; and
- Documentation of emissions occurring within the room, including aeration, EtO storage, EtO dispensing, vacuum pump operation, pre-aeration handling of sterilized material, and post-aeration handling of sterilized material.

If any portion of the facility is required to be operated with PTE, the EPA is proposing that for each NDO inspection, facilities must report the same information that we are proposing to require as part of semi-annual summary reports, as discussed later in this section. If a facility is complying with the requirement to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017, we are proposing that the facility must provide the approach that was used for each unique cycle.

We are soliciting comment on the content required for the initial summary report (Comment C–70).

e. Semi-Annual Summary Reports

For subsequent semi-annual summary reports, we are proposing that facilities record and report the following information:

- EtO use and operating hours of the facility over the previous 12 months;
- If the facility is demonstrating continuous compliance through periodic performance testing, any changes to the corresponding information provided in the previous summary report
- Any changes related to the sterilization chambers;
- If emissions from any room in the facility are subject to an emission limitation, any changes related to the individual rooms;
- If any portion of the facility is required to be operated with PTE, the EPA is proposing that for each NDO inspection, facilities must report the inspection ID, the room ID, the NDO ID, the date and time that the inspection started, the duration of the inspection, the method of inspection (smoke test or streamers), and the direction of air flow through the NDO (into the facility or out of the facility); and
- If a facility is complying with the requirement to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017, we are proposing that the facility must provide the approach that was used for each unique cycle.

We are soliciting comment on the content required for the subsequent semi-annual summary reports (Comment C–71).

f. Quarterly Summary Reports

We are proposing different reporting requirements for facilities where EtO use is less than 20 tpy. Specifically, we are proposing that these facilities submit summary reports on a quarterly basis and include in these reports the following additional information for each room whether there is the potential for EtO emissions:

- Number of RACs per hour;
- Average hourly temperature; and

[60] IDs that are referenced in all reports would be generated by the owner or operator of the facility.

• Average hourly EtO concentration.

We are also proposing that these facilities may instead submit summary reports once every three years if they meet the following requirements:

• Operate all areas of the facility that contain Group 2 room air emissions with PTE, with all exhaust gas streams being captured and routed to a control system or through a stack(s),

• Limit Group 2 room air emissions of EtO to 2.8E–3 lb/hr (facilities where EtO use is less than 20 tpy), and

• Meet the requirements of 40 CFR 63.363.

These emission rates are the most stringent limits for which all facilities within these groups can demonstrate compliance using currently available technology. We solicit comment on different requirements for these facilities (Comment C–72).

g. Electronic Reporting

The EPA is proposing that owners and operators of commercial sterilization facilities submit electronic copies of required compliance reports, performance test reports, and performance evaluation reports through the EPA's Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI). A description of the electronic data submission process is provided in the memorandum *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules,* available in the docket for this action. Following a processing period in CEDRI, each report will be sent to the EPA's Web Factor and Information Retrieval (WebFIRE) database, where it is publicly accessible. The standard processing period is 60 days for performance test reports and performance evaluation reports and 30 days for all other report submissions. Agency reviewers may extend the processing period for individual reports by up to 60 days for performance test reports and performance evaluation reports and up to 30 days for all other report submissions. The proposed rule requires that performance test results collected using test methods that are supported by the EPA's Electronic Reporting Tool (ERT) as listed on the ERT website [61] at the time of the test are submitted in the format generated through the use of the ERT or an electronic file consistent with the extensible markup language (XML) schema on the ERT website, and other performance test results be submitted in portable document format (PDF) using the attachment module of the ERT. Similarly, performance evaluation results of continuous emissions monitoring systems (CEMS) measuring relative accuracy test audit (RATA) pollutants that are supported by the ERT at the time of the test must be submitted in the format generated through the use of the ERT or an electronic file consistent with the XML schema on the ERT website, and other performance evaluation results be submitted in PDF using the attachment module of the ERT. The proposed rule requires that Notification of Compliance Status (NOCS) reports be submitted as a PDF upload in CEDRI. For compliance reports, both initial and ongoing, the proposed rule requires that facilities use the appropriate spreadsheet template to submit information to CEDRI. A draft version of the proposed template for these reports is included in the docket for this rulemaking.[62] The EPA specifically requests comment on the content, layout, and overall design of the template.

While the ERT does not directly support submittal for EPA Reference Method 320 or ASTM D6384–12e1, a facility may complete the WebFIRE template with the performance test data and submit to the ERT as an attachment, along with a PDF version of the full performance test report. The WebFIRE template is included in the docket for this action. The EPA specifically requests comment on the content, layout, and overall design of the template(s) for use with EPA Method 320 and ASTM D6348–12e1 (Comment C–73).

Additionally, the EPA has identified two broad circumstances in which electronic reporting extensions may be provided. These circumstances are (1) Outages of the EPA's CDX or CEDRI that preclude an owner or operator from accessing the system and submitting required reports and (2) *force majeure* events, which are defined as events that will be or have been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevent an owner or operator from complying with the requirement to submit a report electronically. Examples of *force majeure* events are acts of nature, acts of war or terrorism, or equipment failure or safety hazards beyond the control of the facility. The EPA is providing these potential extensions to protect owners and operators from noncompliance in cases where they cannot successfully submit a report by the reporting deadline for reasons outside of their control. In both circumstances, the decision to accept the claim of needing additional time to report is within the discretion of the Administrator, and reporting should occur as soon as possible.

The electronic submittal of the reports addressed in this proposed rulemaking will increase the usefulness of the data contained in those reports, is in keeping with current trends in data availability and transparency, will further assist in the protection of public health and the environment, will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements and by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance, and will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public. Moreover, electronic reporting is consistent with the EPA's plan [63] to implement Executive Order 13563 and is in keeping with the EPA's Agency-wide policy [64] developed in response to the White House's Digital Government Strategy.[65] For more information on the benefits of electronic reporting, see the memorandum *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules,* referenced earlier in this section.

3. Other Changes

a. Single-Item Sterilizers

The EPA has identified nine commercial sterilization facilities that use single-item sterilizer processes, where all of these facilities have APCDs

[61] See *https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert.*

[62] See *EtO Compliance Report Draft Template.xlsx,* available at Docket ID. No. EPA–HQ–OAR–2019–0178.

[63] The EPA's Final Plan for Periodic Retrospective Reviews, August 2011. Available at: *https://www.regulations.gov/document?D=EPA-HQ-OA-2011-0156-0154.*

[64] E-Reporting Policy Statement for EPA Regulations, September 2013. Available at: *https://www.epa.gov/sites/production/files/2016-03/documents/epa-ereporting-policy-statement-2013-09-30.pdf.*

[65] Digital Government: Building a 21st Century Platform to Better Serve the American People, May 2012. Available at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/egov/digital-government/digital-government.html.*

in place to reduce EtO emissions. While a traditional sterilization chamber tends to be a larger vessel that accommodates pallets containing diverse products, a single-item sterilizer is generally smaller and may use much less EtO to sterilize products. In the single-item sterilization process, operators place the product into a plastic pouch, a slight vacuum is applied, and EtO gas is injected into the pouch and sealed. Sealed pouches with product and EtO are placed in bins and then loaded into a cabinet or chamber under specific temperature and humidity conditions where EtO both sterilizes the product and off-gasses or aerates from the pouch. The EtO slowly dissipates from the pouch or bag by diffusion. Once the pouch and product are removed from the cabinet or chamber, the product is held in the shipping/warehouse area before being sent offsite. EtO is stored in a pressurized cylinder at single-item sterilization facilities, and these cylinders are smaller than EtO storage drums used at traditional sterilization facilities. Some single-item sterilizers may use EtO ampules, and place the ampule in the pouch, seal the pouch, then break the ampule prior to placement in the cabinet or chamber.

In this proposal, the EPA is clarifying that the cabinet or chambers where sterilization and aeration occur at single-item sterilizer facilities are subject to the SCV emission standards under subpart O. The process activities, including the dwell period to expose the product to EtO and ensure sterile product, as well as aeration of the product to remove residual EtO, occur at single-item sterilization facilities in the same way as at other EtO commercial sterilization facilities. The cabinet or chamber includes air flow that is routed to a vent to an APCD or to the atmosphere. There is no technical or process difference between single-item sterilization and those at other traditional sterilizer chamber and aeration room operations that impact adopting measures to reduce EtO emissions. The cabinet or chamber where pouches are placed should be referred to as combination sterilizer chambers, *i.e.,* where both sterilization and aeration occur in the same chamber. EtO usage at single-item sterilizer facilities range from 0.43 to 2.5 tpy. There are five single-item sterilizer facilities where EtO use is at least 1 tpy but less than 10 tpy, and these facilities are subject to the SCV emission standard for sources using 1 to 10 tons of EtO per year. There are four facilities that are using less than 1 ton, and these facilities are subject to the SCV emission standard for sources using less than 1 ton. These sources were included in the ample margin of safety analysis for SCV at sources using 1 to 10 tons (see section III.D.3) and for the proposed SCV standards at facilities using less than 1 ton (see section III.B.1). In addition, the facilities would be subject to the proposed emission standards for Group 1 room air emissions, specifically for EtO injection room air emissions, and for Group 2 room air emissions (for shipping/warehouse rooms).

b. Title V

Section 502(a) of the Clean Air Act establishes the list of sources required to obtain operating permits under title V. This list of sources includes ''any other source (including an area source) subject to standards or regulations under section 111 or 112 [NESHAP].'' See 40 CFR 70.3(a) and 71.3(a). Section 502(a) provides that, ''The Administrator may, in the Administrator's discretion and consistent with the applicable provisions of this Act, promulgate regulations to exempt one or more source categories (in whole or in part) from the requirements of this subsection if the Administrator finds that compliance with such requirements is impracticable, infeasible, or unnecessarily burdensome on such categories, except that the Administrator may not exempt any major source from such requirements.'' Pursuant to this authority, the EPA published a final rule on December 19, 2005 (70 FR 57320), that exempted area source EtO commercial sterilizers from title V permitting.

In the December 2005 final rule, the EPA articulated a four-factor balancing test to evaluate whether title V permitting requirements would be ''unnecessarily burdensome'' for an area source category. The four factors evaluated by the EPA were: (1) Whether title V would result in significant improvements to the compliance requirements, including monitoring, recordkeeping, and reporting that are proposed for the area source category; (2) whether title V permitting would impose significant burdens on the area source category and whether the burdens would be aggravated by any difficulty in obtaining assistance from permitting authorities; (3) whether the costs of title V permitting for area sources would be justified taking into consideration any potential gains in compliance likely to occur for such sources; and (4) whether adequate oversight by state and local permitting authorities could achieve high compliance with the NESHAP requirements without relying on title V permitting. In addition, the EPA stated that ''. . . the legislative history of Section 502(a) suggests that EPA should not grant exemptions where doing so would adversely affect public health, welfare, or the environment. See Chafee-Baucus Statement of Senate Managers, Environment and Natural Resources Policy Division 1990 CAA Leg. Hist. 905, Compiled November 1993 (in that '[t]he Act requires EPA to protect the public health, welfare and the environment, . . . this provision of the permits title prevents EPA from exempting sources or source categories from the requirements of the permit program if such exemptions would adversely affect public health, welfare, or the environment')."

At the time of the December 2005 final rule, the EPA's analyses of the four-factor balancing test and consideration of the legislative history of section 502(a) weighed in favor of exempting area source EtO commercial sterilizers from title V permitting. Since that time, the EPA has gained a better understanding of the risks associated with EtO emissions. In 2016, the EPA released its updated IRIS value for EtO, which indicated that cancer risks from EtO emissions were significantly higher than characterized in the prior 1985 assessment. Subsequently, the 2014 National Air Toxics Assessment released in August 2018 identified EtO emissions as an important risk driver in several areas across the country. Following this, the EPA has engaged in assessments of community census tracts that potentially have elevated cancer risks from exposure to EtO in ambient air. Related to these risk findings, there has been significant public interest in the Commercial Sterilization Facilities source category, including robust participation in public hearings and public comment on permitting actions.

In addition to an improved understanding of the risks and ambient concentrations of EtO, the EPA has more information available to support this proposal's evaluation than was available during the 2005 rulemaking. The EPA conducted its December 2019 questionnaire and September 2021 ICR (OMB Control No. 2060–0733) as part of this rulemaking, which included gathering data from area source EtO sterilizers related to EtO usage and emissions, parent company ownership, and revenue generation related to sterilization services. In contrast, the 2005 rulemaking was in part based upon

the absence of information available to the EPA at the time.[66]

In a 2019 ICR renewal for the part 70 state operating permits program (OMB Control No. 2060–0243), the EPA estimated the burden for title V permitting. At the time, the EPA estimated the average burden for all affected sources at $19,031 per year (in year 2018 dollars). This burden value was calculated based upon estimates of the labor hours required for title V permitting related activities, including application preparation, monitoring development and operation, and reporting. See *2nd Notice Supporting Statement for ICR No. 1587.14 OMB No. 2060–0243,* February 2019, available in the ''40 CFR part 70 State Operating Permit Regulations, EPA Renewal ICR'' docket (Docket ID No. EPA–HQ–OAR–2004–0015). The EPA utilized the activity labor hour estimates from the 2019 ICR to develop a tailored estimate for this rulemaking of the labor hour and cost burden for area source EtO commercial sterilizers to comply with title V permitting requirements. The EPA estimates this burden at 391 labor hours and $67,211 in total cost (inclusive of labor and operating permit fees) for the first year of compliance, and 43 labor hours and $6,287 in total cost for the second and third years of compliance. Note that the activity labor hour estimates used in this burden estimate are based upon the average for all sources subject to the title V program, including both area sources and complex major sources. Compared to area sources, major sources experience greater burden from title V associated activities, particularly in application preparation, and are associated with increased delegated authority burden which, by law, is required to be passed onto sources in the form of permit fees. As a result, the average burden estimate is likely to overstate the costs imposed upon area source EtO commercial sterilizers. While this burden is not insignificant, it represents a small portion of the anticipated costs related to the amendments of this proposed rule. Further, we have determined that this burden is not significant and is justified when considering the anticipated benefits from requiring title V permitting for area source EtO commercial sterilizers.

In the March 2005 proposed rule to exempt area source EtO commercial sterilizers from title V permitting, the EPA evaluated the relationship to the legislative history of section 502(a) as follows: ''The EPA believes the vast majority of area sources proposed today for exemption from title V permitting in this notice are typically subject to not more than one NESHAP, and few other requirements under the Act, and that these NESHAP are relatively simple in how they apply to these sources. One of the primary purposes of the title V program is to clarify, in a single document, the various and sometimes complex regulations that apply to sources in order to improve understanding of these requirements and to help sources to achieve compliance with the requirements.'' (See 70 FR 15254) In contrast to the subpart O rule requirements as they existed at that time, the rule amendments proposed in this rule provide for a greater degree of complexity and requirements to achieve and demonstrate compliance for area sources. While the EPA maintains the understanding that the majority of area source EtO sterilizers are subject only to a single NESHAP, the compliance benefits of title V are greater today than in 2005.

For the reasons articulated above, the EPA has determined that it is not appropriate to exempt area source EtO commercial sterilizers from the requirement to obtain a title V permit under section 502(a). Based upon this determination, we are proposing to require that any sterilization facility subject to subpart O obtain a title V permit from the delegated authority in which the source is located. Corresponding revision is proposed to the General Provisions table entry for 40 CFR 63.1(c)(2) to remove the comment discussing the exemption of area sources from the obligation to obtain a title V operating permit. The additional public participation and compliance benefits of additional informational, monitoring, reporting, certification, and enforcement requirements that exist in title V should be required for these sources. These additional requirements are important to ensure that these sources are maintaining compliance with the requirements of this rule. While there is additional burden associated with title V permitting on the affected facilities, this burden is not significant compared to the expected benefits to public health and compliance.[67] We estimate that approximately 86 affected area sources will be required to obtain title V permits. The EPA solicits comment on the requirement for area sources in the source category to obtain a title V permit (Comment C–74).

c. Definitions

We are proposing the addition, revision, and deletion of numerous terms in the regulatory text, which is provided as part of this rulemaking. Specifically, we are proposing to add terms for:

- Emission process units and sources (combination sterilizer, EtO dispensing, Group 1 room air emission, Group 2 room air emissions, indoor EtO storage, pre-aeration handling of sterilized material, post-aeration handling of sterilized material, vacuum pump operation),
- Emissions capture (natural draft opening, PTE),
- APCDs and related terminology (acid-water scrubber, catalytic oxidizer, gas/solid reactor, peak shaver, residence time),
- Monitoring (continuous monitor, maximum daily mass of EtO charged to the sterilization chamber(s), maximum scrubber liquor pH, minimum room air EtO concentration, minimum temperature at the inlet to the catalyst bed, minimum temperature difference across the catalyst bed, minimum temperature in or immediately downstream of the firebox, minimum stack volumetric flow rate, rolling average), and
- Others (aeration, single-item sterilization).

It should be noted that while aeration is a defined process, there is still off-gassing of EtO from sterilized product that occurs after aeration (and before if a combination sterilizer is not used). We solicit comment on these new definitions (Comment C–75). We are also proposing to revise existing definitions in the regulatory text.

- Adding acronyms and alternative terms to the definitions for aeration room vent, chamber exhaust vent, and sterilization chamber vent,
- Replacing ''at least 99-percent control of ethylene oxide emissions'' with ''the appropriate control of EtO emissions'' in the definitions for

[66] See 70 FR 75325, December 19, 2005: ''For E.O. sterilizers, as in the proposal, the EPA has no reliable information on the economic resources of area sources but, as described below, believes that a number of area sources are small businesses with limited economic resources.''

[67] EPA believes that more involvement from local permitting authorities and the public will result in requirements that properly address the health needs and concerns of individual communities. A benefit in a title V permit is increased transparency and public participation, so that members of affected communities can know where sources are, what they are emitting, and the standards they are subject to, as well as having an opportunity to participate in the process. title V permits also generally include specific monitoring, recordkeeping, and reporting requirements that allow for greater transparency and assurance of sources' compliance with standards.

maximum ethylene glycol concentration and maximum liquor tank level,

- Clarifying the definition for aeration room to indicate that if a facility uses only combination sterilizers, there are no aeration rooms at the facility,
- Revising the definition for sterilization facility to clarify that facilities that engage in single-item sterilization are included in this definition, and
- Broadening the definition for sterilization operation to include times when EtO is stored within the building, EtO is dispensed from a container to a chamber, when material is moved from sterilization to aeration, or when materials are handled post-aeration.

We solicit comment on these revised definitions (Comment C–76). Finally, we are proposing to delete the following definitions from the regulatory text:

- Baseline temperature.
- Compliance date.
- Effective date.
- Manifolding emissions.
- Source(s) using less than 1 ton.
- Source(s) using 1 ton.
- Source(s) using 1 to 10 tons.
- Source(s) using less than 10 tons.
- Source(s) using 10 tons.

We are proposing to remove the definition for baseline temperature because the proposed operating limits for oxidizers depend on the type of oxidizer being used, and we believe it is best to provide definitions for individual operating limits, like what is done for acid-water scrubbers. We are also proposing to remove the definitions for compliance date and effective date because the definitions are already provided in the General Provisions. Because we are proposing detailed requirements for combined emissions streams, we are proposing to remove the definition for manifolding emissions. Finally, we are proposing to remove the definitions for source(s) using less than 1 ton, source(s) using 1 ton, source(s) using 1 to 10 tons, source(s) using less than 10 tons, and source(s) using 10 tons because these terms are not descriptive enough (*i.e.,* they do not specify the duration of use). We solicit comment on the removal of these definitions (Comment C–77).

d. Standards for Combined Emissions Streams

The EPA's understanding of control configurations at commercial sterilization facilities has changed since the rule was promulgated in 1994. In recent years, companies have implemented a wide variety of combinations when controlling emission streams at these facilities. As a result, it can be difficult to determine whether one vent type is in compliance with the rule when it is being combined with other vent types. Therefore, the EPA is proposing to structure the rule requirements so that facilities can combine emission streams based on the best approach for their facilities. The EPA is proposing different emission limitations based on the format of the standard (*i.e.,* removal efficiency or emission rate) with which the facility is complying. If complying with a removal efficiency standard, the EPA is proposing that the facility must comply with the removal efficiency standard for the emission source in the composite stream that has the most stringent removal efficiency. For example, at a facility where EtO use is at least 10 tpy, a combined stream that consists of emissions from ARVs subject to a removal efficiency of 99.5 percent and CEVs subject to a removal of 96 percent would be subject to a removal efficiency standard of 99.5 percent removal efficiency for the combined emission stream. If complying with an emission rate standard, the EPA is proposing that the facility must comply with an emission rate standard that is equal to the sum of the emission rate standards for each emission source type in the composite stream. For example, at a facility where EtO use is at least 10 tpy, a combined stream that consists of emissions from ARVs subject to an EtO emission rate of 7.0E–3 lb/hr and CEVs subject to an EtO emission rate of 3.4E–3 lb/hr must comply with an EtO emission rate standard of less than 1.0E–2 lb/hr from the combined emission stream. This approach is necessary because of the multiple configurations of emissions streams, and results in standards that are equivalent and equally protective compared to the standards for individual emissions streams. When determining compliance, it is important for facilities to understand how their emission streams are configured and what the ultimate emissions from these streams are. The EPA solicits comment on the proposed standards for combined emissions streams (Comment C–78).

e. Negative Pressure for SCVs and CEVs

The current subpart O rule does not include capture requirements for emissions. For ARVs and room air emissions, we are proposing PTE requirements to ensure complete capture of EtO from these sources. It is also important to ensure that emissions from other sources such as SCV and CEV are completely captured and routed to control systems. The EPA is proposing to require that emissions from SCVs and CEVs be routed under negative pressure when ducted to a control system. The EPA solicits comment on this proposed requirement (Comment C–79).

H. What compliance dates are we proposing, and what is the rationale for the proposed compliance dates?

Amendments to the subpart O NESHAP proposed in this rulemaking for adoption under CAA sections 112(d)(2), (3), (5), and (6), as well as CAA section 112(f)(2), are subject to the compliance deadlines outlined in the CAA under section 112(i).

For the requirements we are proposing under CAA sections 112(d)(2)–(3), (d)(5), and (d)(6), we are proposing all existing affected sources must comply with all amendments no later than 18 months after the effective date of the final rule. In addition, we are proposing all new affected sources must comply with all amendments upon startup. For existing sources, CAA section 112(i) provides that the compliance date shall be as expeditious as practicable, but no later than 3 years after the effective date of the standard. (''Section 112(i)(3)'s three-year maximum compliance period applies generally to any emission standard . . . promulgated under [section 112].'' *Association of Battery Recyclers* v. *EPA,* 716 F.3d 667, 672 (D.C. Cir. 2013)). In determining what compliance period is as expeditious as practicable, we consider the amount of time needed to plan and construct projects and change operating procedures. As provided in CAA section 112(i), all new affected sources would be required to comply with these requirements by the effective date of the final amendments to the subpart O standards or startup, whichever is later.

We are proposing updated operating and monitoring requirements for capture and control systems. We anticipate that these requirements would require the installation of monitoring equipment, and we project most commercial sterilization facilities would install additional or replacement systems to monitor and adjust process variables that impact the parameters being monitored. Like the addition of control equipment, these monitoring requirements for capture and control systems would require engineering evaluations, solicitation and review of vendor quotes, contracting and installation of the equipment, and operator training. Installation of additional or replacement systems to monitor and adjust process variables may require the capture and control system(s) to be taken out of service and may also require a significant portion of

the commercial sterilization facility to be shutdown. Therefore, we are proposing that it is necessary to provide 18 months after the effective date of the final rule (or upon startup, whichever is later) for facilities to comply with the updated operating and monitoring requirements for capture and control systems.

Additionally, as previously discussed in this preamble, we are proposing under CAA section 112(f), provisions for SCVs, ARVs, CEVs, and room air emissions at certain groups of facilities. The proposed provisions may require additional time to plan, purchase, and install equipment for capture and control. For example, for SCVs at facilities where EtO use is at least 40 tpy, if the affected source cannot demonstrate 99.94 percent control of EtO emissions, then a new control system will need to be installed. Therefore, we are proposing a compliance date of 18 months after the effective date of the final rule. For all new affected sources that commenced construction or reconstruction after April 13, 2023, we are proposing facilities comply with the requirements that are being proposed upon startup.

Finally, we are proposing to change the requirements for SSM by removing the exemption from the requirements to meet the standards during SSM periods. We are also proposing electronic reporting requirements. We are positing that facilities would need some time to successfully accomplish these revisions, including time to read and understand the amended rule requirements, to evaluate their operations to ensure that they can meet the standards during periods of startup and shutdown, as defined in the rule, and make any necessary adjustments, including making adjustments to standard operating procedures, and to convert reporting mechanisms to install necessary hardware and software. The EPA recognizes the confusion that multiple different compliance dates for individual requirements would create and the additional burden such an assortment of dates would impose. From our assessment of the timeframe needed for compliance with the entirety of the proposed revisions to SSM requirements as well as the new proposed electronic reporting requirements for compliance reports and performance evaluation reports, the EPA considers a period of 18 months after the effective date of the final rule to be the most expeditious compliance period practicable and, thus, is proposing that all affected sources be in compliance with these revised SSM and electronic reporting requirements upon initial startup or within 18 months of the effective date of the final rule, whichever is later. However, we are proposing to provide 60 days after the effective date of the final rule (or upon startup, whichever is later) for facilities to comply with the requirement to report performance test and evaluation results, notices of compliance status, and initial and ongoing compliance reports electronically. There are several factors that either support or undermine the justification for an expedited compliance timeframe for existing sources. We are aware that, in order to implement the capture and emission reduction systems necessary to comply with the requirements that we are proposing, facilities will need to cease operations for a certain period of time in order to implement these systems. However, an expedited compliance timeframe could result in more facilities needing to cease operations simultaneously. This means that increased coordination would be needed to ensure that the supply of medical devices is not adversely impacted. We also recognize the health risks that this source category currently poses and that the risks of EtO exposure have been made known to the public for some time. In addition, a significant portion of the industry is already operating the types of capture and control systems that we anticipate will be needed to comply with the proposed standards. We solicit comment on the appropriate compliance timeframe for existing sources. To aid in our decision-making, we solicit comment on the amount of time that a facility would need to comply with the proposed standards, as well as the amount of time the facility would need to cease EtO sterilization operations (either fully or partially) and how this may impact the medical device supply chain. (Comment C–80).

IV. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected sources?

There are 86 facilities in the Commercial Sterilization Facilities source category that are currently operating.[68] A complete list of facilities that are currently subject to the NESHAP is available in Appendix 1 of the *Risk and Technology Review* memorandum, which is available in the docket for this rulemaking. We anticipate that an additional 2 facilities will commence operation and become subject to the rule in the next 3 years.

B. What are the air quality impacts?

For the standards that we are proposing, we estimated an EtO emissions reduction of 19 tpy for the total source category reductions from sterilizer chambers, aeration rooms, chamber exhaust, and room air emission sources. See the *Technology Review* memorandum.

C. What are the cost impacts?

The nationwide costs of the proposed amendments are presented in Table 1 of this preamble. As described in this preamble, we are proposing to reduce EtO emissions from SCV, CEV, ARV, Group 1 room air, and Group 2 room air emission sources. The capital costs, for facilities with controls already in place, include addition of add-on dry scrubber controls to meet the emission reduction determined under the technology review; ductwork; an interlock system, damper, and in-chamber EtO concentration monitor for the CEV; and performance testing. The capital costs also include a PTE, an add-on dry scrubber control device, pressure monitoring device, and performance testing for room air emission sources. Annual costs include annualized capital costs, media replacement cost, operating and maintenance labor, recordkeeping and reporting, electricity, and taxes and insurance. The total annual costs of the proposed rule are estimated to be $68 million in 2021 dollars.

D. What are the economic impacts?

The present value (PV) of the estimated compliance costs from 2023 to 2042 for the proposed option is $640 million in 2021 dollars, discounted at a 7 percent rate. The equivalent annualized value (EAV) of the costs for the proposed rule is $74 million, using a 7 percent discount rate. Using a 3 percent discount rate, the PV and EAV of the cost impacts are estimated to be $784 million and $53 million, respectively.

The EPA conducted economic impact analyses for this proposal, as detailed in the document *Regulatory Impact Analysis for the Proposed National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations,* which is available in the docket for this action. For the proposed amendments, the EPA performed a screening analysis which compared facility-level annualized compliance

[68] As discussed in section III.C.1, the risk assessment was conducted on these 86 facilities, as well as 11 research and development facilities, for a total of 97 facilities. To exercise caution, we included research facilities in our assessment because there is a lack of certainty over whether these are true research facilities, for which CAA section 112(c)(7) requires that a separate category be established.

costs to annual revenues of the ultimate owner of the facility (or facilities), known as the ultimate parent company. These cost-to sales ratios underpin the ''sales test'' methodology the EPA uses to assess small business impacts for a rulemaking.

There are 88 facilities affected by the proposed amendments and they are owned by 48 ultimate parent companies.[69] Of these 88 facilities, 24 facilities, or 27 percent, are owned by 20 small entities at the ultimate parent company level. We calculated the cost-to-sales ratios for all the affected parent companies to assess the magnitude of the costs of the proposed amendments and determine whether there is potential for significant impacts on small entities. For all firms, the average cost-to-sales ratio is approximately 7.9 percent; the median cost-to-sales ratio is approximately 0.3 percent; and the maximum cost-to-sales ratio is approximately 68 percent. For large firms, the average cost-to-sales ratio is approximately 0.3 percent; the median cost to-sales ratio is approximately 0.03 percent; and the maximum cost-to-sales ratio is approximately 3.9 percent. For small entities, the average cost-to-sales ratio is approximately 19 percent; the median cost to-sales ratio is approximately 7.3 percent; and the maximum cost-to-sales ratio is approximately 68 percent. Large firms incur most of the total costs estimated for the proposed rule and they incur higher total annual costs per firm on average than small firms. However, when estimated costs are examined relative to revenues, large firms are much less affected by the proposed rule than small firms.

Under the proposed amendments, 17 out of 20 (85 percent) parent companies identified as small entities are estimated to incur total annual costs greater than 1 percent of annual revenues. Additionally, 12 out of 20 small entities (60 percent) are estimated to incur annualized costs greater than 3 percent of annual revenues. The 12 small entities with cost-to-sales ratios of 3 percent or greater collectively own 16 facilities.

The EtO sterilization industry is an integral part of the supply chain for many medical devices and capacity constraints have been reported. As described in section I.A.1 of this preamble, we have been engaged with FDA regarding the potential impacts of this proposal on commercial sterilization facilities that play a key role in the availability of certain medical devices. Based on the data we analyzed/considered, we project that the largest impacts are limited to a handful of companies, and many of them are already in the planning stage for additional controls. We believe large firms account for a large percentage of the output of this industry, and they appear much less affected by the proposed rule than small firms when examining costs relative to revenues. See the Regulatory Impact Analysis for further detail on the cost estimates, small entity impact analysis, and a discussion of potential market and economic impacts.

E. What are the benefits?

The EPA did not monetize the benefits from the estimated emission reductions of HAP associated with this proposed action. This does not imply that there are no benefits associated with the EtO emission reductions estimated for this proposed rule. We expect this proposed action would provide benefits associated with lower risk of adverse health effects (*e.g.,* cancer incidence) in communities near facilities subject to the NESHAP.

V. Request for Comments

We solicit comments on this proposed action. In addition to general comments on this proposed action, we are also interested in additional data that may improve the analyses. We are specifically interested in receiving any information regarding developments in practices, processes, and control technologies that reduce EtO emissions. In addition, we solicit comment on several aspects of the requirements herein, including the true effectiveness of these requirements on reducing EtO emissions, any capital and annual costs that we did not account for, the time that is needed to comply with requirements, and any other potential barriers to or impacts of imposing these requirements.

VI. Incorporation by Reference (IBR)

We are proposing to incorporate by reference ISO 11135—Sterilization of health-care products—Ethylene oxide—Requirements for the development, validation and routine control of a sterilization process for medical devices (Approved July 25, 2014), as part of a GACT management practice standard for existing Group 2 room air emissions at area source facilities where EtO use is less than 20 tpy (proposed to be IBR approved for Table 5 to 40 CFR part 63, subpart O). This ISO standard ''describes requirements that, if met, will provide an EtO sterilization process intended to sterilize medical devices, which has appropriate microbicidal activity''. We are also proposing to incorporate by reference ISO 11138–1—Sterilization of health care products—Biological indicators—Part 1: General requirements (Approved March 2017), as part of a GACT management practice standard for existing Group 2 room air emissions at area source facilities where EtO use is less than 20 tpy (proposed to be IBR approved for Table 5 to 40 CFR part 63, subpart O). This ISO standard ''specifies general requirements for production, labelling, test methods and performance requirements for the manufacture of biological indicators including inoculated carriers and suspensions intended for use in validation and monitoring of sterilization processes''. Compliance with the requirements ensures that validations conducted following this International Standard will provide products that meet the defined requirements for sterile products with a high degree of confidence. We are proposing to require certain facilities to follow either the Cycle Calculation Approach or the Bioburden/Biological Indicator Approach to achieve sterility assurance in accordance with ISO 11135:2014 and ISO 11138–1:2017, which will result in lower EtO emissions throughout the facility. In addition, we are proposing to incorporate by reference ISO 17025—General requirements for the competence of testing and calibration laboratories (Approved November 2017). This ISO standard ''contains requirements for laboratories to enable them to demonstrate they operate competently and are able to generate valid results''. The ISO standards are available from the International Organization for Standardization, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland. See *https://www.iso.org.*

VII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

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

This action is a significant regulatory action under section 3(f)(1) of Executive Order 12866 that was submitted to OMB for review because it may adversely affect in a material way the economy, a sector of the economy, productivity,

[69] This includes the 86 facilities that are currently operating, as well as two planned facilities that are expected to start operating before the proposed compliance deadline.

competition, jobs, the environment, public health or safety, or state, local, or tribal governments. Any changes made in response to OMB recommendations have been documented in the docket. The EPA prepared an analysis of the potential economic impacts and benefits associated with this action. This analysis, *Regulatory Impact Analysis for the Proposed National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations,* is available in the docket for this rulemaking.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to OMB under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 1666.12. You can find a copy of the ICR in the docket for this rulemaking, and it is briefly summarized here.

We are proposing amendments that change the reporting and recordkeeping requirements for several emission sources at commercial sterilization facilities (*e.g.,* SCV, ARV, CEV, and room air emissions). The proposed amendments also require electronic reporting, removes the SSM exemption, and imposes other revisions that affect reporting and recordkeeping. This information would be collected to assure compliance with 40 CFR part 63, subpart O.

Respondents/affected entities: Owners or operators of commercial sterilization facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart O).

Estimated number of respondents: 86 facilities.

Frequency of response: Quarterly, semiannual, or annual. Responses include notification of compliance status reports and semiannual compliance reports.

Total estimated burden: 34,351 hours (per year) for the responding facilities and 9,174 hours (per year) for the Agency. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $5,140,563 (per year), which includes $2,549,368 annualized capital and operation and maintenance costs for the responding facilities.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *OIRA_submission@omb.eop.gov,* Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than May 15, 2023. The EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 603 of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) that examines the impact of the proposed rule on small entities along with regulatory alternatives that could minimize the impact. The complete IRFA is available in section 5.2 of the regulatory impact assessment (RIA) in the docket and is summarized here.

As discussed in section II.A., the statutory authority for this action is provided by sections 112 and 301 of the CAA, as amended (42 U.S.C. 7401 *et seq.*). The EPA is proposing to revise the NESHAP for Commercial Sterilization Facilities by both amending existing standards and establishing additional standards for this source category, exercising authority under multiple provisions of section 112 of the CAA.

For purposes of assessing the impacts of this rule on small entities, a small entity is defined as a small business in the commercial EtO sterilization industry whose parent company has revenues or numbers of employees below the Small Business Administration (SBA) Size Standards for the relevant NAICS code. We have identified 20 different NAICS codes within this source category. A complete list of those NAICS codes and SBA Size Standards is available in section 5.2 of the RIA. The proposed rule contains provisions that would affect approximately 20 small entities. These small entities are involved in sterilizing various types of medical devices and spices. In addition, at least eight of these small entities are involved in sterilizing the types of medical devices discussed in section I.A.1 of this preamble. Under the proposed rule requirements, small entities would be required to comply with various emission standards, which may require the use of a new control device. Some small entities would also be required to comply with a BMP, which would require them to re-validate some or all of their sterilization cycles if they are not already in compliance. Small entities would also need to demonstrate compliance with the emission standards through periodic performance testing and parametric monitoring or through the use of an EtO CEMS. This proposed rule includes reporting, recordkeeping, and other administrative requirements. Under the proposed rule, EPA estimates that approximately 12 small entities (60 percent of small entities) could incur total annual costs associated with the proposal that are at least three percent of their annual revenues. Considering the level of total annual costs relative to annual sales for these small entities, EPA determined that there is potential for the proposed requirements to have a 'Significant Impact on a Substantial Number of Small Entities' (SISNOSE). See section 5.2 of the RIA for more information on the characterization of the impacts under the proposed rule.

As required by section 609(b) of the RFA, EPA also convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations from small entity representatives (SERs) that potentially would be subject to the rule's requirements. On December 10, 2020, EPA's Small Business Advocacy Chairperson convened the Panel, which consisted of the Chairperson, the Director of the Sector Policies and Programs Division within EPA's Office of Air Quality Planning and Standards, the Administrator of the Office of Information and Regulatory Affairs within OMB, and the Chief Counsel for Advocacy of the Small Business Administration (SBA).

Prior to convening the Panel, EPA conducted outreach and solicited comments from the SERs. After the Panel was convened, the Panel provided additional information to the SERs and requested their input. In light of the SERs' comments, the Panel considered the regulatory flexibility issues and elements of the IRFA specified by RFA/Small Business Regulatory Enforcement and Fairness Act (SBREFA) and developed the findings and discussion summarized in the SBAR report. The SBAR Panel recommended several flexibilities relating to the format of the standards, room air emissions requirements, subcategorization, the compliance timeframe, the consideration of GACT standards, incentivizing lower EtO use, a compliance alternative for combined emission streams, proximity requirements, and the consideration of interactions with OSHA standards. EPA

is including some of these flexibilities as a part of the proposed rule requirements and soliciting comment on others that may be considered for the final rule. The report was finalized on April 26, 2021, and transmitted to the EPA Administrator for consideration. A copy of the full SBAR Panel Report is available in the rulemaking docket.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments.

E. Executive Order 13132: Federalism

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

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

This action does not have tribal implications as specified in Executive Order 13175. None of the commercial sterilization facilities that have been identified as being affected by this action are owned or operated by tribal governments or located within tribal lands. Thus, Executive Order 13175 does not apply to this action.

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

Executive Order 13045 (62 FR 19885, April 23, 1997) directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonable feasible alternatives. This action is subject to Executive Order 13045 because it is an economically significant regulatory action as defined by Executive Order 12866, and the EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children. The EPA's Policy on Children's Health [70] also applies to this action. Accordingly, we have evaluated the environmental health or safety effects of EtO emissions and exposures on children. The protection offered by these standards may be especially important for children.

Because EtO is mutagenic (*i.e.,* it can damage DNA), children are expected to be more susceptible to its harmful effects. To take this into account, as part of the risk assessment in support of this rulemaking, the EPA follow its guidelines [71] and applied age-dependent adjustment factors (ADAFs) for childhood exposures (from birth up to 16 years of age). With the ADAF applied to account for greater susceptibility of children, the adjusted EtO inhalation URE is $5 \times 10 - 3$ per $\mu g/m^3$. It should be noted that, because EtO is mutagenic, emission reductions proposed in this preamble will be particularly beneficial to children.

More detailed information on the evaluation of the scientific evidence and policy considerations pertaining to children, including an explanation for why the Administrator judges the proposed standards to be requisite to protect public health, including the health of children, with an adequate margin of safety, in addition to the summaries of this action's health and risk assessments are contained in sections II.E and G and sections III.C and D of this preamble and further documented in the risk report, *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2022 Risk and Technology Review Proposed Rule,* which is available in Docket ID No. EPA–HQ–OAR–2019–0178.

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

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The overall energy impact of this proposed rule should be minimal for commercial sterilization facilities and their parent companies. EPA was unable to quantify the degree to which manufacturers would need to switch sites, so we cannot estimate potential energy impacts related to transportation. EPA solicits comment on any potential impacts the proposed standards may have in relation to energy use for transportation (Comment C–81).

I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This action involves technical standards. Therefore, the EPA conducted searches for the EtO Commercial Sterilization NESHAP through the Enhanced National Standards Systems Network (NSSN) Database managed by the American National Standards Institute (ANSI). We also contacted voluntary consensus standards (VCS) organizations and accessed and searched their databases. We conducted searches for EPA Methods 204 of 40 CFR part 51, appendix M; EPA Methods 1, 1, 2, 2A, 2C, and 3B of 40 CFR part 60, appendix A; and EPA Method 320 of 40 CFR part 63, appendix A. During the EPA's VCS search, if the title or abstract (if provided) of the VCS described technical sampling and analytical procedures that are similar to the EPA's reference method, the EPA considered it as a potential equivalent method. We reviewed all potential standards to determine the practicality of the VCS for this rule. The EPA may reconsider determinations of impracticality when additional information is available for particular VCS.

No applicable VCS were identified for EPA Methods 204, 1, 1, 2, 2A, and 2C. The following VCS were identified as acceptable alternatives to the EPA test methods for the purpose of this rule.

The EPA proposes to use the VCS ANSI/ASME PTC 19.10–1981 Part 10 (2010), ''Flue and Exhaust Gas Analyses,'' as an acceptable alternative to EPA Method 3B for the manual procedures only and not the instrumental procedures. The ANSI/ASME PTC 19.10–1981–Part 10 method incorporates both manual and instrumental methodologies for the determination of oxygen content. The manual method segment of the oxygen determination is performed through the absorption of oxygen. The EPA is not proposing to incorporate this VCS by reference. This method is available both in the docket for this rulemaking and at the American National Standards Institute (ANSI), 1899 L Street NW, 11th floor, Washington, DC 20036 and the American Society of Mechanical Engineers (ASME), Three Park Avenue, New York, NY 10016–5990. See *https://www.ansi.org* and *https://www.asme.org.*

In addition, the EPA proposes to use the VCS ASTM D6348–12e1, ''Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy,'' as an acceptable alternative to EPA Method

[70] Children's Health Policy available at: *https://www.epa.gov/children/childrens-health-policy-and-plan.*

[71] U.S. EPA. 2005. Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens. U.S. Environmental Protection Agency, Washington, DC, EPA/630/R–03/003F. *https://www.epa.gov/sites/default/files/2013-09/documents/childrens_supplement_final.pdf.*

320 of appendix A to 40 CFR part 63 with caveats requiring inclusion of selected annexes to the standard as mandatory. The ASTM D6348–12e1 method is an extractive FTIR spectroscopy-based field test method and is used to quantify gas phase concentrations of multiple target compounds in emission streams from stationary sources. The EPA is not proposing to incorporate this VCS by reference. We are proposing the test plan preparation and implementation in the Annexes to ASTM D 6348–03, Sections Al through A8 are mandatory; and in ASTM D6348–03 Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (Equation A5.5). We are proposing that in order for the test data to be acceptable for a compound, %R must be 70% < R ≤ 130%. If the %R value does not meet this criterion for a target compound, the test data are not acceptable for that compound and the test must be repeated for that analyte (*i.e.,* the sampling and/or analytical procedure should be adjusted before a retest). We are proposing that the %R value for each compound be reported in the test report, and all field measurements be corrected with the calculated %R value for that compound by using the following equation:

$$Reported\ Results = \frac{Stack\ Concentration}{\%R}\ x\ 100$$

The ASTM D6348–12e1 method is available both in the docket for this rulemaking and at ASTM International, 1850 M Street NW, Suite 1030, Washington, DC 20036. See *https://www.astm.org/.*

In this rule, the EPA is proposing regulatory text for Tables 1 through 5 to 40 CFR part 63, subpart O, that includes IBR in accordance with requirements of 1 CFR 51.5. Specifically, the EPA is incorporating by reference ISO 11135:2014. The ISO standards are available from the International Organization for Standardization, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland. See *https://www.iso.org.*

The EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially applicable VCS, and to explain why the EPA should use such standards in this regulation (Comment C–82).

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

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or indigenous peoples) and low-income populations.

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 people of color, low-income populations and/or indigenous peoples. A total of 19.4 million people live within 10 km of the 97 facilities that were assessed. The percent of the population that is Hispanic or Latino is substantially higher than the national average (34 percent versus 19 percent), driven by the seven facilities in Puerto Rico, where an average of 99 percent of the 658,000 people living within 10 km of the facilities are Hispanic or Latino. The proportion of other demographic groups living within 10 km of commercial sterilizers is similar to the national average. The EPA also conducted a risk assessment of possible cancer risks and other adverse health effects, and found that prior to this proposed regulation, cancer risks were above acceptable levels for several areas in which these demographic groups live. See section III.E for an analysis that characterizes populations living in proximity of facilities and risks prior to the proposed regulation.

The EPA believes that this action is likely to reduce existing disproportionate and adverse effects on people of color, low-income populations and/or indigenous peoples. This action proposed to establish standards for SCVs, ARVs, and CEVs at facilities where EtO use is less than 1 tpy, ARVs and CEVs at facilities where EtO use is at least 1 tpy but less than 10 tpy, CEVs at facilities where EtO use is at least 10 tpy, and room air emissions. In addition, it proposes to tighten standards for SCVs at facilities where EtO use is at least 1 tpy, as well as ARVs at facilities where EtO use is at least 10 tpy. This action also proposes amendments to correct and clarify regulatory provisions related to emissions during periods of SSM, including removing general exemptions for periods of SSM and adding work practice standards for periods of SSM where appropriate. As a result of these proposed changes, we expect zero people to be exposed to risk levels above 100-in-1 million. See sections III.B and III.D for more information about the control requirements of the regulation and the resulting reduction in cancer risks.

The EPA additionally identified and addressed environmental justice concerns by engaging in outreach activities to communities we expect to be impacted most by the rulemaking.[72] The EPA is also proposing that owners and operators of commercial sterilization facilities submit electronic copies of required compliance reports, performance test reports, and performance evaluation reports, which will provide greater access to information for impacted communities.

The information supporting this Executive order review is contained in section III.E of this preamble, as well as in a technical report, *Analysis of Demographic Factors for Populations Living Near Ethylene Oxide Commercial Sterilization and Fumigation Operations,* available in the docket for this action.

List of Subjects in 40 CFR Part 63

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

Michael S. Regan,

Administrator.

[FR Doc. 2023–06676 Filed 4–12–23; 8:45 am]

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[72] *https://www.epa.gov/newsreleases/epa-launches-community-engagement-efforts-new-ethylene-oxide-risk-information.*



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Part V

Department of Education

34 CFR Part 106
Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance: Sex-Related Eligibility Criteria for Male and Female Athletic Teams; Proposed Rule

DEPARTMENT OF EDUCATION

34 CFR Part 106

[Docket ID ED–2022–OCR–0143]

RIN 1870–AA19

Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance: Sex-Related Eligibility Criteria for Male and Female Athletic Teams

AGENCY: Office for Civil Rights, Department of Education.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The U.S. Department of Education (Department) proposes to amend its regulations implementing Title IX of the Education Amendments of 1972 (Title IX) to set out a standard that would govern a recipient's adoption or application of sex-related criteria that would limit or deny a student's eligibility to participate on a male or female athletic team consistent with their gender identity. The proposed regulation would clarify Title IX's application to such sex-related criteria and the obligation of schools and other recipients of Federal financial assistance from the Department (referred to below as ''recipients'' or ''schools'') that adopt or apply such criteria to do so consistent with Title IX's nondiscrimination mandate.

DATES: Comments must be received on or before May 15, 2023.

ADDRESSES: Comments must be submitted via the Federal eRulemaking Portal at *https://www.regulations.gov.* However, if you require an accommodation or cannot otherwise submit your comments via *https://www.regulations.gov,* please contact the program contact person listed under **FOR FURTHER INFORMATION CONTACT**. Comments that are not submitted via *https://www.regulations.gov* will not be accepted absent such a request. The Department will not accept comments submitted after the comment period closes. To ensure that the Department does not receive duplicate copies, please submit your comments only once. Additionally, please include the Docket ID at the top of your comments.

Federal eRulemaking Portal: Please go to *https://www.regulations.gov* to submit your comments electronically. Information on using *https://www.regulations.gov,* including instructions for finding a rule on the site and submitting comments, is available on the site under ''FAQ.''

Note: The Department's policy is generally to make comments received from members of the public available for public viewing on the Federal eRulemaking Portal at *https://www.regulations.gov.* Therefore, commenters should include in their comments only information about themselves that they wish to make publicly available. Commenters should not include in their comments any information that identifies other individuals or that permits readers to identify other individuals. If, for example, your comment describes an experience of someone other than yourself, please do not identify that individual or include information that would allow readers to identify that individual. The Department reserves the right to redact at any time any information in comments that identifies other individuals, includes information that would allow readers to identify other individuals, or includes threats of harm to another person.

FOR FURTHER INFORMATION CONTACT: Alejandro Reyes, U.S. Department of Education, 400 Maryland Ave. SW, PCP–6125, Washington, DC 20202. Telephone: 202–245–7705. You may also email your questions to *T9AthleticsNPRM@ed.gov,* but as described above, comments must be submitted via the Federal eRulemaking Portal at *https://www.regulations.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:

Executive Summary

The Department's July 2022 Proposed Rulemaking

On July 12, 2022, the Department published in the **Federal Register** a notice of proposed rulemaking to amend its regulations implementing Title IX (July 2022 NPRM). 87 FR 41390 (July 12, 2022), *https://www.federalregister.gov/documents/2022/07/12/2022-13734/nondiscrimination-on-the-basis-of-sex-in-education-programs-or-activities-receiving-federal.* In the July 2022 NPRM, the Department announced plans to issue a separate notice of proposed rulemaking to address whether and how the Department should amend its Title IX regulations to clarify what criteria, if any, a recipient of Federal funding [1] should be permitted to use to establish students' eligibility to participate on a particular male or female athletic team. 87 FR 41537. This notice of proposed rulemaking, referred to below as the Athletics NPRM, addresses that issue. The comment period for the July 2022 NPRM closed on September 12, 2022.

Purpose of This Regulatory Action

The purpose of this regulatory action, the Athletics NPRM, is to propose a regulatory standard under Title IX that would govern a recipient's adoption or application of sex-related criteria that would limit or deny a student's eligibility to participate on a male or female athletic team consistent with their gender identity (referred to below as ''sex-related criteria'' or ''sex-related eligibility criteria''). The proposed regulation also would provide needed clarity, in response to questions from stakeholders, on how recipients can ensure that students have equal opportunity to participate on male and female athletic teams as required by Title IX.

In particular, the Department proposes amending § 106.41(b) of its Title IX regulations to provide that, if a recipient adopts or applies sex-related criteria that would limit or deny a student's eligibility to participate on a male or female athletic team consistent with their gender identity, those criteria must, for each sport, level of competition, and grade or education level: (i) be substantially related to the achievement of an important educational objective, and (ii) minimize harms to students whose opportunity to participate on a male or female team consistent with their gender identity would be limited or denied. As discussed below, the proposed regulation would not prohibit a recipient's use of sex-related criteria altogether. Instead, the proposed regulation would require that a recipient meet this standard for any sex-related criteria that would limit or deny students' eligibility to participate on a male or female team consistent with their gender identity. The Department recognizes that prevention of sports-related injury is an important educational objective in recipients' athletic programs and that—as courts have long recognized in cases involving

[1] The text of Title IX states that the statute applies to ''any education program or activity receiving Federal financial assistance.'' 20 U.S.C. 1681(a). The definition of the term ''Federal financial assistance'' under the Department's Title IX regulations is not limited to monetary assistance, but encompasses various types of in-kind assistance, such as a grant or loan of real or personal property, or provision of the services of Federal personnel. *See* 34 CFR 106.2(g)(2) and (3). Throughout this preamble, terms such as ''Federal funding,'' ''Federal funds,'' and ''federally funded'' are used to refer to ''Federal financial assistance,'' and are not meant to limit application of the statute or its implementing regulations to recipients of certain types of Federal financial assistance.

sex-separate athletic teams—fairness in competition may be particularly important for recipients in some sports, grade and education levels, and levels of competition. The Department anticipates that some uses of sex-related eligibility criteria would satisfy the standard in the proposed regulation in some sports, grade and education levels, and levels of competition.

The Department makes this proposal based on an extensive review of its regulations implementing Title IX, as well as the statute's text and legislative history; Federal and State case law; relevant State laws and the policies of schools and athletic associations; live and written comments received during a nationwide virtual public hearing on Title IX held in June 2021; and other information provided by stakeholders. *Executive Order on Regulatory Planning and Review,* Exec. Order No. 12866, 58 FR 51735 (Oct. 4, 1993), *https://www.govinfo.gov/content/pkg/FR-1993-10-04/pdf/FR-1993-10-04.pdf.*

Costs and Benefits

As further detailed below in the *Regulatory Impact Analysis,* the Department estimates that the total monetary cost to recipients of the proposed regulation over 10 years would be in the range of $23.4 million to $24.4 million, assuming a seven percent and three percent discount rate, respectively. Because of the lack of available quantitative data, the Department cannot fully quantify the economic impact of the proposed regulation. The Department believes that the benefits associated with the proposed regulation—providing a standard to clarify Title IX obligations for recipients that adopt or apply sex-related eligibility criteria and protecting students' equal opportunity to participate on male and female teams consistent with Title IX—far outweigh the costs.

In particular, the Department believes the proposed regulation would offer greater clarity regarding how a recipient can comply with its nondiscrimination obligation under Title IX if the recipient offers an athletic program and adopts or applies sex-related criteria that would limit or deny a student's eligibility to participate on a male or female athletic team consistent with their gender identity. The Department recognizes that there is a valuable, even if not readily quantifiable, benefit of increasing students' equal opportunity to participate consistent with their gender identity under sex-related eligibility criteria that meet the proposed regulation's requirements, which some recipients' current eligibility criteria may not provide. The Department also recognizes that, without the proposed regulation's requirements for a recipient's sex-related eligibility criteria, some students may suffer harm as a result of being unable to gain the benefits associated with equal opportunity to participate on athletic teams at school.

Participation in team sports has been associated with many valuable physical, emotional, academic, and interpersonal benefits for students, and athletic participation has the potential to help students develop skills that benefit them in school and throughout life, including teamwork, discipline, resilience, leadership, confidence, social skills, and physical fitness. *See, e.g.,* Scott L. Zuckerman et al., *The Behavioral, Psychological, and Social Impacts of Team Sports: A Systematic Review and Meta-analysis,* 49 Physician & Sports Med. 246 (2021); Ryan D. Burns et al., *Sports Participation Correlates with Academic Achievement: Results From a Large Adolescent Sample Within the 2017 U.S. National Youth Risk Behavior Survey,* 127 Perceptual & Motor Skills 448 (2020); President's Council on Sports, Fitness & Nutrition Sci. Bd., *Benefits of Youth Sports* (Sept. 17, 2020), *https://health.gov/sites/default/files/2020-09/YSS_Report_OnePager_2020-08-31_web.pdf; Parker* v. *Franklin Cnty. Cmty. Sch. Corp.,* 667 F.3d 910, 916 (7th Cir. 2012) (noting that ''[s]tudies have shown that sports participation provides important lifetime benefits to participants'' (quoting Dionne L. Koller, *Not Just One of the Boys: A Post-Feminist Critique of Title IX's Vision for Gender Equity in Sports,* 43 Conn. L. Rev. 401, 413 (2010))).

The Department also recognizes that a recipient could incur some costs in complying with the proposed regulation if it adopts or applies certain sex-related eligibility criteria for participation on male or female athletic teams. The Department acknowledges that past agency statements on Title IX's coverage of discrimination based on gender identity have varied, and the proposed regulation would shift away from some of those statements. The Department believes that any costs associated with an individual recipient's compliance would be minimal if the proposed regulation is made final. For example, the proposed regulation may require updating of existing policies or training materials, but the Department does not expect that the proposed regulation would require other types of expenditures.

Invitation to Comment: The Department invites you to submit comments regarding the proposed regulation. To ensure that your comments have the maximum effect on developing the final regulation, you should identify clearly the specific part of the proposed regulation or directed question that each of your comments addresses.

The Department also invites you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 (explained further below) and their overall goal of reducing the regulatory burden that might result from the proposed regulation. Please let the Department know of any further ways it may reduce potential costs or increase potential benefits, while preserving the effective and efficient administration of the Department's programs and activities. The Department also welcomes comments on any alternative approaches to the subjects addressed by the proposed regulation.

During and after the comment period, you may inspect public comments about the proposed regulation by accessing *Regulations.gov.* You may also inspect the comments in person. Please contact the person listed under **FOR FURTHER INFORMATION CONTACT** to make arrangements to inspect the comments in person.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: Upon request, the Department will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for the proposed regulation. To schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Background

The mission of the Department's Office for Civil Rights (OCR) is to ensure equal access to education and to promote educational excellence through vigorous enforcement of civil rights in our Nation's schools. One of the Federal civil rights laws that OCR enforces is Title IX, which prohibits discrimination on the basis of sex under education programs or activities that receive Federal financial assistance. 20 U.S.C. 1681–1688. Athletic programs have long been recognized by Congress, the Department, and Federal courts as an integral part of a recipient's education program or activity subject to Title IX. *See, e.g.,* Education Amendments of 1974, Public Law 93–380, section 844, 88 Stat. 484, 612 (Javits Amendment); *see also* U.S. Dep't of Health, Educ., and

Welfare, *Final Rule: Nondiscrimination on the Basis of Sex in Education Programs and Activities Receiving or Benefiting from Federal Financial Assistance,* 40 FR 24128, 24134 (June 4, 1975) (citing cases); U.S. Dep't of Health, Educ., and Welfare, Office for Civil Rights, *A Policy Interpretation: Title IX and Intercollegiate Athletics,* 44 FR 71413 (Dec. 11, 1979) (1979 Policy Interpretation), *https://www.govinfo.gov/content/pkg/FR-1979-12-11/pdf/FR-1979-12-11.pdf* (also available at *https://www.ed.gov/ocr/docs/t9interp.html*); *N. Haven Bd. of Educ.* v. *Bell,* 456 U.S. 512, 516, 531–32, 532 n.22 (1982) (noting the broad sweep of Title IX; that the original Title IX regulations, reviewed by Congress, covered athletics; and that a Senate resolution disapproving the regulations' application to athletics was introduced but not ''acted upon'').

In June 2020, the Supreme Court issued its decision in *Bostock* v. *Clayton County,* 140 S. Ct. 1731 (2020), holding that discrimination based on sexual orientation or gender identity is sex discrimination under Title VII of the Civil Rights Act of 1964. In January 2021, President Joseph R. Biden, Jr. issued Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation, which set out this Administration's policy ''to prevent and combat discrimination on the basis of gender identity or sexual orientation, and to fully enforce Title VII [of the Civil Rights Act of 1964] and other laws that prohibit discrimination on the basis of gender identity or sexual orientation.'' *Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation,* Exec. Order No. 13988, 86 FR 7023 (Jan. 25, 2021), *https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01761.pdf.* Executive Order 13988 directed the Secretary of Education, in consultation with the Attorney General, to ''review all existing orders, regulations, guidance documents, policies, programs, or other agency actions'' promulgated under any statute or regulation that prohibits sex discrimination for their consistency with the stated policy. *Id.*

The President subsequently issued Executive Order 14021 to ensure ''that all students [are] guaranteed an educational environment free from discrimination on the basis of sex, including discrimination in the form of sexual harassment, which encompasses sexual violence, and including discrimination on the basis of sexual orientation or gender identity.'' *Executive Order on Guaranteeing an Educational Environment Free from Discrimination on the Basis of Sex, Including Sexual Orientation or Gender Identity,* Exec. Order No. 14021, 86 FR 13803 (Mar. 11, 2021), *https://www.govinfo.gov/content/pkg/FR-2021-03-11/pdf/2021-05200.pdf.* This Executive Order, like Executive Order 13988, directed the Secretary of Education, in consultation with the Attorney General, to review all existing regulations, orders, guidance documents, policies and any other similar agency actions for consistency with Title IX, other governing laws, and the stated policy.

As these Executive Orders directed, the Department extensively reviewed its Title IX regulations and policy documents for consistency with Title IX's statutory prohibition on sex discrimination in federally funded education programs or activities. Based on this review and consideration of, among other things, substantial input from stakeholders, the Department published the July 2022 NPRM to amend its regulations implementing Title IX. 87 FR 41390.

In the course of its review, the Department also received feedback that the current regulations do not explicitly address the criteria, if any, a recipient may use to determine a student's eligibility to participate on a male or female athletic team consistent with Title IX and the Department's regulations. Based on this review and consideration of substantial input from stakeholders, the Department proposes amending its current regulations to address the unique circumstances of male and female athletic teams consistent with Title IX's prohibition on discrimination on the basis of sex. In particular, this Athletics NPRM proposes amending the Department's Title IX regulations to set out a standard that would govern a recipient's adoption or application of sex-related criteria that would limit or deny a student's eligibility to participate on male or female athletic teams consistent with their gender identity.

History of Title IX's Application to Athletic Programs

Enacted in 1972, Title IX provides that ''[n]o person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance.'' 20 U.S.C. 1681(a). Title IX includes several statutory exemptions and exceptions from its coverage, including for the membership practices of certain organizations, admissions to private undergraduate colleges, educational institutions that train individuals for the military services or merchant marine, and educational institutions that are controlled by a religious organization to the extent that application of Title IX would be inconsistent with the religious tenets of the controlling organization. 20 U.S.C. 1681(a)(1)–(9). Title IX authorizes and directs the Department, as well as other agencies, ''to effectuate the provisions of section 1681 of this title with respect to such program or activity by issuing rules, regulations, or orders of general applicability which shall be consistent with achievement of the objectives of the statute authorizing the financial assistance in connection with which the action is taken.'' 20 U.S.C. 1682.

In 1974, Congress enacted the Javits Amendment in response to concerns that Title IX would disrupt existing practices in intercollegiate athletics. It read:

> The [Department of Health, Education, and Welfare (HEW)] Secretary shall prepare and publish, not later than 30 days after the date of enactment of this Act, proposed regulations implementing the provisions of title IX of the Education Amendments of 1972 relating to the prohibition of sex discrimination in federally assisted education programs which shall include with respect to intercollegiate athletic activities reasonable provisions considering the nature of particular sports.

Education Amendments of 1974 section 844; *see also* S. Rep. No. 93–1026 (1974) (Conf. Rep.), *as reprinted in* 1974 U.S.C.C.A.N. 4206, 4271.

In 1975, HEW, the Department's predecessor, first promulgated regulations under Title IX[2] after multiple congressional hearings. 121 Cong. Rec. 20467 (1975) (statement of Sen. Birch Bayh). The regulations were subject to a statutory ''laying before'' provision, designed to afford Congress an opportunity to examine the proposed regulations and disapprove them by resolution within 45 days if Congress deemed them to be inconsistent with Title IX. *N. Haven Bd. of Educ.,* 456 U.S. at 531–32. The Supreme Court has stated that the fact that no such disapproval resolution was adopted

[2] 45 CFR part 86 (1975). In 1980, Congress created the U.S. Department of Education. Public Law 96–88, section 201, 93 Stat. 669, 671 (1979); Exec. Order No. 12212, 45 FR 29557 (May 5, 1980). By operation of law, all of HEW's determinations, rules, and regulations continued in effect, and all functions of HEW's Office for Civil Rights with respect to educational programs were transferred to the Secretary of Education. 20 U.S.C. 3441(a)(3). The regulations implementing Title IX were recodified without substantive change in 34 CFR part 106. *See* 45 FR 30802, 30955–65 (May 9, 1980).

''strongly implies that the [Title IX] regulations accurately reflect congressional intent.'' *Grove City Coll.* v. *Bell,* 465 U.S. 555, 568 (1984);[3] *see also N. Haven Bd. of Educ.,* 456 U.S. at 533–35.

Since 1975, the Department's regulations have specified that separate or differential treatment on the basis of sex is presumptively a form of prohibited sex discrimination. *See, e.g.,* 34 CFR 106.31(b)(4), (7) (''Except as provided for in this subpart, in providing any aid, benefit, or service to a student, a recipient shall not, on the basis of sex . . . [s]ubject any person to separate or different rules of behavior, sanctions, or other treatment; . . . [or] [o]therwise limit any person in the enjoyment of any right, privilege, advantage, or opportunity.''); *see also id.* at 106.34(a) (''Except as provided for in this section or otherwise in this part, a recipient shall not provide or otherwise carry out any of its education programs or activities separately on the basis of sex.''). These regulations reflect the understanding that subjecting students to differential treatment on the basis of sex in the education context is presumptively harmful and cannot be justified by reliance on ''overbroad generalizations about the different talents, capacities, or preferences of males and females.'' *United States* v. *Virginia,* 518 U.S. 515, 533 (1996).

Despite the general principle reflected in the Department's regulations that differential treatment or separation based on sex presumptively results in prohibited sex discrimination, Congress indicated in the Javits Amendment that a different approach to athletics was appropriate and that the Title IX regulations should include ''reasonable'' provisions governing intercollegiate athletic activities in light of ''the nature of particular sports.'' Education Amendments of 1974 section 844. HEW responded to this congressional direction by promulgating a regulation permitting sex separation in certain circumstances in ''any interscholastic, intercollegiate, club or intramural athletics offered by a recipient.'' 45 CFR 86.41 (1975) (currently codified at 34 CFR 106.41). As noted above, Congress had the opportunity to examine and disapprove HEW's regulations, including this athletics provision. Congress did not disapprove them, and the Title IX regulations took effect on July 21, 1975.

The now-longstanding athletics regulation states that ''[n]o person shall, on the basis of sex, be excluded from participation in, be denied the benefits of, be treated differently from another person or otherwise be discriminated against in any interscholastic, intercollegiate, club or intramural athletics offered by a recipient, and no recipient shall provide any such athletics separately on such basis.'' 34 CFR 106.41(a). The regulation then provides that when selection for an athletic team is based upon competitive skill or the activity involved is a contact sport, a recipient may offer sex-separate teams (though it is not required to do so). 34 CFR 106.41(b) (''[A] recipient may operate or sponsor separate teams for members of each sex where selection for such teams is based upon competitive skill or the activity involved is a contact sport.''). The regulation contemplates that in some circumstances, female students may try out for a male team, or vice versa: ''[W]here a recipient operates or sponsors a team in a particular sport for members of one sex but operates or sponsors no such team for members of the other sex, and athletic opportunities for members of that sex have previously been limited, members of the excluded sex must be allowed to try-out for the team offered unless the sport involved is a contact sport.'' *Id.* The regulation thus recognizes that in some instances individual students may be denied the opportunity to participate on a particular team on the basis of sex.

Importantly, the regulation goes on to say that a recipient must still provide equal opportunity in its athletic program as a whole. 34 CFR 106.41(c). Thus, a recipient that excludes a boy from the girls' golf team and does not offer a boys' golf team, for example, would have to provide equal opportunity based on sex across the totality of its athletic program, and disparities in overall participation opportunities in that program, including on male and female teams, could violate § 106.41(c), depending on the facts at issue. As one court explained, ''the provisions of title IX grant flexibility to the recipient of federal funds to organize its athletic program as it wishes, so long as the goal of equal athletic opportunity is met.'' *Williams* v. *Sch. Dist. of Bethlehem,* 998 F.2d 168, 171 (3d Cir. 1993) (citation omitted); *see also* U.S. Dep't of Health, Educ., and Welfare, Office for Civil Rights, *Sex Discrimination in Athletic Programs,* 40 FR 52655, 52656 (Nov. 11, 1975) (explaining that ''an institution would not be effectively accommodating the interests and abilities of women if it abolished all its women's teams and opened up its men's teams to women, but only a few women were able to qualify for the men's team'').

Although the Department's Title IX regulations have never explicitly addressed the criteria, if any, a recipient may use to determine a student's eligibility to participate on a male or female athletic team, OCR has previously articulated various interpretations of current § 106.41(b) as applied to transgender students (*i.e.,* students whose gender identity is different from the sex they were assigned at birth). In May 2016, OCR and the Civil Rights Division of the U.S. Department of Justice (DOJ) issued a joint Dear Colleague Letter stating that while a recipient may not ''adopt or adhere to requirements that rely on overly broad generalizations or stereotypes . . . or others' discomfort with transgender students[,] Title IX does not prohibit age-appropriate, tailored requirements based on sound, current, and research-based medical knowledge about the impact of the students' participation on the competitive fairness or physical safety of the sport.'' U.S. Dep't of Justice, Civil Rights Division, and U.S. Dep't of Educ., Office for Civil Rights, Dear Colleague Letter on Title IX and Transgender Students at 3 (May 13, 2016) (rescinded in 2017) (2016 Dear Colleague Letter on Title IX and Transgender Students) (footnote omitted), *https://www2.ed.gov/about/offices/list/ocr/letters/colleague-201605-title-ix-transgender.pdf.* In cases alleging gender identity discrimination in sex-separate programs and activities outside the context of athletic teams—*e.g.,* denying students access to sex-separate facilities consistent with their gender identity—several Federal courts have held that the Department's interpretation of 34 CFR 106.33 of its Title IX regulations, as reflected in the 2016 Dear Colleague Letter on Title IX and Transgender Students, was reasonable. *See, e.g., G.G. ex rel. Grimm* v. *Gloucester Cnty. Sch. Bd.,* 822 F.3d 709, 723 (4th Cir. 2016) (according controlling weight to the ''Department's interpretation of its own regulation,

[3] The Supreme Court in *NCAA* v. *Smith* subsequently described *Grove City College* as holding ''that Title IX, as originally enacted, covered only the specific program receiving federal funding.'' 525 U.S. 459, 466 n.4 (1999) (citing *Grove City Coll.,* 465 U.S. at 570–74). That part of the Court's holding was superseded by the Civil Rights Restoration Act (CRRA), in which Congress ''correct[ed] what it considered to be an unacceptable'' interpretation by the Supreme Court of the scope of Title IX. *Id.* (quoting *Franklin* v. *Gwinnett Cnty. Pub. Schs.,* 503 U.S. 60, 73 (1992)). The CRRA codifies Congress's interpretation of the terms ''program or activity'' and ''program'' as encompassing ''all of the operations of * * * . . . (2)(A) a college, university, or other postsecondary institution . . . * * * or (B) a local education agency . . . * * * or other school system . . .* * * any part of which is extended Federal financial assistance.'' 20 U.S.C. 1687.

§ 106.33''), *vacated and remanded,* 137 S. Ct. 1239, 197 L. Ed. 2d 460 (2017); *Bd. of Educ. of the Highland Loc. Sch. Dist.* v. *U.S. Dep't of Educ.,* 208 F. Supp. 3d 850, 870 (S.D. Ohio 2016) (same); *Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.,* No. 16–CV–943–PP, 2016 WL 5239829, at *3 (E.D. Wis. Sept. 22, 2016) (same), *aff'd sub nom. Whitaker by Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.,* 858 F.3d 1034 (7th Cir. 2017), *abrogated on other grounds as recognized by Ill. Republican Party* v. *Pritzker,* 973 F.3d 760, 762 (7th Cir. 2020).

In August 2016, however, a Federal district court issued an opinion finding that the interpretation set out in the 2016 Dear Colleague Letter on Title IX and Transgender Students did not undergo the notice-and-comment process required by the Administrative Procedure Act and was contrary to law. The district court granted a preliminary injunction barring the Departments of Education and Justice from relying on the 2016 Dear Colleague Letter on Title IX and Transgender Students in their enforcement of Title IX with respect to access to certain sex-separate facilities. *Texas* v. *United States,* 201 F. Supp. 3d 810, 836 (N.D. Tex. 2016); *see also Texas* v. *United States,* No. 7:16–CV–00054–O, 2016 WL 7852331, at *4 (N.D. Tex. Oct. 18, 2016) (clarifying that the preliminary injunction is ''limited to the issue of access to intimate facilities''). In February 2017, DOJ's Civil Rights Division and OCR issued a letter withdrawing the statements of policy and guidance reflected in the 2016 Dear Colleague Letter on Title IX and Transgender Students, stating that they made this change ''in order to further and more completely consider the legal issues involved.'' U.S. Dep't of Justice, Civil Rights Division, and U.S. Dep't of Educ., Office for Civil Rights, Dear Colleague Letter on Transgender Students at 1 (Feb. 22, 2017) (under review in light of Exec. Order No. 13988), *https://www2.ed.gov/about/offices/list/ocr/letters/colleague-201702-title-ix.pdf.* On March 3, 2017, the Federal district court dissolved the preliminary injunction when the plaintiffs voluntarily dismissed the lawsuit. Plaintiff's Notice of Voluntary Dismissal, *Texas* v. *United States,* No. 7:16–cv–00054 (N.D. Tex. Mar. 3, 2017), ECF No. 128.

In the months immediately following the Supreme Court's June 2020 decision in *Bostock,* 140 S. Ct. 1731, OCR made several statements on *Bostock*'s application to Title IX. For instance, on August 31, 2020, OCR issued a revised Letter of Impending Enforcement Action in its investigation of the Connecticut Interscholastic Athletic Conference (CIAC) and six school districts. OCR Case No. 01–19–4025, *Conn. Interscholastic Athletic Conf. et al.* (Aug. 31, 2020) (revised letter of impending enforcement action) (archived and marked not for reliance in February 2021) (Revised CIAC Letter), *https://www2.ed.gov/about/offices/list/ocr/docs/investigations/more/01194025-a2.pdf.* The letter stated that OCR was providing an update in light of *Bostock* and took the position that when a recipient provides ''separate teams for members of each sex'' under 34 C.F.R. §106.41(b), ''the recipient must separate those teams on the basis of biological sex'' and not on the basis of gender identity. Revised CIAC Letter at 36. The letter departed from OCR's typical practice concerning enforcement letters by stating that it ''constitutes a formal statement of OCR's interpretation of Title IX and its implementing regulations and should be relied upon, cited, and construed as such.'' *Id.* at 49.

In January 2021, the Department posted a memorandum from its General Counsel's office commenting on *Bostock*'s application to Title IX. U.S. Dep't of Educ., Memorandum from Principal Deputy General Counsel delegated the authority and duties of the General Counsel Reed D. Rubinstein to Kimberly M. Richey, Acting Assistant Secretary of the Office for Civil Rights re *Bostock* v. *Clayton Cnty.* (Jan. 8, 2021) (archived and marked not for reliance in March 2021) (Rubinstein Memorandum), *https://www2.ed.gov/about/offices/list/ocr/correspondence/other/ogc-memorandum-01082021.pdf.* The Rubinstein Memorandum stated that ''if a recipient chooses to provide 'separate teams for members of each sex' under 34 C.F.R § 106.41(b), then it must separate those teams solely on the basis of biological sex, male or female, and not on the basis of transgender status or sexual orientation, to comply with Title IX.''

In February 2021, OCR withdrew the Revised CIAC Letter, citing its inconsistency with Executive Order 13988 (describing *Bostock*) and the fact that it was issued without following the appropriate procedures required for issuing guidance.[4] Similarly, in March 2021, the Department archived the Rubinstein Memorandum and marked it ''not for reliance,'' citing its inconsistency with Executive Order 13988 and the fact that it was issued without the review required under the then-applicable Department's Rulemaking and Guidance Procedures, 85 FR 62597 (Oct. 5, 2020) (rescinded effective September 29, 2021).

In June 2021, the Departments of Justice and Education filed a Statement of Interest in a Title IX and equal protection challenge to a State law limiting students' eligibility to participate on female athletic teams consistent with their gender identity, emphasizing that ''[a]t its core, Title IX is about ensuring equal educational opportunities to all students regardless of their sex.'' Statement of Interest of the United States at 12, *B.P.J.* v. *W. Va. State Bd. of Educ.,* 550 F. Supp. 3d 347 (S.D. W. Va. 2021) (No. 2:21–cv–00316), *https://www.justice.gov/crt/case-document/file/1405541/download* (supporting the Title IX and equal protection claims raised by a transgender girl in middle school challenging the application of a State law prohibiting her from participating on her school's girls' athletic teams).[5] In April 2023, the Department of Justice filed a brief as amicus curiae in support of plaintiff-appellant B.P.J.'s appeal to the Fourth Circuit. *See* Brief for the United States as Amicus Curiae in Support of Plaintiff-Appellant and Urging Reversal, *B.P.J.* v. *W. Va. State Bd. of Educ.,* No. 23–1078 (4th Cir. Apr.

[4] OCR Case No. 01–19–4025, *Conn. Interscholastic Athletic Conf. et al.* (Feb. 23, 2021) (letter withdrawing Revised CIAC Letter), *https://www2.ed.gov/about/offices/list/ocr/docs/investigations/more/01194025-a5.pdf.* In December 2022, in related Federal court litigation over CIAC's athletic eligibility policy, a panel of the U.S. Court of Appeals for the Second Circuit noted that the policy—which permits high school students to participate on male and female athletic teams consistent with their gender identity—could not be said to fall ''within the scope of Title IX's proscriptions.'' *Soule by Stanescu* v. *Conn. Ass'n of Schs.,* 57 F.4th 43, 55 (2d Cir. 2022). Subsequently, the Second Circuit vacated the panel's opinion pending rehearing en banc. *See Soule by Stanescu* v. *Conn. Ass'n of Schs.,* No. 21–1365 (2d Cir. Feb. 13, 2023).

[5] The Federal district court initially granted a preliminary injunction barring implementation of the West Virginia law to exclude a transgender girl in middle school from participating on her school's girls' track and cross-country teams, *B.P.J.,* 550 F. Supp. 3d at 357. On January 5, 2023, the court granted a motion for summary judgment upholding West Virginia's law, concluding that the law does not violate the Equal Protection Clause or Title IX, and dissolving the preliminary injunction. *B.P.J.* v. *W. Va. State Bd. of Educ.,* No. 2:21-cv-00316, 2023 WL 111875, at *8–10 (S.D. W. Va. Jan. 5, 2023), *appeal docketed,* No. 23–1078 (4th Cir. Jan. 24, 2023). On February 22, 2023, a panel of the Fourth Circuit granted B.P.J.'s Motion for Stay of the District Court's January 5, 2023, Order dissolving the preliminary injunction pending appeal. *See B.P.J.* v. *W. Va. State Bd. of Educ.,* No. 23–1078 (4th Cir. Feb. 22, 2023). On March 9, 2023, the Defendants-Appellees submitted an application to the U.S. Supreme Court seeking to vacate the Fourth Circuit's injunction pending appeal. *See* Application to Vacate the Injunction Entered by the United States Court of Appeals for the Fourth Circuit, *W. Va. State Bd. of Educ.* v. *B.P.J.,* No. 22A800 (U.S. Mar. 9, 2023). The discussion below further addresses the district court's now-dissolved January 5, 2023, Order.

3, 2023), *https://www.justice.gov/crt/case-document/file/1577891/download.*

Separately, also in June 2021, in light of the Supreme Court's decision in *Bostock,* the Department issued a Notice of Interpretation to explain the Department's enforcement authority over discrimination based on sexual orientation and gender identity under Title IX. U.S. Dep't of Educ., Office for Civil Rights, Notice of Interpretation: Enforcement of Title IX with Respect to Discrimination Based on Sexual Orientation and Gender Identity in Light of *Bostock* v. *Clayton County,* 86 FR 32637 (June 22, 2021) (2021 Bostock Notice of Interpretation), *https://www.govinfo.gov/content/pkg/FR-2021-06-22/pdf/2021-13058.pdf.*[6] Against this backdrop and for reasons described in this preamble, the Secretary proposes to amend the Department's Title IX regulation in 34 CFR 106.41.

The Department's Review of Its Title IX Regulations

On April 6, 2021, OCR issued a letter to students, educators, and other stakeholders that informed them about the steps the Department was taking to review its regulations, orders, guidance, policies, and other similar agency actions under Title IX. U.S. Dep't of Educ., Office for Civil Rights, Letter from Acting Assistant Secretary Suzanne B. Goldberg to Students, Educators, and other Stakeholders re Executive Order 14021 (Apr. 6, 2021), *https://www.ed.gov/ocr/correspondence/stakeholders/20210406-titleix-eo-14021.pdf.* As directed by Executive Order 14021, this comprehensive review included OCR's review of all agency actions to determine whether changes to the Department's Title IX regulations are necessary to fulfill Title IX's mandate and OCR's commitment to ensuring equal and nondiscriminatory access to education for students at all education levels, regardless of sex. *See id.* at 2.

On May 20, 2021, OCR published a notice in the **Federal Register** announcing a nationwide virtual public hearing (referred to below as the ''June 2021 Title IX Public Hearing'') to gather information for the purpose of improving enforcement of Title IX. U.S. Dep't of Educ., Office for Civil Rights, Announcement of Public Hearing; Title IX of the Education Amendments of 1972, 86 FR 27429 (May 20, 2021), *https://www.govinfo.gov/content/pkg/FR-2021-05-20/pdf/2021-10629.pdf.* OCR expressed particular interest in comments about discrimination based on gender identity in educational environments, as well as other topics. *Id.* The virtual hearing was held from June 7, 2021, to June 11, 2021, during which time OCR received live comments through the virtual hearing platform and written comments via email. Over 280 students, parents, teachers, faculty members, school staff, administrators, and other members of the public provided live comments, and OCR received over 30,000 written comments by email. The transcript of live comments is available at *https://www2.ed.gov/about/offices/list/ocr/docs/202106-titleix-publichearing-complete.pdf,* and the written comments may be viewed at *https://www2.ed.gov/about/offices/list/ocr/public-hearing.html.*

In addition to soliciting live and written comments as part of the June 2021 Title IX Public Hearing, OCR also conducted listening sessions with stakeholders expressing a variety of views, including individuals and organizations focused on Title IX and athletics. Among these stakeholders were students, including current and former student-athletes; parents; athletic associations; organizations representing elementary schools, secondary schools, and postsecondary institutions; organizations representing teachers, administrators, parents, and current and former student-athletes; attorneys representing students and schools; State officials; Title IX Coordinators and other school administrators; and individuals who provide Title IX training to schools.

In the June 2021 Title IX Public Hearing, in listening sessions, and in correspondence, stakeholders posed questions and presented concerns regarding Title IX's application to determinations of whether a student is eligible to participate on a recipient's male or female athletic team, particularly in light of the shifting OCR guidance on this issue and the divergent approaches to such eligibility criteria taken by State laws and organizations that set eligibility rules for specific sports. Stakeholders highlighted the many benefits that students gain from participating on athletic teams, including learning skills that promote personal health, wellness, and leadership; being part of a team; and fostering social relationships.

Some stakeholders asserted that allowing students to participate on male or female athletic teams that align with their gender identity is consistent with Title IX's guarantee of nondiscrimination on the basis of sex. In the same vein, some stakeholders stressed that preventing transgender students from participating on their schools' male or female athletic teams consistent with their gender identity deprives those students of the benefits of athletic team participation because it is not tenable to require a transgender girl or woman to participate on a male athletic team or a transgender boy or man to participate on a female athletic team. Some stakeholders expressed concern that some policies and State laws restricting athletic eligibility to a student's sex assigned at birth may also disqualify intersex students (generally, persons with variations in physical sex characteristics, including variations in anatomy, hormones, chromosomes or other traits that differ from expectations generally associated with male and female bodies) from participating on male or female teams consistent with their gender identity if the sex assigned to those students at birth does not accurately reflect their gender identity. Stakeholders also expressed concern that certain policies and State laws might preclude nonbinary students (generally, persons who do not identify as exclusively male or female) from participating on either male or female teams, including in contexts in which those students' school records or other official documents indicate a nonbinary gender marker and the school's eligibility criteria limit participation to students with a male or female gender marker. By contrast, other stakeholders expressed concerns that participation of some transgender girls and women on female athletic teams could deprive other girls and women of access to the benefits associated with participation on athletic teams. Many stakeholders representing a range of views urged the Department to clarify whether and, if so, how students can participate on male or female athletic teams that align with their gender identity while ensuring fair and safe sports participation for all.

The Department's July 2022 NPRM proposed amendments to the Department's Title IX regulations would clarify, among other things, that Title IX prohibits discrimination based on gender identity and sex characteristics in federally funded education programs and activities. *See* 87 FR 41571. In addition, the proposed amendments would clarify that (a) in the limited circumstances in which Title IX or the Department's Title IX regulations permit different treatment or separation on the basis of sex, a recipient must not carry out such different treatment or

[6] A Federal district court preliminarily enjoined and restrained the Department from implementing the 2021 Bostock Notice of Interpretation against 20 States. *See Tennessee* v. *U.S. Dep't of Educ.,* No. 3:21–cv–308, 2022 WL 2791450, at *24 (E.D. Tenn. July 15, 2022), *appeal docketed,* No. 22–5807 (6th Cir. Sept. 13, 2022). This Athletics NPRM is not based on the 2021 Bostock Notice of Interpretation.

separation in a manner that discriminates on the basis of sex by subjecting a person to more than de minimis harm, unless otherwise permitted by Title IX or the Department's Title IX regulations; and (b) a policy or practice that prevents a person from participating in an education program or activity consistent with their gender identity subjects a person to more than de minimis harm on the basis of sex. *Id.* at 41534–37. The July 2022 NPRM also recognized that despite Title IX's general prohibition on sex discrimination against an individual, there are circumscribed situations, including with respect to sex-related eligibility criteria for male or female teams, in which Title IX or its regulations may permit a recipient to separate students on the basis of sex, even when doing so may cause some students more than de minimis harm. *Id.* at 41537. The July 2022 NPRM did not propose any changes to the Department's Title IX regulation governing athletics, however, instead reserving that issue for this Athletics NPRM. *Id.*

The Department now proposes amending its Title IX regulations to help ensure implementation of Title IX in what Congress has recognized as the unique context of athletics. *Cf.* Education Amendments of 1974 section 844 (specifying a requirement for ''reasonable provisions considering the nature of particular sports'' in the Department's Title IX regulations regarding intercollegiate athletics). The Department acknowledges the interest of some stakeholders in preserving current athletic-team policies and procedures regarding sex-related eligibility criteria and in avoiding potential additional costs to comply with the proposed regulation. However, the Department believes that the current regulations are not sufficiently clear to ensure Title IX's nondiscrimination requirement is fulfilled if a recipient adopts or applies sex-related criteria that would limit or deny students' eligibility to participate on male or female athletic teams consistent with their gender identity. This clarification regarding Title IX's application to sex-related eligibility criteria is particularly important as some States have adopted criteria that categorically limit transgender students' eligibility to participate on male or female athletic teams consistent with their gender identity. *See, e.g.,* Ind. Code section 20–33–13–4 (2022) (''A male, based on a student's biological sex at birth in accordance with the student's genetics and reproductive biology, may not participate on an athletic team or sport designated under this section as being a female, women's, or girls' athletic team or sport.''); W. Va. Code section 18–2–25d(c)(1) (2021) (designating participation on interscholastic, intercollegiate, intramural, or club athletic teams sponsored by any public secondary school or state institution of higher education as based on ''biological sex''); Idaho Code section 33–6203 (2020) (same). In so doing, these State laws have created additional uncertainty for stakeholders regarding what Title IX permits and requires with respect to male and female teams.

The standard proposed in this Athletics NPRM is consistent with the framework in the current § 106.41 for providing overall equal athletic opportunity regardless of sex for students who seek to participate in a recipient's athletic program. Taking into account extensive stakeholder questions about Title IX's application to sex-related eligibility criteria for male and female athletic teams, the Department's proposed regulation would provide that if a recipient adopts or applies sex-related criteria that would limit or deny a student's eligibility to participate on a male or female team consistent with their gender identity, such criteria must, for each sport, level of competition, and grade or education level, be substantially related to the achievement of an important educational objective and minimize harms to students whose opportunity to participate on a male or female team consistent with their gender identity would be limited or denied. The proposed regulation would continue to recognize, as has current § 106.41(b) since its promulgation in 1975, that some sex-related distinctions in sports are permissible as long as a recipient ensures overall equal athletic participation opportunity regardless of sex.

Further, it is the Department's intent that the severability clauses set out in the relevant subparts of 34 CFR part 106 would remain applicable to the proposed changes in this Athletics NPRM. It is also the Department's position that the proposed regulation, if adopted as a final rule, would serve an important purpose that is distinct from other provisions in part 106 and would operate independently of other regulatory provisions, such that any potential invalidity of the proposed regulation should not affect any other provisions in part 106.

Significant Proposed Regulation:

Section 106.41 Athletics

Statute: Title IX prohibits discrimination on the basis of sex under any education program or activity receiving Federal financial assistance. 20 U.S.C. 1681(a). The Department has the authority to regulate with regard to discrimination on the basis of sex in education programs or activities receiving Federal financial assistance, specifically under 20 U.S.C. 1682 and generally under 20 U.S.C. 1221e-3 and 3474. And the Javits Amendment reflects that the Department has discretion to tailor its regulations in the athletics context that it might not have in other contexts and to adopt ''reasonable provisions considering the nature of particular sports.'' Education Amendments of 1974 section 844.

Current regulations: Paragraph (a) of current § 106.41 establishes a baseline rule that no person shall, on the basis of sex, be excluded from participation in, be denied the benefits of, be treated differently from another person, or otherwise be discriminated against in any interscholastic, intercollegiate, club or intramural athletics offered by a recipient, and that no recipient may provide any such athletics separately on the basis of sex. Section 106.41(b) sets forth an exception that permits a recipient to offer separate male and female athletic teams when selection for such teams is based upon competitive skill or the activity involved is a contact sport. Paragraph (b) also states that when a recipient operates or sponsors a team in a particular sport for members of one sex but operates or sponsors no such team for members of the excluded sex, and athletic opportunities for members of the excluded sex have previously been limited, members of the excluded sex must be allowed to try out for the team offered unless the sport involved is a contact sport. The same paragraph lists examples of contact sports. Paragraph (c) states that even when a recipient offers separate male and female athletic teams, a recipient must provide overall equal athletic opportunity for the sexes.

Proposed regulation: The Department proposes adding to § 106.41(b) a standard that would govern a recipient's adoption or application of sex-related criteria that would limit or deny a student's eligibility to participate on a male or female team consistent with their gender identity. Specifically, the Department proposes renumbering current § 106.41(b) as proposed § 106.41(b)(1) and adding a new paragraph as proposed § 106.41(b)(2) to state that any such criteria a recipient adopts or applies must, for each sport, level of competition, and grade or education level (i) be substantially related to the achievement of an important educational objective, and (ii)

minimize harms to students whose opportunity to participate on a male or female team consistent with their gender identity would be limited or denied.

Reasons: In light of its review of Title IX and its regulations, stakeholder feedback, and developments in case law and in the sex-related eligibility criteria set by some school districts, States, and other organizations (including athletic associations and sport governing bodies), the Department proposes amending its regulations to provide greater clarity as to the standard that applies if a recipient adopts or applies sex-related criteria that would limit or deny a student's eligibility to participate on a male or female athletic team consistent with their gender identity. The proposed regulation is consistent with § 106.41's framework for providing equal opportunity regardless of sex in a recipient's athletic program as a whole and with Congress's direction that the Title IX regulations include ''reasonable provisions'' regarding athletics that ''consider[ ] the nature of particular sports.'' Education Amendments of 1974 section 844.

Development of the Proposed Regulation

In listening sessions, correspondence, and through the June 2021 Title IX Public Hearing, OCR received feedback from stakeholders on the educational and other benefits of student participation on athletic teams and the application of Title IX's nondiscrimination mandate to all student-athletes. The feedback also focused on how schools can provide nondiscriminatory athletic opportunities for all students and on factors that influence fairness in competition and prevention of sports-related injury. Amidst this variety of views, OCR heard that students, recipients, athletic associations, and others need clarity from the Department about the legal standards that would apply to ensure Title IX's nondiscrimination requirement is fulfilled if a recipient adopts or applies sex-related criteria that would limit or deny students' eligibility to participate on male or female athletic teams consistent with their gender identity. In developing the proposed regulation, the Department reviewed this stakeholder input as well as Title IX's statutory text and purpose, Title IX's regulatory framework, courts' interpretations of Title IX and the U.S. Constitution, and the existing approaches to sex-related eligibility criteria taken by a wide range of States, school districts and other organizations, including athletic associations and sport governing bodies.[7]

The Text and Purpose of Title IX

In developing the proposed regulation, the Department considered Title IX's statutory text, purpose, and legislative history, as well as the current regulatory framework and constitutional principles.

As noted above, Congress has been clear that Title IX prohibits sex discrimination in a recipient's athletic program and, recognizing the unique circumstances of athletics, that the Title IX regulations should include ''reasonable provisions'' governing athletic activities that ''consider[ ] the nature of particular sports.'' Education Amendments of 1974 section 844. The Department's now-longstanding Title IX regulation on athletics therefore reflects the unique circumstances of athletics, including intercollegiate athletics. The Department's proposed regulation would similarly reflect the unique circumstances of athletics by considering whether sex-related criteria adopted or applied by a recipient to determine eligibility for male and female athletic teams, for each sport, level of competition, and grade or education level, are substantially related to the achievement of an important educational objective and minimize harms to students whose opportunity to participate on a male or female team consistent with their gender identity would be limited or denied.

The proposed regulation would thus preserve and build on the current regulatory framework the Department has long used to evaluate whether a recipient offers its students an equal opportunity to participate in athletics consistent with Title IX. It is also consistent with current § 106.41, which prohibits sex discrimination in a recipient's athletic program in paragraph (a) and recognizes in paragraph (c) that while a recipient must provide equal opportunity regardless of sex in its athletic program *as a whole,* it may, in limited and defined circumstances set out in paragraph (b), deny individual students the opportunity to participate on a particular male or female team on the basis of their sex. In addition, the proposed regulation is consistent with OCR's longstanding policy of encouraging compliance with the Department's Title IX athletics regulation ''in a flexible manner that expands, rather than limits, student athletic opportunities.'' *See* Dear Colleague Letter: Athletic Activities Counted for Title IX Compliance (Sept. 17, 2008) (2008 Dear Colleague Letter on Title IX and Athletic Activities), *https://www2.ed.gov/about/offices/list/ocr/letters/colleague-20080917.pdf; see also* 1979 Policy Interpretation, 44 FR 71414 (noting that effectively accommodating the interests and abilities of male and female students in the selection of sports and levels of competition will, in most cases, ''entail development of athletic programs that substantially expand opportunities for women to participate and compete at all levels'').

The proposed regulation is also informed by constitutional principles. In particular, Federal courts' equal protection analysis provides a helpful framework for evaluating when certain sex-based classifications may be justified. *See, e.g.,* 34 CFR 106.34(b) (setting out Title IX regulatory standard for single-sex classes that reflects certain aspects of Federal courts' equal protection framework); U.S. Dep't of Educ., Office for Civil Rights, *Final Rule: Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance,* 71 FR 62530, 62533 (Oct. 25, 2006) *https://www.govinfo.gov/content/pkg/FR-2006-10-25/pdf/E6-17858.pdf.* Notably, however, because the scope of Title IX differs from the scope of the Equal Protection Clause, the Department's current and proposed Title IX regulations, while informed by constitutional principles, exclusively implement Title IX. *See* 71 FR 62533.

Court Decisions Regarding Sex-Related Eligibility Criteria

In developing the proposed regulation, the Department also reviewed court decisions analyzing allegations that various policies governing transgender students' eligibility to participate on male or female athletic teams discriminate impermissibly based on sex. Several courts have found that excluding transgender students from participating

[7] The policies of athletic associations, sport governing bodies, State agencies, and other entities, or excerpts thereof referenced throughout this document are examples of various approaches that these entities have taken regarding sex-related eligibility criteria for male and female athletic teams. The Department includes them here to illustrate various points in this preamble; it does not require a recipient to adopt or apply the examples mentioned here, and their inclusion in this preamble is not an endorsement by the Department of any policy or practice, nor does it indicate whether the policy or practice would comply with the standard proposed in this Athletics NPRM. Any links to websites from outside of the Department are provided for the reader's convenience only. The Department does not control or guarantee the accuracy, relevance, timeliness, or completeness of this outside information. Examples and links included in this preamble do not constitute legal advice, create legal obligations, or impose new requirements.

on athletic teams consistent with their gender identity impermissibly discriminates against these students based on sex. In one case, for example, a Federal district court preliminarily enjoined a school district from excluding a fifth-grade transgender girl from the girls' softball team under an Indiana law that categorically precluded transgender girls and women from being treated consistent with their gender identity for purposes of female athletic teams. *A.M.* v. *Indianapolis Pub. Schs.,* No. 1:22–cv–01075–JMS–DLP, 2022 WL 2951430, at *14 (S.D. Ind. July 26, 2022), *vacated as moot,* (S.D. Ind. Jan. 19, 2023).[8] Adopting the Supreme Court's reasoning in *Bostock* and following controlling Seventh Circuit authority, the court held that the plaintiff had ''established a strong likelihood that she will succeed on the merits of her Title IX claim'' that the Indiana law discriminated against her on the basis of sex. *Id.* at * 11. As the court explained, prohibiting an individual from playing on a team consistent with their gender identity '''punishes that individual for his or her gender non-conformance,' which violates the clear language of Title IX.'' *Id.* (citations omitted). The court also stated that under current case law, this conclusion was ''not even a close call.'' *Id.*

In another case, a Federal district court preliminarily enjoined the State of Idaho from enforcing a state law that ''excludes transgender women from participating on women's sports teams.'' *Hecox* v. *Little,* 479 F. Supp. 3d 930, 943, 988 (D. Idaho 2020), *appeal argued,* No. 20–35815 (9th Cir. Nov. 22, 2022). In *Hecox,* the court found that, in light of ''the dearth of evidence in the record to show excluding transgender women from women's sports supports sex equality, provides opportunities for women, or increases access to college scholarships,'' the transgender student plaintiff was likely to succeed in establishing that the Idaho statute violates her right to equal protection. *Id.* at 978–85. The court explained that the Idaho law, which draws a distinction based on the quasi-suspect classifications of sex and transgender status, must, under the Supreme Court's established equal protection doctrine, ''serve important governmental objectives and must be substantially related to achievement of those objectives.'' *Id.* at 973 (quoting *Craig* v. *Boren,* 429 U.S. 190, 197 (1976)). Although the court recognized that '''redressing past discrimination against women in athletics and promoting equality of athletic opportunity between the sexes' is 'a legitimate and important governmental interest' justifying rules excluding males from participating on female teams,'' it concluded that that interest does ''not appear to be implicated by allowing transgender women to participate on women's teams.'' *Id.* at 976 (quoting *Clark ex rel. Clark* v. *Ariz. Interscholastic Ass'n,* 695 F.2d 1126, 1131 (9th Cir. 1982)). On this point, the court noted both that the small population of transgender athletes would not ''substantially displace'' cisgender female athletes and that ''it is not clear that transgender women who suppress their testosterone have significant physiological advantages over cisgender women.'' *Id.* at 978. As the court explained, ''[t]hat the Act essentially bars consideration of circulating testosterone illustrates the Legislature appeared less concerned with ensuring equality in athletics than it was with ensuring exclusion of transgender women athletes.'' *Id.* at 984.

The court's equal protection analysis in *Hecox* is instructive and relevant to the Department's proposed Title IX regulation in several respects: the court examined interests commonly proffered to defend policies denying transgender students the opportunity to participate on male or female athletic teams consistent with their gender identity, considered whether such policies actually advance any important objectives, and further considered the effects of those policies on students' equal opportunity to participate in and benefit from their schools' education programs and activities. *See, e.g., Hecox,* 479 F. Supp. 3d at 977 (''[T]he Act's categorical exclusion of transgender women and girls entirely eliminates their opportunity to participate in school sports. . . .'').

Conversely, another Federal district court upheld a West Virginia law against a challenge brought by a transgender girl who, because of the law, was excluded from participating on her middle school's girls athletic teams, concluding that the law satisfied both equal protection and Title IX. *B.P.J.,* 2023 WL 111875, at * 8, * 10.[9] The court agreed with the plaintiff that the law classified students based on sex. It then observed, in its equal protection analysis, that the State could ''allow transgender individuals to play on the team with which they, as an individual, are most similarly situated at a given time,'' but concluded that the categorical ban on participation by transgender students consistent with their gender identity was substantially related to the State's asserted interest in providing equal athletic opportunity for girls and women. *Id.* at *8. With respect to Title IX, the court observed that: (1) current § 106.41(b) permits sex-separate athletic teams; (2) '' 'the motivation for the promulgation of the regulation' was to increase opportunities for women and girls in athletics''; and (3) § 106.41(b)'s ''endorsement of sex separation in sports refers to biological sex.'' *Id.* at *9 (citation omitted).

With regard to the court's third observation, the Department notes that current § 106.41(b) permits a recipient to offer ''teams for members of each sex,'' without defining that term, and also notes the longstanding application of this provision to permit a recipient to offer teams for women and men, and for girls and boys. The Department recognizes that although the court in *B.P.J.* interpreted the Title IX statute and § 106.41(b) in a way that permits categorical exclusion of transgender students from participating consistent with their gender identity, other courts have set out a different interpretation of Title IX and its implementing regulations governing sex-separation in education programs and activities, *see, e.g., Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 618–19 (4th Cir.), *as amended* (Aug. 28, 2020), *cert. denied,* 141 S. Ct. 2878 (2021); *A.M.,* 2022 WL 2951430, at *7–11, underscoring the value of this proposed rulemaking in clarifying the Department's interpretation of its Title IX regulations.[10]

[8] On January 19, 2023, after the parties filed a Joint Stipulation to Dismiss Case Because of Mootness indicating that the plaintiff had enrolled in a charter school not operated by defendant Indianapolis Public Schools, the Federal district court issued an Acknowledgement of Dismissal and vacated the preliminary injunction because of mootness. *A.M.,* No. 1:22–cv–01075–JMS–DLP (S.D. Ind. Jan. 19, 2023). In its Acknowledgement of Dismissal, the court did not repudiate its prior determination that the plaintiff had a strong likelihood of success on the merits of her Title IX claim, as discussed in this preamble.

[9] As explained in Note 5 above, the district court initially issued a preliminary injunction barring enforcement of a State law that would ban the plaintiff from participating on girls' sports teams at school based on the strong likelihood that the West Virginia law violated the Equal Protection Clause and Title IX. *B.P.J.,* 550 F. Supp. 3d 347, 357. On January 5, 2023, the District Court issued an order dissolving the preliminary injunction and finding the West Virginia law did not violate the Equal Protection Clause or Title IX. 2023 WL 111875, at *8, *10. The plaintiff appealed and a panel of the Fourth Circuit enjoined the District Court's January 5, 2023, Order pending the outcome of the appeal, *see B.P.J.* v. *W. Va. State Bd. of Educ.,* No. 23–1078 (4th Cir. Feb. 22, 2023), which the Defendants-Appellees have petitioned the U.S. Supreme Court to vacate. *See* Application to Vacate the Injunction Entered by the United States Court of Appeals for the Fourth Circuit, *W. Va. State Bd. of Educ.* v. *B.P.J.,* No. 22A800 (U.S. Mar. 9, 2023).

[10] A decision of the United States Court of Appeals for the Eleventh Circuit likewise highlights

Courts have not addressed Title IX's application to intersex or nonbinary student-athletes. The Department believes the proposed regulation would provide an appropriate Title IX framework for analyzing a recipient's adoption or application of sex-related criteria that limit or deny an intersex student's eligibility to participate on a male or female team consistent with their gender identity. When applying sex-related criteria to nonbinary students, a recipient may need to determine whether the criteria do, in fact, limit or deny a nonbinary student's eligibility to participate on a male or female team consistent with their gender identity to determine whether the proposed regulation would apply.

Existing Approaches to Eligibility Criteria for Male and Female Teams

In addition to the considerations just discussed in developing this proposed regulation, the Department considered a variety of existing approaches to eligibility criteria for male and female teams that affect students' opportunity to participate on such teams consistent with their gender identity. Some States, as well as many school districts and athletic associations, have for many years adopted or applied eligibility criteria that do not restrict students from participating on male or female athletic teams consistent with their gender identity. Other States and organizations have, particularly in recent years, adopted policies that exclude some or all transgender students from participating on male or female athletic teams consistent with their gender identity or have adopted eligibility criteria that relate to birth certificates, physical examinations, or medical treatment.

At the postsecondary level, for example, the National Collegiate Athletic Association (NCAA) in 2022 replaced its longstanding policy describing transgender students' eligibility to participate on a male or female college athletic team in the NCAA with a sport-by-sport approach. *See* NCAA, *Transgender Student-Athlete Participation Policy* (Jan. 2022) (NCAA 2022 Policy); *https://www.ncaa.org/sports/2022/1/27/transgender-participation-policy.aspx;* NCAA, *2010 NCAA Policy on Transgender Student-Athlete Participation* (2010), *https://ncaaorg.s3.amazonaws.com/inclusion/lgbtq/INC_TransgenderStudentAthleteParticipationPolicy.pdf.* The NCAA 2022 Policy calls for its member colleges and universities to follow the criteria for transgender students' participation in college sports set by national bodies governing individual sports, which are subject to review by the NCAA's Committee on Competitive Safeguards and Medical Aspects of Sports. In announcing these changes, the NCAA emphasized its support for preserving transgender students' opportunity to participate in team sports and the importance of inclusive, fair, safe, and respectful environments for competition across college sports. *See* NCAA, *Board of Governors Updates Transgender Participation Policy* (Jan. 19, 2022), *https://www.ncaa.org/news/2022/1/19/media-center-board-of-governors-updates-transgender-participation-policy.aspx.*

This change in the NCAA's policy follows a similar change by the International Olympic Committee (IOC) regarding athletes' participation in high-level international competition. IOC, *IOC Framework on Fairness, Inclusion, and Non-Discrimination on the Basis of Gender Identity and Sex Variations* (Nov. 2021) (IOC Framework), *https://stillmed.olympics.com/media/Documents/News/2021/11/IOC-Framework-Fairness-Inclusion-Non-discrimination-2021.pdf;* IOC, *IOC Consensus Meeting on Sex Reassignment and Hyperandrogenism* (Nov. 2015), *https://stillmed.olympic.org/Documents/Commissions_PDFfiles/Medical_commission/2015-11_ioc_consensus_meeting_on_sex_reassignment_and_hyperandrogenism-en.pdf.* The IOC Framework recognizes ''the need to ensure that everyone, irrespective of their gender identity or sex variations, can practise sport in a safe, harassment-free environment that recognises and respects their needs and identities'' and that its new ''principles . . . aim to ensure that competition [in male and female] categories is fair and safe and that athletes are not excluded solely on the basis of their transgender identity or sex variations.'' IOC Framework at 1, 2. The IOC Framework encourages bodies governing individual sports—''particularly those in charge of organising elite-level competition''—to develop eligibility criteria for sex-separate competition that ''tak[e] into consideration the nature of each sport,'' *id.* at 1, to work together to ''advance inclusion and prevent discrimination based on gender identity and/or sex variations,'' *id.* at 2, and to ensure that any eligibility restrictions are ''evidence-based'' and account for any unique competitive advantage or risk associated with a specific sport, *id.* at 4. The IOC Framework also provides that ''until evidence . . . determines otherwise, athletes should not be deemed to have an unfair or disproportionate competitive advantage due to their sex variations, physical appearance and/or transgender status.'' *Id.* at 4.

In response to the shift by the NCAA and IOC to a sport-specific approach, several sport governing bodies that set criteria for certain non-school-based national and international competition, as well as postsecondary athletic competition, have announced plans to review their policies or have adopted or applied new policies regarding sex-related eligibility criteria. Governing bodies in gymnastics, rowing, and volleyball, for example, have announced policies that allow athletes to participate consistent with their gender identity at lower or non-elite levels of

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the need for the Department to clarify Title IX's application to transgender students in those limited and discrete contexts in which Title IX or its implementing regulations otherwise allow a recipient to separate students on the basis of sex. *See Adams* v. *Sch. Bd. of St. Johns Cnty.,* 57 F.4th 791 (11th Cir. 2022) (en banc). In *Adams,* the court determined a school policy that excluded a transgender boy from using the male restroom at his school did not violate the Equal Protection Clause, *id.* at 810–11, or Title IX, *id.* at 811–17. The *Adams* court recognized that the school's restroom policy classified students based on sex. *Id.* at 801. The court held, however, that the term ''sex'' in 34 CFR 106.33, which allows a recipient to ''provide separate toilet . . . facilities on the basis of sex,'' should be understood to mean ''biological sex,'' *see Adams,* 57 F.4th at 814–15. It further concluded that the regulation therefore permitted a recipient to deny transgender students access to restrooms consistent with their gender identity, without considering the distinct sex-based harms that such students suffer from such exclusion. For the Department's views on some of the issues raised in *Adams,* see En Banc Brief for the United States as Amicus Curiae in Support of Plaintiff-Appellee and Urging Affirmance at 22–28, *Adams,* 57 F.4th 791 (No. 18–13592), *https://www.justice.gov/crt/case-document/file/1458461/download. See, e.g., id.* at 22 (recognizing that the Department's Title IX regulation allows for sex-separate restrooms, but noting that the regulation does not speak to how it applies to transgender students).

The claims in *Adams* did not involve athletics or the athletics regulation that is the subject of this Athletics NPRM (34 CFR 106.41). The Department notes the court's statement in dicta, in reference to the Department's current athletics regulation, that ''equating 'sex' to 'gender identity' or 'transgender status' would also call into question the validity of sex-separated sports teams,'' *Adams,* 57 F.4th at 816–17, differs from the approach proposed in this Athletics NPRM. As discussed above, the Department's longstanding view is that sex-separate teams can in some instances advance Title IX's goals, and that as a general matter, a recipient may offer male and female athletic teams as long as they provide overall equal athletic opportunity consistent with Title IX's nondiscrimination guarantee. The proposed regulation would not alter this position and instead, for reasons discussed throughout this preamble, would provide the necessary clarity to help ensure that recipients continue to provide equal opportunity for students, consistent with Title IX, on their male and female athletic teams.

competition, such as in competitions where athletes are not competing for a place on a national team to represent the United States in international competition, or where the rules of international sport governing bodies would not apply. *See, e.g.,* USA Gymnastics, *Transgender & Non-Binary Athlete Inclusion Policy* at 2 (Apr. 2022), *https://usagym.org/PDFs/About USAGymnastics/transgender_policy.pdf* (''Transgender and non-binary athletes in levels other than Elite are permitted to compete without restriction in the gender category with which they identify.''); USRowing, *Gender Identity Policy* (Feb. 13, 2023), *https://usrowing.org/documents/2022/11/28/Gender_Identity_Policy_021323.pdf* (''*A*thletes at the youth level (youth, junior, high school, scholastic, [and certain other levels, excluding collegiate and international competition]) shall be allowed to participate in a rowing activity in accordance with their expressed gender identity irrespective of the sex listed on the athlete's birth certificate or student records, and regardless of whether the athlete has undergone any medical treatment . . . .''); USA Volleyball, *Gender Competition Guidelines (2022–23 Season), https://usavolleyball.org/about/gender-guidelines* (last visited Apr. 1, 2023) (''[n]o restrictions'' for transgender girls ages 12 and under seeking to play on girls' teams outside of international competition).

In the international, non-school-based context, some sport governing bodies have adopted policies restricting participation in high-level international women's competition to female athletes who have not experienced male puberty, *see, e.g.,* International Swimming Federation (FINA), *Policy on Eligibility for the Men's and Women's Competition Categories* (June 19, 2022) (FINA Policy on Eligibility), *https://resources.fina.org/fina/document/2022/06/19/525de003-51f4-47d3-8d5a-716dac5f77c7/FINA-INCLUSION-POLICY-AND-APPENDICES-FINAL-.pdf;* or restricting participation in international events and setting of certain recognized world records to those who satisfy specific testosterone suppression criteria for a set period of time, *see, e.g.,* Union Cycliste Internationale, *Eligibility Regulations for Transgender Athletes* (June 22, 2022) (UCI Eligibility Regulations), *https://assets.ctfassets.net/761l7gh5x5an/Et9v6Fyux9fWPDpKRGpY9/96949e5f7bbc8e34d536731c504ac96f/Modification_Transgender_Regulation_22_Juin_2022_ENG.pdf.* In addition, at least one international governing body has announced plans to revisit its existing criteria with the stated goal of creating inclusive policies that allow for safe participation and fairness in high-level international competition. *See, e.g.,* World Lacrosse, *World Lacrosse Forms Partnership with National Center for Transgender Equality to Create Trans-Inclusive Participation Policy* (June 9, 2022), *https://world lacrosse.sport/article/world-lacrosse-forms-partnership-with-national-center-for-transgender-equality.*

At the secondary school level, State athletic associations have discussed whether and how to adopt sex-related eligibility criteria against the backdrop of State and Federal law, schools' experiences with transgender students' participation in athletics, and the context and purpose of interscholastic athletics. *See, e.g.,* Luke Modrovsky, *Transgender Athletes—Participation, Equity and Competition* (May 12, 2022), *https://www.nfhs.org/articles/transgender-athletes-participation-equity-and-competition.* A report on these discussions includes an observation from a statewide athletic official that although competition is an integral aspect of athletics, the opportunity to participate in athletics at the elementary and secondary levels also serves other educational purposes, including learning to work as a team and building skills. *See id.* (quoting the executive director of a State athletic association explaining that ''the purpose of interscholastic activities is meant to be education-based and not for the sole purpose of achieving scholarships, championship titles and wider recognition in the sport'' and that ''[i]nterscholastic activities remain an opportunity to develop a connection with teammates and the school community, in addition to social, emotional, physical and cognitive development'').

A number of State athletic associations that oversee interscholastic athletics at the secondary school level, as well as school districts, have adopted policies permitting transgender students to participate on athletic teams consistent with their gender identity with minimal or no restrictions. *See, e.g.,* Wash. State Interscholastic Activities Ass'n, *Gender Diverse Youth Sport Inclusivity Toolkit* at 8, 11 (2021), *http://wiaa.com/ConDocs/Con1914/GenderDiverseToolkit.pdf* (''All students should have the opportunity to participate in WIAA athletics and/or activities in a manner that is consistent with their gender identity. . . . Athletes will participate in programs [offered separately for boys and girls] consistent with their gender identity . . . .''); R.I. Interscholastic League, *Rules & Regulations* at art. 3, § 3(B) (2022), *https://www.riil.org/page/3033* (''The RIIL has concluded that it would be fundamentally unjust and contrary to applicable state and federal laws, to preclude a student from participation on a gender specific sports team that is consistent with the public gender identity of that student for all other purposes.''); L.A. Unified Sch. Dist., *Policy Bulletin: Gender Identity and Students—Ensuring Equity and Nondiscrimination* at section II.H.2 (May 17, 2019), *https://achieve.lausd.net/cms/lib/CA01000043/Centricity/Domain/383/BUL-6224.2%20Transgender%20Policy%205%2013%2019.pdf (*''Participation in competitive athletics, intramural sports, athletic teams, competitions and contact sports shall be facilitated in a manner consistent with the student's gender identity. . . .''). Other State athletic associations governing interscholastic sports at the middle school and high school level have adopted sex-related criteria that may restrict some students from participating on male or female teams consistent with their gender identity. *See, e.g.,* N.M. Activities Ass'n, *Eligibility Bylaws* section 6.1 (July 1, 2022), *https://www.nmact.org/file/Section_6.pdf* (''Participating students are required to compete in the gender listed on their original or amended birth certificate.''); Wis. Interscholastic Athletic Ass'n, *Transgender Participation Policy* (2018), *https://www.wiaawi.org/Portals/0/PDF/Eligibility/WIAAtransgenderpolicy.pdf* (requiring, among other things, that transgender girls undergo one year of testosterone suppression therapy to be eligible to participate on a female team).

The Department finds the work of these organizations on this issue to be informative to the extent the organizations aim to balance important interests, minimize harm to students whose opportunity to participate on a male or female team consistent with their gender identity would be limited or denied, and take account of the sport, level of competition, and grade or education level of students.

Opportunity To Participate on Male and Female Teams Consistent With Gender Identity

In light of the many positive benefits of participation in school athletics discussed above, the Department's proposed regulation reflects the understanding that students may be harmed significantly if a school denies them the opportunity to participate in its athletic program consistent with their gender identity. As discussed

elsewhere in this preamble, participation on a team that is inconsistent with a student's gender identity is not a viable option for many students. *See, e.g., A.M.,* 2022 WL 2951430, at * 11 (describing a policy that prohibited students from participating on teams consistent with their gender identity as ''punish[ing]'' those students); *Hecox,* 479 F. Supp. 3d at 977 (''Participating in sports on teams that contradict one's gender identity is equivalent to gender identity conversion efforts, which every major medical association has found to be dangerous and unethical.'' (internal quotation marks and citation omitted)).

Federal and State courts also have identified additional, specific harms to transgender students from being excluded from team participation consistent with their gender identity, which the Department recognizes are distinct from the harms to students who are denied the opportunity to participate on a particular team based on sex under the circumstances permitted in the Department's longstanding athletics regulation. *See, e.g., A.M.,* 2022 WL 2951430, at * 6, * 12 (noting that ''[p]laying softball helps to lessen the distressing symptoms of gender dysphoria that A.M. suffers from and has allowed her to experience life more fully as a girl'' and ''[s]oftball participation has resulted in a better self-image and confidence for A.M.'' whereas ''prohibiting A.M. from playing on the girls' softball team will 'out' her to her classmates'' and ''undermine her social transition''); *Hecox,* 479 F. Supp. 3d at 987 (finding that a State law preventing transgender women from participating on women's athletic teams sponsored by public schools would harm the plaintiff, a transgender woman, by denying her the opportunity to try out for and compete on women's teams, subjecting her to the State's moral disapproval of her identity, and subjecting her to the possibility of embarrassment, harassment, and invasion of privacy through having to verify her sex); *Roe* v. *Utah High Sch. Activities Ass'n,* No. 220903262, 2022 WL 3907182, at * 9–10 (Utah 3d Jud. Dist. Aug. 19, 2022) (describing irreparable harm to mental and physical health that the plaintiffs, three transgender girls, ''have suffered, and will continue to suffer'' as a result of a Utah law banning transgender girls from participating on girls' athletic teams and recognizing that ''the stigma caused by the Ban has been immediate'').

Federal courts have also recognized that, because of these harms, excluding transgender students from participating on male or female athletic teams consistent with their gender identity can violate Title IX's prohibition on sex discrimination. *See, e.g., A.M.,* 2022 WL 2951430, at * 11 (finding strong likelihood of success on the merits of the Title IX claim because prohibiting an individual from playing on a team consistent with their gender identity '''punishes that individual for his or her gender non-conformance,' which violates the clear language of Title IX'' (citation omitted)); *see also Hecox,* 479 F. Supp. 3d at 977, 987 (in a case involving an equal protection claim, finding that a transgender college student faced ''irreparable harm'' from Idaho law categorically barring transgender girls and women from participating on girls' or women's teams and that the law ''entirely eliminates their opportunity to participate in school sports''). As noted above, the court in *B.P.J.* reached a different conclusion about the permissibility under Title IX of a ban on transgender students participating in team sports consistent with their gender identity, based on its view that the current regulation would permit such an exclusion and that transgender girls could try out for the boys' teams. 2023 WL 111875, at * 9 (citing 34 CFR 106.41(b) and (c)).

Elements of the Proposed Regulation

The proposed regulation would require that if a recipient adopts or applies sex-related criteria that would limit or deny a student's eligibility to participate on a male or female team consistent with their gender identity, such criteria must, for each sport, level of competition, and grade or education level: (i) be substantially related to the achievement of an important educational objective, and (ii) minimize harms to students whose opportunity to participate on a male or female team consistent with their gender identity would be limited or denied. The proposed regulation would not affect a recipient's discretion under current § 106.41(b) to offer separate male and female athletic teams when selection is based on competitive skill or the activity involved is a contact sport. The following discussion separately addresses key elements of the proposed regulation.

Eligibility Criteria Covered by the Proposed Regulation

The proposed regulation would govern a narrow category of athletic eligibility criteria: only those sex-related criteria that would limit or deny a student's eligibility to participate on a male or female team consistent with their gender identity. Many schools have adopted criteria that govern students' eligibility to participate on athletic teams that are unrelated to sex, such as attendance or academic standing requirements (*e.g.,* minimum grade-point average for all student-athletes). Criteria such as these are outside the scope of the proposed regulation.

By contrast, eligibility criteria would fall within the scope of the proposed regulation if they are sex-related (*e.g.,* they relate to how a student's sex is determined for team-eligibility purposes, including by imposing eligibility requirements related to a student's sex characteristics) and they would limit or deny students' eligibility to participate on a male or female team consistent with their gender identity. These criteria could include, for example, a requirement limiting or denying a student's eligibility for a male or female team based on a sex marker on an identification document, such as a birth certificate, passport, or driver's license. Criteria requiring physical examinations or medical testing or treatment related to a student's sex characteristics would also fall within the proposed regulation's scope if the results of such examinations or testing or requiring such treatment could be used to limit or deny a student's eligibility to participate consistent with their gender identity. Such criteria, like other sex-related eligibility criteria, would have to adhere to the proposed regulation's requirements, including the requirement to minimize harms.

The proposed regulation would not prohibit all uses of sex-related criteria; rather, it would require that if such criteria limit or deny a student's eligibility to participate on a male or female team consistent with their gender identity, those criteria, for each sport, level of competition, and grade or education level, would have to be substantially related to the achievement of an important educational objective and minimize harms to students whose opportunity to participate on a male or female team consistent with their gender identity would be limited or denied.

Additionally, the proposed regulation would apply only to those sex-related criteria that would ''limit or deny'' students' eligibility to participate consistent with their gender identity. Sex-related criteria would ''limit'' eligibility if, for example, they do not allow transgender students to participate fully on a male or female team consistent with their gender identity (*e.g.,* by permitting a student to participate in some but not all competitions). Sex-related criteria

would ''deny'' students' eligibility to participate consistent with gender identity if they foreclose students' opportunity to participate on male or female teams consistent with their gender identity (*e.g.,* by requiring transgender students to participate consistent with their sex assigned at birth or by prohibiting transgender girls who have undergone endogenous puberty from participating on girls' teams).

Substantially Related to the Achievement of an Important Educational Objective

The proposed regulation would require that sex-related criteria be ''substantially related to the achievement of an important educational objective'' if those criteria would limit or deny students' eligibility to participate on male or female athletic teams consistent with their gender identity. Proposed § 106.41(b)(2) does not specify the objectives that a recipient may assert and instead would implement Title IX's guarantee of equal opportunity in education by, in part, specifying that the criteria must serve an important educational objective.

The Department's proposed regulation is similar to the approach in the Department's current Title IX regulation governing single-sex classes, 34 CFR 106.34(b), which permits certain recipients to offer single-sex classes when the single-sex nature of the class is ''based on the recipient's important objective'' and ''substantially related to achieving that objective.'' That regulation limits a recipient to one of two specific important educational objectives.[11] Although the proposed athletics regulation would not limit the important educational objectives a recipient may seek to achieve, ensuring fairness in competition and prevention of sports-related injury are examples of possible important educational objectives that recipients have asserted and might assert in the future. As with the single-sex classes regulation, this proposed regulation is informed by case law interpreting the Equal Protection Clause, which requires public schools to demonstrate that any sex-based classification they seek to impose is substantially related to the achievement of an important governmental objective. *See Virginia,* 518 U.S. at 532–33; *Hecox,* 479 F. Supp. 3d at 973; *see also* 71 FR 62533.

The Department notes that a recipient could not satisfy the proposed regulation's requirement that criteria be substantially related to achieving an important educational objective if its objective is communicating or codifying disapproval of a student or a student's gender identity. *See, e.g., Hecox,* 479 F. Supp. 3d. at 987 (describing Idaho's restriction as impermissibly communicating the State's moral disapproval of the transgender plaintiff's identity); *cf. Romer* v. *Evans,* 517 U.S. 620, 634–35 (1996) (''[I]f the constitutional conception of ''equal protection of the laws'' means anything, it must at the very least mean that a bare . . . desire to harm a politically unpopular group cannot constitute a *legitimate* governmental interest.'' '' (alterations and emphasis in original) (quoting *Dep't of Agric.* v. *Moreno,* 413 U.S. 528, 534 (1973))). Nor may a recipient adopt sex-related criteria solely for the purpose of excluding transgender students from sports, *Hecox,* 479 F. Supp. 3d at 984–85 (noting the State of Idaho failed to identify a legitimate interest served by the State law that State and athletic association rules did not already address, ''other than an invalid interest of excluding transgender women and girls from women's sports entirely, regardless of their physiological characteristics''), or to require adherence to sex stereotypes, *Virginia,* 518 U.S. at 533 (affirming that States ''must not rely on overbroad generalizations about the different talents, capacities, or preferences of males and females''), or solely for the purpose of administrative convenience. *See Wengler* v. *Druggists Mut. Ins. Co.,* 446 U.S. 142, 151–52 (1980) (rejecting justification for providing death benefit to women only based on assertion that ''it is more efficient to presume [women's] dependency [on men . . .] than to engage in case-to-case determination''); *Frontiero* v. *Richardson,* 411 U.S. 677, 689–90 (1973).

An asserted purpose also would not satisfy the proposed regulation if, rather than being a genuine educational objective of the recipient, it is a pretext for an impermissible interest in singling out transgender students for disapproval or harm. *See, e.g., Hecox,* 479 F. Supp. 3d at 984 (noting Idaho ''[l]egislature appeared less concerned with ensuring equality in athletics than it was with ensuring exclusion of transgender athletes''); *cf. Virginia,* 518 U.S. at 533 (explaining that a State's justification for sex-related differential treatment ''must be genuine, not hypothesized or invented *post hoc* in response to litigation'').

Separately, interests in fairness in competition and in preventing sports-related injury to students have been advanced by some stakeholders and discussed by Federal courts in evaluating sex-related eligibility criteria for limiting or denying students' participation on male or female teams consistent with their gender identity. Thus, the Department anticipates that a recipient might assert fairness in competition or prevention of sports-related injury as an important educational objective in its athletic programs, particularly for older students in competitive athletic programs.

The Department recognizes that competition is an integral part of many team sports, particularly at the high school and collegiate level, and that schools have an interest in ensuring competition is fair, including that competitors meet the relevant criteria for competition in their league, such as age and skill level, following applicable rules, and otherwise engaging in fair play. *See, e.g.,* 2008 Dear Colleague Letter on Title IX and Athletic Activities (considering competition, among other factors, when determining whether an activity is a sport that can be counted as part of a recipient's athletic program for the purpose of evaluating Title IX compliance and noting that competitive interscholastic and intercollegiate athletic opportunities are generally ''governed by a specific set of rules of play . . . which include objective, standardized criteria by which competition must be judged''). Likewise, the Department recognizes that schools have an interest in the prevention of sports-related injury. As some stakeholders expressed, ensuring fair competition and prevention of sports-related injury does not necessarily require schools to adopt or apply sex-related criteria that would limit or deny a student's eligibility to participate on a male or female team consistent with their gender identity. As discussed above, many schools do not impose such restrictions, and some sport governing bodies impose such restrictions only for older students in highly competitive settings. *See, e.g.,* USRowing, *Gender Identity Policy* at 1; FINA Policy on Eligibility.

Some stakeholders expressed their views that fairness in competition depends on having generally applicable competition rules and cannot be

[11] Specifically, § 106.34(b)(1)(i) provides that a recipient must choose one of these two important educational objectives: ''(A) To improve educational achievement of its students, through a recipient's overall established policy to provide diverse educational opportunities, provided that the single-sex nature of the class or extracurricular activity is substantially related to achieving that objective; or (B) To meet the particular, identified educational needs of its students, provided that the single-sex nature of the class or extracurricular activity is substantially related to achieving that objective.''

determined based on whether a particular student wins or loses, and that schools and athletic associations use various strategies to address injury-related concerns, recognizing that student-athletes vary widely in size and strength on any given team. Strategies noted by stakeholders included appropriate coaching and training, requiring use of protective equipment, and specifying rules of play, all of which can protect against sports-related injury without imposing sex-related eligibility criteria that would limit or deny student participation consistent with their gender identity. Some of these stakeholders thus asserted that the goals of fair competition and prevention of sports-related injury could be achieved while allowing all students the opportunity to participate on athletic teams consistent with their gender identity, particularly at pre-collegiate and college club and intramural levels.

On the other hand, other stakeholders noted that they would view eligibility rules that permit participation by transgender students as unfair or unsafe and asserted that some female students might choose not to participate on female teams under such rules. Many of these stakeholders focused their comments on participation by transgender girls and women who have undergone endogenous puberty, resulting in potentially unfair advantages in size, weight, and strength differences and potentially posing a risk of injury to others. Other stakeholders countered, as noted above, that there are significant differences in size, weight, and strength among girls and women who are not transgender. Some of these stakeholders also indicated that mitigating measures would be sufficient to address any risk of unfair advantage in competition or risk of sports-related injury on female teams.

Courts have found fairness in competition to be an important educational objective in the context of determining whether schools could provide sex-separate athletic teams. For example, in *Clark ex rel. Clark* v. *Arizona Interscholastic Ass'n,* 695 F.2d 1126, 1131 (9th Cir. 1982), the Ninth Circuit recognized the importance of ''providing equal opportunities for women'' athletes and agreed with the Arizona Interscholastic Association that male students would displace female students in volleyball ''to a substantial extent'' if not excluded from competition. And, in *Hecox,* the court and all parties recognized Idaho's important governmental interest in promoting sex equality by providing female athletes from elementary school through college a fair opportunity ''to demonstrate their skill, strength, and athletic abilities'' in school-sponsored athletic competition. 479 F. Supp. 3d at 978.

The Department recognizes fairness in competition and prevention of sports-related injury can be important educational objectives. This recognition is consistent with stakeholder feedback, case law, and current § 106.41(b), which permits teams to be separated by sex where selection for such teams is based upon competitive skill or the activity involved is a contact sport. Although many schools presently work to ensure fairness in competition and prevention of sports-related injury while allowing all students to participate on male or female teams consistent with their gender identity, the proposed regulation would permit a recipient to take a different approach as long as the criteria used to determine who can participate on a particular male or female athletic team are substantially related to achieving that important educational objective and comply with the proposed regulation's other requirements.

Substantial Relationship Requirement

Under the Department's proposed regulation, sex-related criteria that would limit or deny a student's eligibility to participate on a male or female team consistent with their gender identity would need to be, for each sport, level of competition, and grade or education level, ''substantially related'' to achieving an important educational objective.

As discussed above, the substantial relationship requirement, like the achievement of an important educational objective, is similar to the standard in the Department's Title IX regulation governing access to single-sex classes, 34 CFR 106.34, and informed by case law interpreting the Equal Protection Clause. *See Virginia,* 518 U.S. at 532–33; *Hecox,* 479 F. Supp.3d at 978. Under the proposed regulation, consistent with courts' equal protection analysis, sex-related criteria would be substantially related to achievement of an important educational objective if there is a ''direct, substantial relationship between'' a recipient's objective and the means used to achieve that objective, *see Miss. Univ. for Women* v. *Hogan,* 458 U.S. 718, 724 (1982), and if the criteria do not rely on overly broad generalizations about the talents, capacities, or preferences of male and female students, *see, e.g., Virginia,* 518 U.S. at 533; *Hecox,* 479 F. Supp. 3d at 982 (''[I]t appears the 'absolute advantage' between transgender and cisgender women athletes [claimed by defendants] is based on overbroad generalizations without factual justification.'').

Under proposed § 106.41(b)(2), for example, a recipient would be permitted, consistent with Title IX's requirement to provide overall equal athletic opportunity for students regardless of sex, to rely on fairness in competition as an important educational objective to justify its use of sex-related criteria that would limit or deny students' eligibility to participate consistent with their gender identity—but only if those criteria are substantially related to ensuring fairness in competition in that particular sport at the applicable level of competition and grade or education level. *Cf. Clark,* 695 F.2d at 1127 (upholding policy excluding boys from girls' high school volleyball teams to preserve participation opportunities for girls). As courts have noted, for example, it would not be reasonable to assume that all transgender girls and women are similarly situated in their physical abilities to cisgender boys and men. *See, e.g., Hecox,* 479 F. Supp. 3d. at 978. Therefore, criteria that assume all transgender girls and women possess an unfair physical advantage over cisgender girls and women in every sport, level of competition, and grade or education level would rest on a generalization that would not comply with the Department's proposed regulation. The court in *Hecox* made a similar point when it rejected the premise of an Idaho law that, in every circumstance, ''transgender women and girls have 'an absolute advantage' over non-transgender girls'' because evidence in the record ''undermine[s] this conclusion.'' 479 F. Supp. 3d at 980–81. The court found that although ''[t]he Equal Protection Clause does not require courts to disregard the physiological differences between men and women,'' the specific principles that support ''sex separation in sport'' generally ''do not appear to hold true for women and girls who are transgender.'' *Id.* at 976–77 (discussing *Clark,* 695 F.2d at 1129, 1131). Criteria that categorically exclude all transgender girls and women from participating on any female athletic teams, for example, would not satisfy the proposed regulation because, in taking a one-size-fits-all approach, they rely on overbroad generalizations that do not account for the nature of particular sports, the level of competition at issue, and the grade or education level of students to which they apply.

A State trial court in Utah observed that ''the evidence suggest[ed] that being transgender is not 'a legitimate accurate proxy' for athletic performance.'' *Utah*

High Sch. Activities Ass'n, 2022 WL 3907182, at *8 (citations omitted). That court explained that ''[m]any transgender girls—including two of the plaintiffs in this case—medically transition at the onset of puberty, thereby never gaining any potential advantages that the increased production of testosterone during male puberty may create.'' *Id.* The court also noted that other transgender girls ''may simply have no discernible advantage in any case, depending on the student's age, level of ability, and the sport in which they wish to participate.'' *Id.* In short, although fairness in competition may be an important educational objective, the recipient's sex-related eligibility criteria must be substantially related to the actual achievement of that objective. That substantial relationship could not be established by reliance on overbroad generalizations based on sex.

Similarly, although some stakeholders expressed a concern that allowing any transgender girls and women to participate in sports consistent with their gender identity could displace cisgender girls and women from participating in sports, other stakeholders observed that very few female student-athletes are transgender and, as just discussed, transgender students do not necessarily have greater physical or athletic ability than cisgender students that would affect cisgender students' equal opportunity to participate in a recipient's athletic program. Some courts have also observed that the very small number of transgender girls and women who are student-athletes must be considered when evaluating claims that those athletes pose an outsized risk to participation by and opportunities for cisgender girls and women who are student-athletes. *See, e.g., Utah High Sch. Activities Ass'n,* 2022 WL 3907182, at *8 (finding ''no support for a claim 'that allowing transgender women to compete on women's teams would substantially displace female athletes' '' (quoting *Hecox,* 479 F. Supp. 3d at 977–78)).

The substantial relationship requirement thus would mean that if a recipient adopts or applies sex-related criteria that would limit or deny students' eligibility to participate on a male or female team consistent with their gender identity, the justification for those criteria must be based on ''reasoned analysis rather than through the mechanical application of traditional, often inaccurate, assumptions.'' *Miss. Univ. for Women,* 458 U.S. at 726; *see also, e.g., Clark,* 695 F.2d at 1129 (explaining that sex-based criteria would not be substantially related to promoting fairness in competition if based on overbroad generalizations ''without factual justification'' (citing *Schlesinger* v. *Ballard,* 419 U.S. 498, 508 (1975), and *Miss. Univ. for Women,* 458 U.S. 718)).

If a school can achieve its objective using means that would not limit or deny a student's participation consistent with their gender identity, its use of sex-related criteria may be pretextual rather than substantially related to achievement of that important educational objective. Thus, under proposed § 106.41(b)(2), whether the objective could be accomplished through alternative criteria that would not limit or deny a student's eligibility to participate on a male or female team consistent with their gender identity would be relevant to the analysis.

Federal courts have taken a similar approach in evaluating challenges to sex-based classifications under the Equal Protection Clause by considering whether government entities could achieve the same goal using other means. For example, the Supreme Court noted that it was uncontested that the Virginia Military Institute could achieve its goal of maintaining its adversative training program with some adjustments short of denying admission to all female applicants. *Virginia,* 518 U.S. at 550 n.19; *see also, e.g., Sessions* v. *Morales-Santana,* 582 U.S. 47, 63 n.13 (2017) (''[O]ur decisions reject measures that classify unnecessarily and overbroadly by gender when more accurate and impartial lines can be drawn.''); *Orr* v. *Orr,* 440 U.S. 268, 283 (1979) (rejecting the use of gender-based classifications where an important governmental interest is ''as well served by a gender-neutral classification'' because a gender-based classification ''carries with it the baggage of sexual stereotypes''); *Caban* v. *Mohammed,* 441 U.S. 380, 393 & n.13 (1970) (rejecting sex-based distinction while noting that the State could achieve its interests ''through numerous other mechanisms more closely attuned to those interests'').

The Department notes that to satisfy the substantial relationship requirement, a recipient would not be permitted to rely on false assumptions about transgender students. For example, criteria that exclude transgender students from participation on a male or female team based on a false assumption that transgender students are more likely to engage in inappropriate conduct than other students would not satisfy the proposed regulation because the criteria would not be substantially related to achieving an important educational objective. *See, e.g., Parents for Privacy* v. *Barr,* 949 F.3d 1210, 1228–29 (9th Cir. 2020) (rejecting Title IX claim because ''[t]he use of facilities for their intended purpose, without more, does not constitute an act of harassment simply because a person is transgender''); *Doe* v. *Boyertown Sch. Dist.,* 897 F.3d 518, 534 (3d Cir. 2018) (rejecting claim that a transgender student's presence in sex-separate facilities violated cisgender students' Title IX rights and distinguishing cases involving voyeurism and sexual harassment as not analogous). Moreover, nothing in Title IX precludes a school from taking nondiscriminatory steps to prevent misconduct and protect privacy for all students.

Grade or Education Level

The Department's proposed regulation would require that sex-related eligibility criteria that would limit or deny a student's eligibility to participate on a male or female team consistent with their gender identity must, for each grade or education level, be substantially related to the achievement of an important educational objective. This requirement would recognize that students of varying grades or education levels are not necessarily similarly situated with respect to the purposes of team participation, the harms resulting from exclusion from participation, their athletic skills development, other developmental factors, or their legal status as a minor or adult. Thus, any sex-related eligibility criteria must account for those factors that affect students in the particular grade or education level to which the criteria would apply.

Although competition is an aspect of many team sports across grades and education levels, athletic teams offered by schools for students in earlier grades, including those in elementary and middle school, also present an important opportunity to introduce students to new activities for which little or no prior experience is required, acquire basic skills associated with a particular sport, and develop introductory skills related to physical fitness, leadership, and teamwork. *See* Kelsey Logan & Steven Cuff, Am. Acad. Pediatrics Council on Sports Med. & Fitness, *Organized Sports for Children, Preadolescents, and Adolescents,* Pediatrics (June 2019), *https://publications.aap.org/pediatrics/article/143/6/e20190997/37135/Organized-Sports-for-Children-Preadolescents-and* (associating participation in organized sports in childhood with long-term participation in organized sports, development of life skills, and a high level of physical fitness later in life).

Reinforcing this point, the Department's review of the publicly available athletic association policies for all 50 States and the District of Columbia and Puerto Rico indicates that the overwhelming majority of State athletic associations do not regulate athletic competition between elementary school teams.

Similarly, the Department's review found that only about half of State athletic associations regulate athletic activities in middle school, and many of those that regulate make clear the mission of athletics in those grades is to encourage broad participation, basic skills development, and other aspects of student well-being. *See, e.g.,* Wis. Interscholastic Athletic Ass'n, *Middle Level Handbook* (2022–23) at 2, *https://www.wiaawi.org/Portals/0/PDF/Publications/jrhandbook.pdf* (''The developmental characteristics of young adolescents should provide the foundation for the middle level athletic programs and philosophy. . . . Programs should promote behaviors that include cooperation, sportsmanship and personal improvement. Winning is not the primary goal of the program. . . . The program should be open to all young adolescents and provide a positive experience. All young adolescents should have the opportunity to participate, play and experience skill improvement.''); Iowa High Sch. Athletic Ass'n, *Junior High Sports Manual* (2021–23) at 1, *https://www.iahsaa.org/wp-content/uploads/2022/08/2021-23-Junior-High-Manual-8.17.22.pdf* (''The primary purpose of the junior high school athletic program is participation, with emphasis on the development of skills, sportsmanship, and citizenship of all students.''); S.C. High Sch. League, *2022–23 Middle School Rules & Regulations* at 1, *https://schsl.org/archives/7950* (''The program must be justified on a basis of contribution to the desirable development of the participants. The welfare of the youth concerned is of greatest importance. All other needs and problems should be secondary.'').

One State athletic association explained, for example, that member schools' goals for offering interscholastic athletic competition and activities for middle school students should encourage broad participation for students in middle school in recognition of the ''great range of individual differences among boys and girls of this age (age; body build; interest; ability; experience; health, and the stages of physiological, emotional and social maturity).'' S.C. High Sch. League, *2022–23 Middle School Rules & Regulations* at 1, *https://schsl.org/archives/7950.* To that end, it directs schools to approach competition ''from as broad a base as possible to offer experience to many boys and girls.'' *Id.*

The Department recognizes that recipients that offer male and female teams to students in early grades have a significant interest in providing all of their students an opportunity to gain foundational physical, emotional, academic, and interpersonal benefits, and other life skills associated with team sports participation regardless of sex. *See* Kelsey Logan & Steven Cuff, Am. Acad. Pediatrics Council on Sports Med. & Fitness, *Organized Sports for Children, Preadolescents, and Adolescents,* Pediatrics (June 2019) (describing the many benefits of youth participation, including children, preadolescents, and adolescents, in organized sports); Anne C. Fletcher et al., *Structured Leisure Activities in Middle Childhood: Links to Well-Being,* J. Community Psychology 31–6, 641–59 (2003) (associating greater psychosocial development with participation in sport activities in elementary school). Barring students from participating on teams consistent with their gender identity may impede them from developing an interest in or aptitude for team sports or for athletic activity altogether, including into adulthood, resulting in negative health and well-being consequences and long-term loss of opportunity. *See, e.g.,* Sandra D. Simpkins et al., *Participating in Sport and Music Activities in Adolescence: The Role of Activity Participation and Motivational Beliefs During Elementary School,* 39 J. Youth Adolescence 1368 (2009), *https://link.springer.com/article/10.1007/s10964-009-9448-2* (concluding that elementary school children who did not participate in sports were unlikely to participate when they become adolescents); *cf. A.M.,* 2022 WL 2951430, at *11 (describing distress and other harms associated with prohibiting students from playing on a team consistent with their gender identity).

Accordingly, the Department currently believes that there would be few, if any, sex-related eligibility criteria applicable to students in elementary school that could comply with the proposed regulation, and that it would be particularly difficult for a recipient to comply with the proposed regulation by excluding students immediately following elementary school from participating on male or female teams consistent with their gender identity. The Department welcomes comments on whether any sex-related eligibility criteria can comply with this proposed regulation when applied to students in these earlier grades and, if so, the types of criteria that may comply with the proposed regulation. The Department anticipates that at the high school and college level, schools' application or adoption of sex-related eligibility criteria to ensure an important educational objective, such as fairness in competition in their athletic programs, may be more likely to satisfy the proposed regulation.

Level of Competition

The proposed regulation would specify that any sex-related criteria that would limit or deny a student's eligibility to participate on a male or female team must be substantially related to achieving an important educational objective for each level of competition to which it applies.

This aspect of the proposed regulation would recognize that school-based athletic team offerings vary widely across the United States. To the extent teams are offered for students at earlier grades and levels of education, many schools prioritize broad participation and teaching basic skills. These teams are often not highly selective, including ''no-cut'' teams that allow all students to join the team and participate, and rarely provide elite competition opportunities, as discussed above in *Existing Approaches to Eligibility Criteria for Male and Female Teams.* Some schools also offer teams at lower levels of competition that are designed to encourage broad participation and help students build basic skills (*e.g.,* intramural, junior varsity, unified) that often permit all or most interested students to participate without an expectation of high-level competition (*e.g.,* varsity). Other teams, more typically for older students who have advanced skills, including at many postsecondary institutions, are more selective and engage in elite competition. *See generally* NCAA, *Overview, https://www.ncaa.org/sports/2021/2/16/overview.aspx* (last visited Mar. 29, 2023) (describing levels of intercollegiate competition for member colleges and universities).

Some stakeholders urged the Department to develop regulations governing the participation of students on male or female teams consistent with their gender identity in a manner that accounts for different levels of competition. In a view expressed by some stakeholders, a one-size-fits-all policy approach would not be appropriate because athletic participation is organized differently at various levels of competition with some male and female teams open to all students and some that accommodate a larger roster of students with widely varying skill levels. Some stakeholders

also noted that at high levels of competition in high school, students may be competing with each other for limited scholarship and recruitment opportunities. Some stakeholders urged that it is appropriate for sex-related criteria that govern the participation of athletes consistent with gender identity to account for differences at these levels of competition.

The Department is also aware of distinctions that national and international sport governing bodies draw among athletes at different levels of competition. In some cases, the criteria that these organizations require transgender athletes to meet to participate on a male or female team consistent with their gender identity differ based on the level of competition. As noted above, for example, USA Gymnastics permits transgender athletes to participate ''without restriction'' in all competition activities below the elite level. USA Gymnastics, *Transgender & Non-Binary Athlete Inclusion Policy* at 2. Similarly, World Athletics, the international governing body for track and field events, has adopted regulations that apply only at the World Rankings competition level or to athletes who wish to have their performance at a lower competition level recognized as a World Record. World Athletics permits member federations to set their own regulations to determine eligibility to participate in lower level competitions consistent with an athlete's gender identity. *See* World Athletics, *Rule C3.5A—Eligibility Regulations for Transgender Athletes* (Mar. 2023) (Rules 2.1 and 2.5), *https://www.worldathletics.org/about-iaaf/documents/book-of-rules.*

In light of these examples, the Department proposes a standard that would specifically require a recipient that adopts or applies sex-related eligibility criteria for male and female teams to account for the level of competition at issue. As noted above, the Department expects sex-related eligibility criteria to be more common and more likely to satisfy the proposed regulation at higher grade levels, particularly high school and postsecondary levels.

Sport

The proposed regulation would specify that any sex-related criteria for eligibility to participate on a male or female team must be substantially related to achievement of an important educational objective for each sport to which it applies. This requirement is consistent with the Javits Amendment's direction that the Title IX regulations include reasonable athletics provisions that ''consider[ ] the nature of particular sports.'' Education Amendments of 1974 section 844.

The Department proposes this requirement because not all differences among students confer a competitive advantage or raise concerns about sports-related injury in every sport, and ''[c]lassification on strict grounds of sex, without reference to actual skill differentials in particular sports, would merely echo 'archaic and overbroad generalizations.' '' *Att'y Gen.* v. *Mass. Interscholastic Athletic Ass'n,* 393 NE2d 284, 293 (Mass. 1979) (citations omitted) (rejecting the athletic association's argument that it was justified in imposing a complete ban on male athletes participating on female athletic teams because of an assertion of the male athletes' competitive advantage in all sports); *see also, e.g., Utah High Sch. Activities Ass'n,* 2022 WL 3907182, at *8–9 (finding that challenged Utah law had a substantial likelihood of violating the State constitution because it ''prevents *all* transgender girls from competing on *all* girls' teams, regardless of any potentially relevant factors, such as . . . the nature of the particular sport'' (emphasis in original)).

School districts and postsecondary institutions offer a wide selection of sports (*e.g.,* badminton, baseball, basketball, bowling, curling, football, golf, gymnastics, riflery, skiing, soccer, softball, swimming and diving, tennis, trap shooting, volleyball, water polo). *See* Nat'l Fed'n of State High Sch. Ass'ns, *High School Athletics Participation Survey (2021–22), https://www.nfhs.org/media/5989280/2021-22_participation_survey.pdf.* These and other sports that schools offer each have unique rules and prioritize varied skills and attributes. Likewise, students on any given team will typically vary significantly in skills, size, strength, and other attributes that may be relevant to their chosen sport or position within a sport. Thus, under the proposed regulation, any sex-related eligibility criteria for male or female teams that would limit or deny participation consistent with gender identity would need to be substantially related to achieving an important educational interest in relation to the particular sport to which the criteria apply. Overbroad generalizations that do not account for the nature of particular sports would not be sufficient to comply with the proposed regulation.

The proposed regulation also would address issues raised in feedback the Department received from stakeholders who suggested that any regulations the Department might adopt should account for variations among sports. Stakeholders noted that outside the educational setting, national and international sport governing bodies set rules for participation and competition that differ by sport. As discussed above, the NCAA and the IOC have directed the entities that set rules for participation and competition in intercollegiate and international sporting events recognized by the NCAA and the IOC respectively to adopt a sport-specific approach for any sex-related eligibility criteria to participate on male or female teams consistent with gender identity. As the IOC explained, sport governing bodies must ensure that any sex-related eligibility criteria included in their policies ''tak[e] into consideration the nature of each sport,'' IOC Framework at 1, and account for any sport-specific competitive advantage or risk, *id.* at 4. The Department notes, however, that the proposed regulation would not necessarily require schools to adopt distinct eligibility criteria for each sport; rather, where sex-related criteria would limit or deny students' eligibility to participate consistent with their gender identity, the criteria must satisfy the proposed regulation as applied to that sport.

The proposed regulation would therefore provide that, in light of the variation among sports, a recipient that adopts or applies sex-related eligibility criteria for male or female teams must demonstrate that its criteria are substantially related to achievement of an important educational objective for the particular sport to which they apply.

Harm Minimization Requirement

Proposed 106.41(b)(2) would also require that, if a recipient adopts or applies sex-related criteria that would limit or deny students' eligibility to participate on a male or female team consistent with their gender identity, it must do so in a way that minimizes harms to students whose opportunity to participate on a male or female team consistent with their gender identity would be limited or denied.

As explained earlier in this preamble, Title IX generally prohibits a recipient from excluding students from an education program or activity on the basis of sex when the exclusion causes more than de minimis harm. When students are separated or treated differently based on sex, a recipient risks harming those students in a way that would ordinarily violate Title IX. *See* 34 CFR 106.31(b)(4) and (7) (providing that, ''[e]xcept as provided in this subpart, in providing any aid, benefit, or service to a student, a recipient shall not, on the basis of sex

. . . [s]ubject any person to separate or different rules of behavior, sanctions, or other treatment . . . [or] [o]therwise limit any person in the enjoyment of any right, privilege, advantage, or opportunity''); *see also, e.g., Grimm,* 972 F.3d at 617 (recognizing that school's imposition of different rules on transgender students than other students in their use of school facilities was ''sufficient to constitute harm under Title IX''). *But see Adams,* 57 F.4th at 814–15 (holding school district policy that excludes transgender students from restrooms that correspond to their gender identity does not violate Title IX regulations because of the language of 34 CFR 106.33). The July 2022 NPRM proposed amendments to the Department's Title IX regulations that would clarify that a recipient must not separate or treat students differently in a manner that discriminates on the basis of sex by subjecting a person to more than de minimis harm unless otherwise permitted by Title IX or the Department's Title IX regulations. 87 FR 41534–37. Those proposed amendments would further clarify that a policy or practice that prevents a person from participating in an education program or activity consistent with their gender identity subjects a person to more than de minimis harm on the basis of sex. *Id.*

Consistent with the Javits Amendment, the Department's Title IX regulations have taken a different approach in the athletics context, permitting a recipient to offer male and female athletic teams to promote equal opportunity for all athletes, even though some harm may be caused when a recipient offers sex-separate athletic teams. In particular, current § 106.41(b), in place since 1975, permits a recipient to offer male and female athletic teams under certain circumstances, and such teams may in those circumstances exclude some students on the basis of sex. This longstanding requirement reflects the Department's recognition that a recipient's provision of male and female teams can advance rather than undermine overall equal opportunity in the unique context of athletics by creating meaningful participation opportunities that were historically lacking for women and girls. *See* 1979 Policy Interpretation, 44 FR 71421 (''If women athletes, as a class, are receiving opportunities and benefits equal to those of male athletes, individuals within the class should be protected thereby.'').

The Department also recognizes that overall equal opportunity does not require identical programs for male and female athletes, *id.* at 71421–22, and thus a recipient may, and has always been permitted to, deny students the opportunity to participate on a particular male or female team based on sex under certain circumstances. For example, a recipient may, in some circumstances, offer a volleyball team for girls but not boys, and a boy who would like to play on the school's volleyball team may not be able to do so for reasons discussed above. But the permissibility of sex-separate teams does not exempt a recipient from its responsibility not to otherwise discriminate based on sex when offering opportunities to participate on those teams.

A school policy of separating students on the basis of particular reproductive or other sex-based characteristics, *see, e.g., B.P.J.,* 2023 WL 111875, at *2 (evaluating West Virginia's classification of students based on ''reproductive biology and genetics at birth''), will not materially harm the vast majority of students, as those sex-related criteria permit them to participate on athletic teams consistent with their gender identity. But when sex-related criteriaLGB do limit or deny a student's eligibility to participate on a male or female athletic team consistent with their gender identity, the student is subjected to harms based on sex that are distinct from the harms otherwise permitted under the Department's longstanding athletics regulation (*e.g.,* a girl who is not selected for the girls' soccer team based on her athletic skills or a boy who is not eligible to play on the girls' volleyball team when the recipient does not offer a boys' or coeducational volleyball team). Criteria that limit or deny students' eligibility to participate in sports consistent with their gender identity can force individual students to disclose that they are transgender, which can be ''extremely traumatic'' and ''undermine [a student's] social transition,'' *A.M.,* 2022 WL 2951430, at *11–12; subject them to ''embarrassment, harassment, and invasion of privacy through having to verify [their] sex,'' *Hecox,* 479 F. Supp. 3d at 987; and can communicate disapproval of transgender students, ''which the Constitution prohibits'' in the context of public schools, *Hecox,* 479 F. Supp. 3d at 987 (citing *Lawrence* v. *Texas,* 539 U.S. 558, 582–83 (2003)). Further, such sex-related exclusion leaves affected students with no viable opportunity to participate in athletics if the only other option is to participate on a team that does not align with their gender identity. *Hecox,* 479 F. Supp. 3d at 977 (citing evidence that, for transgender students, participating on a team that is inconsistent with their gender identity is equivalent to medically harmful gender identity conversion efforts).

The current regulations, however, do not expressly address these distinct harms caused by sex-related criteria that limit or deny students' eligibility to participate on male or female teams consistent with their gender identity. Proposed § 106.41(b)(2) would account for such harms by requiring that such criteria be adopted and applied in a way that minimizes the harms caused to those students. As a result, even sex-related criteria that are substantially related to the achievement of an important educational objective would violate proposed § 106.41(b)(2) if the recipient can reasonably adopt or apply alternative criteria that would be a less harmful means of achieving the recipient's important educational objective. For example, a recipient might adopt sex-related criteria that require documentation of student-athletes' gender identity based on its interest in providing, consistent with Title IX, equal athletic opportunity on male and female teams under § 106.41(c). Under proposed § 106.41(b)(2), the recipient would need to design those criteria to minimize the potential harms imposed on affected students (*e.g.,* difficulty of obtaining documentation, risk of invasion of privacy or disclosure of confidential information). If the recipient can reasonably adopt or apply alternative criteria that cause less harm and still achieve its important educational objective, the recipient would not be permitted to adopt the more harmful criteria.

In sum, the proposed regulation would preclude a recipient from implementing sex-based classifications more broadly than is necessary to implement the statute's underlying goals, consistent with Title IX's guarantee that ''[*n*]*o person* in the United States'' shall be subject to prohibited discrimination on the basis of sex. 20 U.S.C. 1681(a) (emphasis added). Proposed § 106.41(b)(2) would thus provide recipients greater clarity on how to comply with Title IX's nondiscrimination obligation if recipients adopt or apply sex-related criteria that would limit or deny a student's eligibility to participate on male or female athletic teams consistent with their gender identity.

Directed Questions

The Department continues to consider how its Title IX regulations should clarify the permissibility of sex-related criteria that would limit or deny a student's eligibility to participate on a

male or female athletic team consistent with their gender identity. The Department therefore specifically invites further public comment on:

a. Whether any alternative approaches to the Department's proposed regulation would better align with Title IX's requirement for a recipient to provide equal athletic opportunity regardless of sex in the recipient's athletic program as a whole;

b. What educational objectives are sufficiently important to justify a recipient imposing sex-related criteria that would limit or deny a student's eligibility to participate on a male or female athletic team consistent with their gender identity and whether those objectives should be specified in the regulatory text;

c. Whether and how the permissibility of particular sex-related eligibility criteria should differ depending on the sport, level of competition, grade or education level, or other considerations;

d. Whether any sex-related eligibility criteria can meet the standard set out in the proposed regulation when applied to students in earlier grades, and, if so, the type of criteria that may meet the proposed standard for those grades;

e. How a recipient can minimize harms to students whose eligibility to participate on a male or female athletic team consistent with their gender identity is limited or denied by the recipient's adoption or application of sex-related criteria; and

f. Whether regulatory text in addition to the text in the proposed regulation is needed to provide recipients with sufficient clarity on how to comply with Title IX's prohibition on sex discrimination, including gender identity discrimination, in the context of male and female athletic teams, consistent with the principles and concerns identified in the discussion of proposed § 106.41(b)(2).

Regulatory Impact Analysis (RIA)

Under Executive Order 12866,[12] the Office of Management and Budget (OMB) must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by OMB. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This proposed action is ''significant'' and, therefore, subject to review by OMB under section 3(f)(4) of Executive Order 12866. The Department has assessed the potential costs and benefits, both quantitative and qualitative, of this proposed regulatory action and has determined that the benefits would justify the costs.

The Department has also reviewed this proposed regulation under Executive Order 13563,[13] which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select 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 the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

Pursuant to Executive Order 13563, the Department believes that the benefits of this proposed regulation justify its costs. In choosing among alternative regulatory approaches, the Department selected the approach that maximizes net benefits. Based on the analysis that follows, the Department believes that the proposed regulation is consistent with the principles in Executive Order 13563.

The Department also has preliminarily determined that this regulatory action would not unduly interfere with State, local, or Tribal governments in the exercise of their governmental functions.

This RIA discusses the need for regulatory action, the potential costs and benefits, assumptions, limitations, and data sources, as well as regulatory alternatives considered.

1. Need for Regulatory Action

In 2021, the President directed the Department in both Executive Order 13988 [14] and Executive Order 14021 [15] to review its current regulations implementing Title IX for consistency with Title IX's statutory prohibition on sex discrimination by a recipient of Federal financial assistance in its education program or activity. Consistent with those Executive orders, the Department reviewed the current regulations based on Federal case law, its experience in enforcement, and feedback received by OCR from stakeholders, including during the June 2021 Title IX Public Hearing and listening sessions. Over 280 students, parents, teachers, faculty members, school staff, administrators, and other members of the public provided live comments during the June 2021 Title IX Public Hearing, and OCR also received over 30,000 written comments in connection with the hearing. In

[12] *Executive Order on Regulatory Planning and Review,* Exec. Order No. 12866, 58 FR 51735 (Oct. 4, 1993).

[13] *Executive Order on Improving Regulation and Regulatory Review,* Exec. Order No. 13563, 76 FR 3821 (Jan. 18, 2011), *https://www.govinfo.gov/content/pkg/FR-2011-01-21/pdf/2011-1385.pdf.*

[14] *Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation,* Exec. Order No. 13988, 86 FR 7023 (Jan. 25, 2021).

[15] *Executive Order on Guaranteeing an Educational Environment Free from Discrimination on the Basis of Sex, Including Sexual Orientation and Gender Identity,* Exec. Order No. 14021, 86 FR 13803 (Mar. 11, 2021).

addition, OCR conducted listening sessions with stakeholders expressing a variety of views, including individuals and organizations focused on Title IX and athletics. Among these stakeholders were athletic associations; student-athletes; parents; organizations representing elementary schools, secondary schools, and postsecondary institutions (or institutions of higher education (IHEs)); organizations representing teachers, administrators, parents, and current and former student-athletes; attorneys representing students and schools; State officials; Title IX Coordinators and other school administrators; and individuals who provide Title IX training to schools.

Based on this review, the Department proposes amending its regulations to set out a standard that would govern a recipient's adoption or application of sex-related criteria that would limit or deny a student's eligibility to participate on a male or female athletic team consistent with their gender identity. The Department received feedback from many stakeholders during the June 2021 Title IX Public Hearing and listening sessions and through correspondence asking the Department to clarify Title IX's application to students' eligibility to participate on male or female athletic teams and urging adoption of a variety of positions.

The Department proposes amending its Title IX regulations to address stakeholder concerns and anticipates that the proposed regulation would result in many benefits to recipients, students, employees, and others, including by providing clarity to help ensure compliance with Title IX's nondiscrimination requirement by recipients that seek to adopt or apply sex-related criteria to determine student eligibility to participate on male or female teams consistent with their gender identity.

2. Discussion of Costs, Benefits, and Transfers

The Department has analyzed the costs and benefits of complying with the proposed regulation. Although many of the associated costs and benefits are not readily quantifiable, the Department believes that the benefits derived from the proposed regulation would outweigh the associated costs. The Department acknowledges the interest of some stakeholders in preserving certain recipients' current athletic-team policies and procedures regarding sex-related eligibility criteria and in avoiding potential additional costs to comply with the proposed regulation. However, the Department believes the current regulations are not sufficiently clear to ensure Title IX's nondiscrimination requirement is fulfilled if a recipient adopts or applies sex-related criteria that would limit or deny students' eligibility to participate on male or female athletic teams consistent with their gender identity. The Department expects that a primary benefit of the proposed regulation would be to provide greater clarity to recipients and other stakeholders about the standard that a recipient must meet under Title IX if it adopts or applies sex-related criteria that would limit or deny a student's eligibility to participate on a male or female athletic team consistent with their gender identity and, as a result, to protect students' equal opportunity to participate on male and female teams consistent with Title IX.

Title IX applies to approximately 18,000 local education agencies (LEAs) and over 6,000 IHEs. Due to the number of affected entities, the variation in likely responses, and the limited information available about current practices, the Department is not able to precisely estimate the likely costs, benefits, and other effects of the proposed regulation. The Department specifically invites public comment on data sources that would provide additional information on the issues that are the subject of this Athletics NPRM, information regarding the number of recipients operating male or female teams in intramural or club sports, and time estimates for the activities described in the Developing the Model (Section 2.B.2) discussion of the RIA, disaggregated by type of recipient. Despite these limitations and based on the best available evidence as discussed below, the Department estimates that this proposed regulation would result in a net cost to recipients of between $23.4 million to $24.4 million over 10 years.

The assumptions, data, methodology, and other relevant materials, as applicable, on which the Department relied in developing its estimates are described throughout this RIA.

2.A. Benefits of the Proposed Regulation

The Department believes that the proposed regulation would provide numerous important benefits but also recognizes that it is not able to quantify these benefits at this time. Despite the lack of quantitative data available, however, it is the Department's current view that the benefits are substantial and far outweigh the estimated costs of the proposed regulation.

In particular, the Department's current view is that the proposed regulation would benefit educational institutions and their students and applicants for admission by providing greater clarity about the standard a recipient must meet if it adopts or applies sex-related criteria that would limit or deny a student's eligibility to participate on a male or female athletic team consistent with their gender identity. The Department expects that the clarity provided by the proposed regulation would reduce the likelihood of sex discrimination in students' opportunities to participate on male or female teams offered by a recipient. By reducing the sex discrimination resulting from confusion surrounding the permissibility of sex-related eligibility criteria, it is the Department's view that the proposed regulation would produce a demonstrable benefit for educational institutions and their students. The Department anticipates these benefits would be realized by helping protect students' equal opportunity to participate on male and female teams consistent with Title IX, along with the associated health and other benefits to students who are able to participate as a result of the proposed regulation's clarity on Title IX's requirements. The Department further anticipates that the proposed regulation would benefit recipients by helping recipients understand their obligations, thereby supporting their efforts to provide equal athletic opportunity regardless of sex in their athletic programs, as Title IX requires.

Youth participation in athletics is associated with many physical, emotional, academic, and interpersonal benefits for students, including increased cognitive performance and creativity, improved educational and occupational skills, higher academic performance and likelihood of graduation from a 4-year college, improved mental health, and improved cardiovascular and muscle fitness, as well as reduced risk of cancer and diabetes, and has the potential to help students develop traits that benefit them in school and throughout life, including teamwork, discipline, resilience, leadership, confidence, social skills, and physical fitness. *See* President's Council on Sports, Fitness & Nutrition Sci. Bd., *Benefits of Youth Sports* (Sept. 17, 2020), *https://health.gov/sites/default/files/2020-09/YSS_Report_OnePager_2020-08-31_web.pdf.*

There is also evidence suggesting that allowing transgender children to socially transition (*i.e.,* present themselves in everyday life consistent with their gender identity) is associated with positive mental health outcomes for those children. Kristina Olson et al., *Mental Health of Transgender Children Who Are Supported in Their Identities,*

137 Pediatrics 3 (March 2016), *https://publications.aap.org/pediatrics/article/137/3/e20153223/81409/Mental-Health-of-Transgender-Children-Who-Are.* Ensuring that transgender students have the opportunity to participate on male or female teams consistent with their gender identity can be part of a transgender student's social transition and is thus a crucial benefit to those students' health and well-being.

In addition, though the data quantifying the economic impacts of sex discrimination are limited, the Department recognizes that sex discrimination causes harm to students, including when such discrimination results in students being limited in or excluded from the opportunity to participate in athletics consistent with their gender identity and thereby effectively deprived of the many positive benefits of participation in team sports. *See, e.g., Hecox,* 479 F. Supp. 3d at 987 (finding State law caused harm in that it would deny a transgender woman the opportunity to participate on women's team and subject her to the State's moral disapproval of her identity); *Utah High Sch. Activities Ass'n,* 2022 WL 3907182, at *9 (finding immediate harm caused by State law banning transgender girls from participating in sports consistent with their gender identity).

2.B. Costs of the Proposed Regulation

The analysis below reviews the Department's data sources, describes the model used for estimating the likely costs associated with the proposed regulation, and sets out those estimated costs. The costs described below are not intended to reflect the exact burden on any given recipient, but instead intended to reflect an average burden across all recipients. Specific entities may experience higher or lower costs than those estimated below as a result of this proposed regulation. Due to limited quantitative data, the Department emphasizes that the monetary estimates reflect only the likely costs of this proposed regulatory action and do not seek to quantify, in monetary terms, the costs of sex discrimination. There are limited data quantifying the economic impacts of sex discrimination in athletics, and the Department invites comment on suggestions for any data sources that would provide additional information.

2.B.1. Establishing a Baseline

As an initial matter, the analysis that follows separately discusses the effects of the proposed regulation on elementary and secondary education (ESE) entities and postsecondary education or IHE entities. For purposes of this analysis, ESE and IHE entities include educational institutions as well as other entities, such as national athletic associations and sport governing bodies, that are involved in the adoption or application of sex-related eligibility criteria for students participating on a recipient's male or female athletic teams. The Department analyzes the costs associated with the proposed regulation separately for ESE and IHE entities and views this as the best approach for cost analysis because ESE and IHE entities are organized and operate differently, and the costs the proposed regulation would impose on recipients are distinct at these levels, as explained below.

Athletic competition and its governance vary between the ESE and IHE contexts, with most ESE interscholastic competition governed by State-specific athletic associations, while much intercollegiate competition in the United States occurs under the auspices of only a handful of athletic associations, the largest of which is the NCAA. Under the proposed regulation, a recipient would be permitted to adopt or apply sex-related eligibility criteria that would limit or deny a student's eligibility to participate on a male or female athletic team consistent with their gender identity if those criteria, for each sport, level of competition, and grade or education level (i) are substantially related to the achievement of an important educational objective, and (ii) minimize harms to students whose opportunity to participate on a male or female team consistent with their gender identity would be limited or denied. The Department anticipates that the costs associated with implementing the proposed regulation—such as reviewing, adopting, and implementing policies, and training staff—would best align according to whether an entity is an ESE or IHE entity.

With respect to ESE entities, the Department anticipates that the same entities (*e.g.,* LEAs, State education associations, and State athletic associations) would generally review and respond to the regulation for elementary school, middle school, and high school, and, in doing so, would likely address the full range of affected students in any subsequent review or revision of policies. For this reason, the Department projects costs for ESE entities in one category, even though an entity may opt to adopt or apply different eligibility criteria for sex-separate teams in high school, for example, than for students in elementary school and middle school. To separate these entities into different categories for the purpose of projecting costs would unduly confound estimates. For example, there are not separate burdens associated with the time and effort an LEA athletic director may spend reading and understanding the regulation's application to all students in the LEA. Instead, the athletic director would likely read and understand the regulation in its entirety. That LEA athletic director would then develop policies and practices that comply with the regulation, possibly differentiating sex-related eligibility criteria for male and female teams for different sports, levels of competition, and grades or education levels, while ensuring that the criteria minimize harms to students. Similarly, the Department anticipates that a State athletic association with membership comprised of LEAs that serve students in grades pre-K through 12 would review the regulation as a whole and set policies for its member entities' participation in interscholastic competition that align with the regulatory requirements.

In light of these factors, the Department believes it is reasonable to project costs by dividing the cost analyses between ESE and IHE entities. The Department notes that, in light of how athletic competition is structured at both the ESE and IHE levels, some entities that would not otherwise be subject to the proposed regulation may nonetheless be affected by its promulgation as a result of actions by third parties. As noted above, most athletic competition is organized by State athletic associations at the ESE level or under the auspices of the NCAA or similar national athletic associations at the IHE level. It is possible that a State athletic association or relevant governing body would require all of its members, including a private high school, to comply with eligibility and participation criteria that the association sets. The Department thus acknowledges that the implementation of the proposed regulation by these athletic associations may indirectly affect entities that are not directly subject to the proposed regulation. The Department does not currently have sufficient data to estimate the likelihood of these effects or their impact and seeks specific public comment on these issues.

Athletic Competition in ESE Entities

In the 2020–2021 school year, according to data from the National Center on Education Statistics, there were 18,259 LEAs in the United States with either a nonzero enrollment or at

least one operational school.[16] Of the 18,083 LEAs for which the Department has data on the relevant variables,[17] 4,383 do not serve students in grades 9 through 12. Many of these are single school LEAs, such as charter schools. The Department assumes that these LEAs will continue to serve only students in elementary or middle school moving forward. Of the remaining LEAs, 1,268 only serve students in grades 9 through 12. Most LEAs (11,661) serve students in pre-kindergarten or kindergarten through 12th grade.

The Department generally assumes that, to the extent LEAs offer separate male and female intramural athletic teams, they generally establish eligibility criteria for participation on those teams at the LEA level even if the policies differ by sport, level of competition, or grade or education level.

For interscholastic athletic competition, eligibility is generally governed by State-specific athletic associations. The Department reviewed existing, publicly available State athletic associations' policies on sex-related eligibility criteria for students' participation on male or female teams for each of the 50 States, Puerto Rico, and the District of Columbia.[18] This review was conducted for the purpose of informing this Athletics NPRM; the Department has not evaluated these policies to determine whether they would comply with the proposed regulation or current statutory or regulatory Title IX requirements. The Department observed that State athletic association policies range from those that allow all students to participate on male or female athletic teams consistent with their gender identity to those that categorically exclude transgender students from participating on male or female athletic teams consistent with their gender identity. The Department further observed additional variation among State athletic association policies that establish some criteria for determining when a student is eligible to participate on a specific male or female athletic team consistent with their gender identity. For example:

- Approximately 20 percent of State athletic association policies currently allow students to participate on male or female athletic teams consistent with their gender identity without establishing additional criteria or eligibility requirements beyond those that apply to all student-athletes, such as attendance or academic achievement.
- Approximately 25 percent of State athletic associations generally permit participation consistent with students' gender identity and have established some criteria or eligibility requirements for participation, such as various types of documentation (examples include a written statement from the student, their parent or guardian, health care or treatment provider, a community member or teacher identifying the student's consistent gender identity).
- Approximately 20 percent of State athletic associations require students who wish to participate consistent with their gender identity to meet additional criteria prior to participation. Of those athletic associations that impose additional requirements, the vast majority (approximately three-quarters of this group) adopted different policies for male and female teams—many of which require transgender girls to satisfy additional criteria prior to participating on a female team consistent with their gender identity.
- The remaining State athletic associations have adopted a range of policies imposing criteria that severely limit most or all transgender students from participating on male or female athletic teams consistent with their gender identity.

In addition to variations among State athletic associations regarding the criteria for participation on male or female athletic teams, the Department observed variations among State athletic associations regarding the eligibility decision process for participation on male or female athletic teams. In nearly half of States, athletic association policies leave decisions regarding eligibility to the school or to the school and the student-athlete. In approximately 30 percent of States, the athletic association is involved in determining eligibility, either alone or in conjunction with the school.

In general, the Department found that State athletic association policies are silent on the issue of students in elementary school. With respect to middle school, the Department found that about half of State athletic associations regulate athletic competition at that level, but only approximately 35 percent of State athletic associations have policies addressing those students' participation in athletic competition consistent with their gender identity. The remaining State athletic associations are either silent on this issue or explicitly defer to the school or LEA for policies affecting students in middle school.

The Department notes that most States do not have laws prescribing sex-related eligibility criteria for recipients' male and female athletic teams. The Department also notes that at least two States have enacted laws or regulations requiring LEAs to allow ESE students to participate in athletics consistent with their gender identity. Twenty States have enacted laws that, to varying degrees, explicitly require that student-athletes participate on male or female athletic teams consistent with their sex assigned at birth. The Department anticipates athletic associations in some States may adopt policies that align with State law before the Department promulgates its final regulation. The Department further notes that some State laws are currently subject to litigation that may affect their continued applicability. *See, e.g., B.P.J.,* No. 23–1078 (4th Cir. Feb. 22, 2023) (staying the district court's dissolution of preliminary injunction barring enforcement against plaintiff of West Virginia law requiring students to participate on athletic teams consistent with ''biological sex'' pending appeal); *Hecox,* 479 F. Supp. 3d at 978–85 (granting preliminary injunction barring implementation of Idaho law that excludes transgender girls and women from participating in athletics consistent with their gender identity based on strong likelihood the law violates the Equal Protection Clause); *Barrett* v. *State,* Cause No. DV–21–581B (Mont. 18th Jud. Dist. Sept. 14, 2022) (finding Montana law that restricts participation of transgender students in public institutions' athletic programs violates State constitution by infringing on public university's ''authority to oversee student groups and activities''), *appeal docketed,* No. DA 22–0586 (Mont. Oct. 13, 2022); *Utah High Sch. Activities Ass'n,* 2022 WL 3907182, at *1, *9 (granting preliminary injunction to enjoin enforcement of Utah law that ''effectively bans transgender girls from competing in pre-college school-related girls sports,'' based on strong likelihood the law violates the State constitution).

In the absence of the clarity that the proposed regulation would provide, the Department assumes that States, LEAs,

[16] In the 2020–2021 school year, 91 ESE entities had nonzero enrollments and zero operational schools. For purposes of this analysis, the Department assumes these entities operate like other LEAs, although several appear to be regional education services agencies or intermediate school districts where the named entity itself, while enrolling students, may not directly provide education to students. In that same year, 531 ESE entities had operational schools either with zero enrollment or no enrollment data available. A number of these entities are charter schools that may have been in the process of opening or closing, and it is unclear whether they will serve students in future years. Inclusion of these two groups of entities will likely result in an over-estimate of the potential costs of the proposed regulation.

[17] This total excludes one LEA providing only adult education services and 68 LEAs serving only ungraded students.

[18] The Department notes that State athletic association policies on this topic continue to be updated.

schools, and State athletic associations would continue to implement varying policies for students in elementary and secondary education, with a small subset adopting criteria that would not limit or deny the participation of transgender students on male or female athletic teams consistent with their gender identity and a small subset adopting criteria that would substantially limit or deny transgender students from participating on male or female athletic teams consistent with their gender identity. The Department also assumes that almost all of the remaining States (approximately half) would have policies that establish minimal criteria for the participation of transgender students in high school athletics consistent with their gender identity (*e.g.,* a written statement from the student or someone on their behalf confirming the student's consistent gender identity). The Department seeks specific public comment on the reasonableness of this assumption.

Athletic Competition in IHE Entities

In the 2020–2021 school year, according to data from the National Center on Education Statistics, there were 6,045 IHEs participating in programs under Title IV of the Higher Education Act of 1965, 20 U.S.C. 1001 *et seq.* (1965), such as Loans, Federal Work Study, and Pell grants. Except as described above, the Department assumes this represents the universe of potentially impacted IHE entities. Of those, 1,689 IHEs offered an educational program that was less than 2 years in duration (*i.e.,* below the associate's level), 1,602 offered a program of at least 2 but less than 4 years, and 2,754 offered a program of 4 or more years. In total, these institutions enrolled approximately 14.8 million full-time equivalent (FTE) students in fall 2020. Approximately 1 percent of students attended less-than-2-year IHEs, approximately 20 percent attended 2- to 4-year institutions, and approximately 79 percent attended at least 4-year institutions (hereinafter referred to as ''4-year institutions'').

TABLE 1—INSTITUTIONS OF HIGHER EDUCATION BY LEVEL OF INSTITUTIONS AND ENROLLMENT, FALL 2020

Level of institution	Number of entities	Total fall FTE enrollment	% of total fall FTE enrollment	Average fall FTE enrollment
Less-than-2-Year	1,689	228,448	1	138
2- to 4-Year	1,602	2,905,048	20	1,843
4 or more Years	2,754	11,617,659	79	4,317
Total	6,045	14,751,155	100	2,490

In general, the Department assumes that less-than-2-year institutions, which include many trade and technical programs (*e.g.,* cosmetology, HVAC repair, dental assistant) do not engage in interscholastic athletic competition or operate intramural athletic programs. The Department seeks specific public comment on the extent to which less-than-2-year IHEs would be impacted by the proposed regulation.

The Department generally assumes that approximately 50 percent of 2- to 4-year IHEs operate intramural teams, some or all of which are male or female teams, and that the IHEs establish policies governing those programs.

For intercollegiate athletic competition, eligibility is generally governed by national athletic associations, as described above. For purposes of this analysis, the Department assumes that each athletic association independently adopts and applies criteria to determine the eligibility of students to participate on male or female teams consistent with their gender identity. The Department annually collects data on whether IHEs are members of such associations. Of the 3,989 IHEs for which the Department has data,[19] 1,986 were members of a national athletic association in the 2020–2021 school year. Of those IHEs, 1,526 were 4-year institutions and 460 were 2- to 4-year institutions.

TABLE 2—SELECTED CHARACTERISTICS BY NATIONAL ATHLETIC ASSOCIATION MEMBERSHIP AND LEVEL OF INSTITUTION, FALL 2020

Level of institution	Member of National Athletic Association		Not a member of National Athletic Association	
	Number	Average enrollment	Number	Average enrollment
2- to 4-Year IHE	460	3,223	830	1,641
4-Year IHE	1,526	6,440	1,173	1,542
Total	1,986	5,695	2,003	1,583

[19] Data are not available for 312 2- to 4-year institutions and 55 4-year institutions.

TABLE 3—PERCENTAGE OF IHES THAT ARE MEMBERS OF NATIONAL ATHLETIC ASSOCIATIONS BY LEVEL AND CONTROL OF INSTITUTION, FALL 2020

	2- to 4-Year IHEs (%)	4-Year IHEs (%)	All levels (%)
Public	55	77	65
Private Non-Profit	7	57	54
Private For Profit	0	7	3
All Sectors	36	43	50

As part of its annual data collection, the Department gathers information on membership in five specific national athletic associations (referred to below as the ''five named athletic associations''). IHEs reported membership in the five named athletic associations for the 2020–2021 school year as follows:

- The National Collegiate Athletic Association (NCAA)—1,108 IHEs;
- The National Association of Intercollegiate Athletics (NAIA)—250 IHEs;
- The National Junior College Athletic Administration (NJCAA)—498 IHEs;
- The National Small College Athletic Association (NSCAA)—43 IHEs; and
- The National Christian College Athletic Association (NCCAA)—89 IHEs.

Also as part of its data collection, the Department permits IHEs to report membership in national athletic associations other than the five named athletic associations. For the 2020–2021 school year, 138 IHEs reported that they were members of an athletic association other than the five named athletic associations. The Department does not have data on the specific athletic associations to which these IHEs belong. For purposes of this analysis, the Department assumes two additional national athletic associations, beyond the five named athletic associations, would be required to review policies pursuant to the proposed regulation if it were to be promulgated. The Department seeks specific public comment on this estimate.

As explained in the discussion of the proposed regulation, in January 2022, the NCAA replaced its longtime rules for transgender student-athlete participation and adopted a sport-by-sport approach that defers to the eligibility criteria set by national governing bodies—*e.g.,* USA Swimming, USA Gymnastics—subject to review by the NCAA's Committee on Competitive Safeguards and Medical Aspects of Sports. Some of these national groups look to international organizations such as FINA and International Gymnastics Federation (FIG), which set criteria for participation in international competitions involving elite athletes. *See, e.g.,* USA Swimming, *Athlete Inclusion, Competitive Equity, and Eligibility Policy* at 4–5 (Mar. 10, 2023), *https://www.usaswimming.org/docs/default-source/governance/governance-lsc-website/rules_policies/usa-swimming-policy-19.pdf* (noting that athletes who wish to compete in a World Aquatics Competition must meet the eligibility criteria in the World Aquatics Policy, which ''are potentially more difficult to satisfy than'' the USA Swimming policy); USA Gymnastics, *Transgender & Non-Binary Athlete Inclusion Policy* at 3 (Apr. 2022), *https://www.usagym.org/PDFs/About%20USA%20Gymnastics/transgender_policy.pdf* (noting that elite athletes who are transgender must satisfy requirements for participation set by the FIG and IOC). Taking these elite international competition criteria into account, some national governing bodies have developed eligibility criteria that differ based on levels of competition, with certain criteria applying only to athletes who seek to compete internationally or in nationally recognized record-setting events. In addition, eligibility criteria vary by sport. Some international governing bodies permit transgender women to compete at elite levels if they satisfy specific testosterone suppression criteria. *See, e.g.,* Union Cycliste Internationale, UCI Eligibility Regulations. Others exclude from elite competition transgender women who have experienced any aspect of male puberty. *See, e.g.,* FINA Policy on Eligibility. Some sport governing bodies have not yet updated their policies or their criteria for determining transgender students' participation remain under review. For example, World Lacrosse announced it is reviewing and revising its eligibility criteria for everyone involved in the sport, including transgender athletes, to create a policy that ensures that ''everyone has a right to safely participate in sport while maintaining fair competition.'' World Lacrosse, *World Lacrosse Forms Partnership with National Center for Transgender Equality to Create Trans-Inclusive Participation Policy* (June 9, 2022), *https://worldlacrosse.sport/article/world-lacrosse-forms-partnership-with-national-center-for-transgender-equality/.* The Department generally assumes that national and international governing bodies will continue to revise their policies in the coming years and that most or all will seek to develop policies that, in their view, maximize athletes' participation consistent with gender identity while ensuring fair and safe competition.

2.B.2. Developing the Model

Athletic Competition in ESE Entities

In general, the Department assumes that only LEAs that offer male and female athletic teams would be directly affected by the proposed regulation. As part of the 2017–2018 Civil Rights Data Collection, schools in approximately 60 percent of LEAs submitting responses indicated that they operated one or more male or female athletic teams. For purposes of this analysis, the Department assumes approximately 60 percent of all LEAs offer sex-separate athletic teams, for an estimated 10,849 affected LEAs.

As noted above, although recipient LEAs would be subject to the proposed regulation, they generally do not independently establish requirements for participation in interscholastic competition. Instead, LEAs typically participate as members in State athletic associations, which generally establish these requirements. Regardless, the Department notes that recipient LEAs must comply with Title IX and the obligation to do so is not alleviated by any contrary athletic association rule. *See* 34 CFR 106.6(c). Because of this obligation, the Department believes that many LEAs, as members of State athletic associations, would communicate with their State's athletic association about the Department's proposed regulation. As a result, the Department believes it is reasonable to assume that State athletic associations would review and

consider revising their policies on this issue.

Also as noted above, the Department has not evaluated existing State athletic association policies governing interscholastic athletics to determine whether they would comply with the proposed regulation. However, the Department assumes that a range of policies would comply with the proposed regulation. On the other hand, a State athletic association policy with restrictive sex-related eligibility criteria that complies with the proposed regulation in the context of a particular sport (*e.g.,* a sport with significant physical contact) may not comply in the context of a different sport (*e.g.,* one with little or no physical contact) if, for example, a recipient cannot demonstrate how its sex-related criteria are substantially related to achievement of an important educational objective in the context of that particular sport and minimize harms to students whose opportunity to participate on a male or female team consistent with their gender identity would be limited or denied by the criteria. As a result, the Department anticipates that all LEAs and all athletic associations will undertake at least some level of review of their existing policies or the policies of associations to which they belong. The Department does not assume the adoption, elimination, or modification of any specific policy.

The Department believes that the proposed regulation would render State athletic associations that currently prevent transgender students from participating on male or female teams consistent with their gender identity more likely than others to conduct intensive reviews of their existing policies. The Department anticipates this result because athletic association policies that would limit or deny students' eligibility to participate on male or female teams consistent with their gender identity would be more likely to raise questions from member LEAs, student-athletes, and families regarding compliance with Title IX. The Department assumes many of these State athletic associations, or their member LEAs, would engage in some revision to ensure their policies comply with the regulation. By contrast, the Department generally assumes that the 20 percent of State athletic associations that currently allow students to participate on male or female athletic teams consistent with their gender identity would be less likely to engage in intensive review of their policies and implement revisions than other States. For purposes of this analysis, the Department assumes the following:

- All LEAs, including those that do not offer athletic teams, will engage in an initial review of the rule;
- In 20 percent of States, the State athletic association and LEAs offering athletic teams whose policies already permit students to participate on male or female teams consistent with their gender identity will undertake a review but would be unlikely to revise their existing policies;
- In 20 percent of States, the State athletic association and LEAs offering athletic teams whose policies impose requirements that enable most or all transgender students to participate consistent with their gender identity will undertake a more intensive review but would also be unlikely to revise their existing policies; and
- In 60 percent of States, the State athletic association and LEAs offering athletic teams whose policies prohibit or significantly restrict participation by transgender students consistent with their gender identity will undertake a more intensive review and will revise their existing policies.

The Department anticipates that the 60 percent of State athletic associations and LEAs in this final category will experience burdens associated with revising their policies for a variety of reasons. Some of these associations may have more complex policy structures than others (*e.g.,* different policies for different sports as opposed to a single policy affecting all sports). Others may have particular bureaucratic structures (*e.g.,* standing review panels), public participation requirements (*e.g.,* 45 days of public comment), or assent requirements (*e.g.,* a certain percentage of member LEAs must agree to any policy change). The Department seeks specific public comment on the extent to which such structures or requirements may exist and where, how they would impact the estimates included here, and whether, as a result, it would be appropriate for the Department to subdivide this final category to account for variation in the field.

The Department recognizes that LEAs are not evenly distributed across States and, therefore, the policies of a single State athletic association could affect more LEAs than the policies of multiple other State athletic associations that serve a smaller number of schools. However, for purposes of this analysis, the Department assumes that, if 45 percent of State athletic associations implement a particular policy, 45 percent of LEAs offering athletic teams would be affected. More specific estimates would require the Department to develop independent estimates for specific States or groups of States and then correlate those State-specific effects and responses to estimates of the number of LEAs offering athletic teams in each State. There is not enough information available to the Department to develop reliable estimates at this level of granularity, and therefore the Department assumes an equal distribution of LEAs.

The Department also assumes that State athletic associations engage in periodic reviews and updates to their policies. Although the proposed regulation would not require such reviews, the Department believes the proposed regulation would likely factor into these reviews. The Department assumes any subsequent review of policies in this area would be unlikely to occur for several years after the initial review to determine compliance with the proposed regulation, but also assumes that approximately five State athletic associations would review these policies each year thereafter. Of those, the Department estimates approximately one State athletic association would engage in a policy revision each year. The Department requests specific public comment on the extent to which State athletic associations are likely to engage in a review of these policies and on what timeline such reviews may occur.

Finally, as noted above, in the vast majority of States, determinations regarding eligibility of particular student-athletes are made at the local level (*i.e.,* school or LEA). The Department assumes State athletic associations, once they have revised their policies, will train LEA staff (*e.g.,* athletic directors) to make those determinations. LEA staff in these positions likely already receive regular training from the State athletic association; therefore, the Department assumes that any training regarding eligibility determinations would likely supplant other training, or time devoted to other topics would be adjusted to make time to train LEA staff on this topic.

The Department also notes the relatively low number of transgender student-athletes relative to the overall population of student-athletes. *See, e.g., Hecox,* 479 F. Supp. 3d at 982 (noting the ''incredibly small percentage of transgender women athletes''). To the extent additional training is required beyond the standard training to all athletic directors and staff, the Department anticipates that it will be conducted on an ad hoc basis as necessary. The Department therefore assumes that there will be no additional time burdens above baseline associated with training in future years.

Athletic Competition in IHE Entities

In general, the Department assumes that only IHEs offering separate male and female athletic teams would be directly affected by the proposed regulation. However, the Department is unaware of any comprehensive data source on the number of IHEs that offer such teams, including in club and intramural athletics. Based on the information in Establishing a Baseline (Section 2.B.1) above, the Department assumes that participation varies by entity type, including whether an institution is public or private, and size, among other factors. For example, the Department assumes that less-than-2-year private, for-profit IHEs, such as those offering cosmetology or other specific career training programs, are less likely than 4-year IHEs to offer athletic teams. The Department requests specific public comment on the extent to which any high-quality data sources exist regarding IHE offerings of athletic teams, beyond the data from the National Center for Education Statistics cited above, and the extent to which such data can be used for this analysis.

As noted above, although all IHEs that are recipients of Federal financial assistance would be subject to the proposed regulation, they generally do not independently establish requirements for participation in intercollegiate competition. Instead, IHEs typically participate as members of one or more national athletic associations, which generally establish these requirements. However, the Department notes that recipient IHEs, like all recipients of Federal funds, must comply with Title IX and the obligation to do so is not alleviated by any contrary athletic association rule. *See* 34 CFR 106.6(c). Because of this obligation, the Department assumes that many IHEs would advocate, as members of one or more national athletic associations, to ensure that their associations' policies related to students' participation consistent with their gender identity comply with the Department's regulation. As a result, the Department believes it is reasonable to assume that national athletic associations would review and, as necessary, revise their policies to comply with the proposed regulation on this issue.

For purposes of this analysis, the Department has not evaluated existing policies governing intercollegiate athletics such as national athletic association policies to determine whether they would comply with the proposed regulation. However, the Department assumes that due to the nature of the proposed regulation and the potential implications of non-compliance with Title IX for their members, all national athletic associations would engage in some degree of review of their policies to comply with the proposed regulation. Further, the Department assumes that all IHEs offering athletic teams would spend time reviewing their own policies governing athletic participation not sponsored by a national athletic association (*e.g.,* intramural sports leagues). The Department further assumes that, upon revision of policies by a national athletic association, a subset of affected IHEs would conduct an independent review of the revised policies to independently assess whether the policies are compliant with the proposed regulation. The Department assumes that these reviews would most likely occur at larger, better-resourced IHEs, with the remainder of IHEs assuming that the policies promulgated or approved by their respective athletic associations comply with the proposed regulation without conducting further analysis. The Department does not assume the adoption, elimination, or modification of any specific policy.

For purposes of this analysis, the Department assumes the following:

- All IHEs, including those that do not offer athletic teams, will complete an initial review of the proposed regulation;
- Forty percent of IHEs (those offering athletic teams, including intercollegiate as well as intramural) will undertake a more intensive review of the proposed regulation and their existing policies;
- Twenty percent of IHEs will revise their institution-specific policies (*e.g.,* those governing intramural sports) after conducting the more intensive review just described;
- All five named athletic associations and two additional athletic associations will extensively review their policies, and of those seven athletic associations, four will revise their policies to comply with the proposed regulation; and
- As a result of athletic association policy changes, 10 percent of IHEs will conduct a secondary review of those new athletic association policies to assess compliance with the proposed regulation.

Estimating specific effects the proposed regulation would have on IHEs is difficult for a variety of reasons. First, because national athletic associations range in size and number of member IHEs, policy revisions undertaken by one national athletic association may have more far-reaching effects than those of another. Second, of the IHEs reporting membership in an athletic association, 132 IHEs reported membership in more than one association. Each national athletic association would likely have one or more member IHE that is also a member of another athletic association. As a result, it is likely that associations would establish policies that account for other associations' policies and that all associations would have an incentive to promote alignment, which would reduce compliance burdens on dual-member IHEs. Depending on which associations revise their policies, the extent to which they do so, the timing of their revisions, and the degree of motivation on the part of other associations to align their policies, there could be widely varying effects. For example, if the NCAA adopts a significant policy revision based on the proposed regulation, that revision would directly affect more than half of all IHEs offering athletic teams. This revision may also prompt smaller associations to adopt similar policies to align with the NCAA, and as a result, nearly all IHEs offering athletic teams would be impacted. By contrast, if a small association adopts a policy change affecting only a small number of IHEs that are not members of additional associations, effects may be limited because other associations may choose not to align their policies. The Department seeks specific public comment on its analysis and information on how to better evaluate the factors that would contribute to the effects of policy revisions by one athletic association on the policies of other associations.

The Department assumes that national athletic associations periodically review and update their policies. Although the proposed regulation would not require periodic reviews, the Department believes national athletic associations will consider the proposed regulation in their review process. The Department assumes national athletic associations are unlikely to review their policies in this area for several years after completing their initial review, but thereafter assumes that every year there would be approximately two national athletic associations that would review these policies. The Department assumes that most associations review their policies on a 3-year cycle. The Department seeks specific public comment on whether such a timeline is reasonable.

Of those associations that conduct a review, the Department estimates that approximately one athletic association will revise its policies each year. The Department requests specific public comment on the extent to which athletic

associations are likely to review their policies and on what timeline these reviews may occur.

The Department anticipates that IHE entities will incur minimal additional training costs, similar to its projections for ESE entities, as a result of the proposed regulation. The Department assumes national athletic associations provide annual training to IHE staff (*e.g.,* athletic directors) on a range of policy issues, and as a result of the proposed regulation, this annual training would cover any new policies. The Department assumes that there will be no additional time burdens above baseline associated with training in future years. The Department seeks specific public comment on the extent to which these estimates and assumptions are reasonable.

Finally, the Department recognizes that this Athletics NPRM comes at a time when IHEs that offer intercollegiate athletic teams may be affected by changes to national and international sex-related criteria for determining students' eligibility to participate on male or female teams. It is the Department's current view that by regulating during a time when changes are ongoing, the proposed regulation may reduce costs by providing some certainty about what regulatory requirements must be met on this issue to fulfill a recipient's obligations under Title IX; at the same time, because these changes are ongoing, the Department cannot predict the nature of future eligibility criteria that may be adopted by the NCAA or other national athletic associations with any degree of certainty.

2.B.3. Cost Estimates

Athletic Competition in ESE Entities

The Department estimates that, to comply with the proposed regulation, all regulated entities, including those that do not offer an athletic program, would take time to review the regulation to determine whether it applies to their entity, as the Department generally assumes that all regulated entities will have some level of interest in the proposed regulation. At the LEA level, the Department assumes this initial review, which is limited to determining whether the regulation applies, would take an education administrator approximately half an hour to complete (at $100.36/hour)[20] at 18,083 LEAs, for a total Year 1 cost of $907,400.

For State athletic associations and LEAs offering athletic teams, the Department assumes those entities in 20 percent of States will engage in a less intensive review of their existing policies. The Department estimates that all LEAs would also spend time reviewing their own policies for intramural and other athletic activities not otherwise governed by a State athletic association for compliance with the Department's regulation. The Department does not anticipate that this review would be burdensome because the Department assumes that there are fewer activities of this type. The Department assumes that this review would be more burdensome for State athletic associations given the number of LEAs and athletic programs implicated. The Department welcomes comments on the accuracy of these assumptions. At the LEA level, the Department estimates this review would require 2 hours each from an education administrator[21] and management analyst[22] ($81.56/hour) at 2,169 LEAs. For State athletic associations, the Department estimates that this activity would take 4 hours for an education administrator, 4 hours for a management analyst, and 2 hours for an attorney ($148.76/hour) at each of 10 associations. In total, we estimate that these activities would cost approximately $799,420 in Year 1.

In the remaining 80 percent of States, the Department estimates that LEAs and State athletic associations would engage in a more intensive review of their policies on athletic participation because their existing policies restrict, to some degree, the participation of students on male or female teams consistent with their gender identity. This intensive review would be used by LEAs and State athletic associations to determine whether existing policies are compliant as written or whether the policies would need to be revised to comply with the proposed regulation. At the LEA level, the Department estimates that this work will take 4 hours each for an education administrator and a management analyst in 8,679 LEAs to complete. For State athletic associations, the Department estimates that this work would take 6 hours from an education administrator, 6 hours from a management analyst, and 2 hours for one attorney working on behalf of each of 41 associations. In total, the Department estimates this activity would cost approximately $6,372,490 in Year 1.

The Department estimates that State athletic associations in approximately 60 percent of States would opt to revise their existing policies upon completing their review. The Department estimates that some LEA staff would be involved in this process by, for example, commenting on draft proposals or participating in roundtable discussions. At State athletic associations, the Department assumes it would take less time to revise existing policies than to complete the review of the proposed regulation; the Department bases its estimate on the assumption that many issues to be addressed would have already been identified during the initial review. At the LEA level, the Department assumes one education administrator would spend 4 hours at each of 6,509 LEAs on this task. At the State athletic association level, the Department estimates this task would require 4 hours from an education administrator, 20 hours from a management analyst, and 12 hours from an attorney. In total, the Department estimates it would cost approximately $2,731,320 in Year 1 for 31 State athletic associations to revise their policies governing students' eligibility to participate on male or female teams consistent with their gender identity.

After policies have been revised, the Department assumes that State athletic associations would develop and deliver updated training about their new policies to staff in affected LEAs. The Department further assumes that developing the training would require 10 hours from a management analyst, 10 hours from a lawyer, and 1 hour from an education administrator to review and approve the training in each of 31 associations. The Department anticipates that this training would take an additional 30 minutes above existing training obligations for an education administrator in each of 6,509 LEAs. In total, the Department estimates that updated training would cost approximately $401,130 in Year 1.

In future years, the Department assumes that approximately five State athletic associations per year would undertake a review of their policies on students' participation consistent with their gender identity. The Department assumes this task would require 1 hour from an education administrator, 4

[20] For purposes of this regulatory impact analysis, the Department uses wage rates from the U.S. Bureau of Labor Statistics' May 2021 National Industry-Specific Occupational Employment and Wage Estimates (NAICS 611000—Educational Services), available at *https://www.bls.gov/oes/current/naics3_611000.htm.* The Department uses a loading factor of 2.0 to account for the costs of overhead, benefits, and other non-wage expenses.

[21] As used in this regulatory impact analysis, the term ''education administrator'' is intended to encompass staff in leadership and senior leadership roles in an organization, such as a superintendent, assistant superintendent, or athletic director.

[22] As used in this regulatory impact analysis, the term ''management analyst'' is intended to encompass non-legal program and agency staff including, but not limited to, athletic coaches, project officers, or athletic department staff.

hours from a management analyst, and 2 hours from a lawyer for a total cost of approximately $3,620 per year beginning in Year 3.

Each year, the Department assumes that one of those five associations will opt to revise their policies. We estimate that this revision would require 4 hours from an education administrator, 16 hours from a management analyst, and 10 hours from a lawyer for a total cost of approximately $3,190 per year beginning in Year 3.

At the ESE level, the Department estimates that the proposed regulation would generate a present value monetized cost of $10.5 to $10.9 million over 10 years, assuming a seven percent and three percent discount rate, respectively.

Athletic Competition in IHE Entities

The Department estimates that to comply with the proposed regulation, all regulated entities, including those that do not offer an athletic program, would take time to review the proposed regulation to determine whether it applies to their entity, because the Department generally assumes that all regulated entities will have some level of interest in the proposed regulation. At the IHE level, the Department assumes this initial review, which is limited to determining whether the regulation applies, would take an education administrator approximately 1 hour to complete at each of 6,045 IHEs for a total Year 1 cost of $607,580.

For IHEs offering athletic teams, the Department estimates that these entities would spend time reviewing their own policies regarding participation in athletics for compliance with the proposed regulation. At the IHE level, the Department estimates this internal policy review would require 8 hours from an education administrator, 8 hours from a management analyst, and 6 hours for an attorney working on behalf of each of 2,148 IHEs. In total, the Department estimates that these activities would cost approximately $5,043,330 in Year 1.

The Department further estimates that approximately 20 percent of IHEs would, as a result of their internal policy review, opt to make revisions to their policies. The Department estimates that such revisions would require 4 hours from one education administrator, 30 hours from a management analyst, and 16 hours from an attorney at each of 1,210 IHEs. In total, the Department estimates that these activities would have a total cost of $6,326,360 in Year 1.

The Department estimates that the five named athletic associations and two additional national athletic associations would conduct a review of their policies as a result of the proposed regulation. The Department estimates that these internal policy reviews would require 8 hours each from four education administrators, 8 hours each from four management analysts, and 6 hours each from two attorneys. In total, we estimate that this review would cost approximately $53,250 in Year 1.

The Department further estimates that, as a result of their internal policy reviews, four national athletic associations would choose to revise their policies. The Department estimates that this revision would require 15 hours each from four education administrators, 20 hours each from four management analysts, and 12 hours each from two attorneys. Further, after those revisions are finalized, the Department assumes that approximately 10 percent of IHEs would conduct their own review of the policies prior to implementing them. The Department estimates that this secondary review would require 8 hours each from an education administrator and management analyst and 6 hours from an attorney. In total, the Department estimates these revisions would cost approximately $1,484,960.

The Department further assumes that each of those four athletic associations would update training materials consistent with their revised policies. The Department assumes that these revisions would require 8 hours from an education administrator, 32 hours from a management analyst, and 10 hours from an attorney. The Department further estimates that the updated training would require an additional hour for an education administrator at each of 1,289 IHEs. In total, the Department estimates that updated training would cost approximately $148,970 in Year 1.

The Department assumes that in future years approximately two national athletic associations per year would undertake a review of their policies on students' participation consistent with their gender identity. The Department assumes this task would require 4 hours each from four education administrators, 8 hours each from four management analysts, and 6 hours each from two attorneys for a total cost of approximately $12,000 per year beginning in Year 3.

The Department assumes that each year, one of those associations would opt to revise its policies. The Department estimates that this revision would require 8 hours each from four education administrators, 16 hours each from four management analysts, and 10 hours each from two attorneys, for a total cost of approximately $11,410 per year beginning in Year 3.

At the IHE level, the Department estimates the proposed regulation would generate total present value monetized costs of $12.9 to $13.4 million over 10 years, assuming a seven percent and three percent discount rate, respectively.

3. Regulatory Alternatives Considered

The Department reviewed and assessed various alternatives prior to issuing the proposed regulation, drawing from internal sources as well as stakeholder feedback OCR received. Specifically, the Department considered the following actions: (1) leaving the current regulations without amendment; (2) addressing the issue through guidance; (3) proposing amendments to the regulations to specify permissible eligibility requirements; or (4) proposing a regulatory standard that can be effectively implemented, consistent with Title IX, by recipients serving students at varying grade and education levels in a variety of male and female team sports at varying levels of competition.

For the reasons described above, Department currently believes alternative (4) is the best option. In light of its review of Title IX and its regulations, stakeholder feedback, and developments in case law and in the sex-related eligibility criteria set by some school districts, States and other organizations (including athletic associations and sport governing bodies), it is the Department's current view that the proposed regulation would better ensure fulfillment of Title IX's nondiscrimination guarantee and would provide more clarity as to how Title IX applies to sex-related criteria that would limit or deny students' eligibility to participate on male or female teams consistent with their gender identity.

For these reasons and those explained throughout the preamble, and in light of stakeholder feedback received in 2021 and 2022, the Department does not believe alternative (1), which would leave the current regulations without amendment, is a reasonable option. The Department rejected alternative (2), which would address the issue through guidance, because the Department continues to believe it is necessary to establish, through regulations, the legal obligations of a recipient to ensure that its education program or activity is free from all forms of sex discrimination. Guidance documents, which are not legally binding on a recipient, would not serve that function. The Department

rejected alternative (3), which would propose amendments to the regulations to specify permissible eligibility requirements, because it would not allow for the Department to appropriately assess whether a recipient's criteria are responsive to the grade or education level of students, the nature of a particular sport, the level of competition, or other factors.

After careful consideration of these alternatives, the Department proposes that adopting option (4), which is to propose the regulatory standard put forward here, would best clarify recipients' legal obligations and most appropriately implement Title IX's guarantee of nondiscrimination on the basis of sex by recipients of Federal funds in the unique context of athletic teams offered by schools. Specifically, the Department's preliminary conclusion is that alternative (4) would help ensure that recipients understand the standard that would govern if they adopt or apply sex-related eligibility criteria for determining student participation on male or female athletic teams, in a manner that ensures overall equality of athletic opportunity based on sex. The Department's current view is that alternative (4) also strikes the appropriate balance between Title IX's guarantee that a recipient's education program or activity be free from sex discrimination and the unique considerations in the context of athletics.

4. Accounting Statement

As required by OMB Circular A–4, the following table is the Department's accounting statement showing the classification of the expenditures associated with the provisions of the proposed regulation. This table provides the Department's best estimate of the changes in annualized monetized costs, benefits, and transfers because of the proposed regulation.

Category	Benefits
Clarity for recipients and students concerning the standard for adopting and applying sex-related eligibility criteria to participate on a particular male or female athletic team.	Not quantified.
Protecting students' equal opportunity to participate on male and female teams and the physical and mental health and other benefits associated with that team participation.	Not quantified.

	Costs (calculated on an annual basis)	
	3% Discount rate	7% Discount rate
Preliminary Review of the Regulation	$172,000	$202,000
Review of Policies	1,396,000	1,632,000
Revision of Policies	1,200,000	1,403,000
Updated Training	63,000	73,000
Periodic Review of Policies	12,000	12,000
Periodic Updating of Policies	11,000	11,000
Total	2,855,000	3,333,000

Clarity of the Regulations

Executive Order 12866 and the Presidential memorandum ''Plain Language in Government Writing'' require each agency to write regulations that are easy to understand. The Secretary invites comments on how to make the proposed regulation easier to understand, including answers to questions such as the following:

- Are the requirements in the proposed regulation clearly stated?
- Does the proposed regulation contain technical terms or other wording that interferes with their clarity?
- Does the format of the proposed regulation (use of headings, paragraphing, etc.) aid or reduce their clarity?
- Would the proposed regulation be easier to understand if the Department divided it into more (but shorter) sections? (A ''section'' is preceded by the symbol ''section'' and a numbered heading; for example, § 106.41 Athletics.)
- Could the description of the proposed regulation in the **SUPPLEMENTARY INFORMATION** section of this preamble be more helpful in making the proposed regulation easier to understand? If so, how?
- What else might the Department do to make the proposed regulation easier to understand?

To send comments that concern how the Department could make the proposed regulation easier to understand, see the instructions in the **ADDRESSES** section of the preamble.

Regulatory Flexibility Act (Small Business Impacts)

1. Introduction

This analysis, required by the Regulatory Flexibility Act (RFA), presents an estimate of the effect of the proposed regulation on small entities. The U.S. Small Business Administration (SBA) Size Standards define ''proprietary IHEs'' as small businesses if they are independently owned and operated, are not dominant in their field of operation, and have total annual revenue below $7,000,000. ''Nonprofit institutions'' are defined as small entities if they are independently owned and operated and not dominant in their field of operation. ''Public institutions and LEAs'' are defined as small organizations if they are operated by a government overseeing a population below 50,000.

2. Initial Regulatory Flexibility Analysis

As explained in the Establishing a Baseline (Section 2.B.1) section of the RIA, there is a lack of high quality, comprehensive data about whether particular recipients offer athletic teams, whether intramural or interscholastic, whether recipients are likely to revise athletic eligibility policies as a result of the proposed regulation, and the likely impact of any such changes. As a result, the Department could not definitively conclude that burdens on small entities would be sufficiently low to justify certification under the RFA. If an agency is unable to make such a certification, it must prepare an Initial Regulatory Flexibility Analysis (IRFA) as described in the RFA. Based on the data available, the Department has completed an IRFA and requests comments from affected small entities.

The purpose of this analysis is to identify the number of small entities affected, assess the economic impact of the proposed regulation on those small entities, and consider alternatives that may be less burdensome to small entities that meet the Department's

regulatory objectives. Specifically, the Department estimates the number of small entities potentially impacted by the proposed regulation in the discussion of Estimated Number of Small Entities (Section 2.B), assesses the potential economic impact of the proposed regulation on those small entities in the discussion of Estimate of the Projected Burden of the Proposed Regulation on Small Entities (Section 2.C), and examines and considers less burdensome alternatives to the proposed regulation for small entities in the Discussion of Significant Alternatives (Section 2.D). The Department requests comment on the extent to which the burden assumptions described in the RIA are reasonable for small entities (*i.e.,* whether particular activities are likely to take more or less time or cost more or less than otherwise estimated).

2.A. Reasons for Regulating

The Department proposes this regulation to provide greater clarity to recipients and other stakeholders about the standard that a recipient must meet under Title IX if it adopts or applies sex-related criteria that would limit or deny a student's eligibility to participate on a particular male or female athletic team consistent with their gender identity. The proposed regulation is consistent with the current regulations' framework for providing equal opportunity regardless of sex in a recipient's athletic program as a whole and with Congress's direction that the Title IX regulations include ''reasonable provisions'' that ''consider[] the nature of particular sports.'' Education Amendments of 1974 section 844.

2.B. Estimated Number of Small Entities

Consistent with the 2020 amendments to the Department's Title IX regulations (see 85 FR 30026), for purposes of assessing the impacts on small entities, the Department proposes defining a ''small IHE'' as a 2-year institution of higher education with an enrollment of fewer than 500 full time equivalent (FTE) or a 4-year IHE with an enrollment of fewer than 1,000 FTE based on official 2020 FTE enrollment. The Department also proposes defining a ''small LEA'' as a local education agency with annual revenues of less than $7,000,000.

During the 2020–2021 school year, according to the National Center for Education Statistics, of the 6,165 Title IV participating IHEs for which sufficient data are available, 2,803 were 4-year institutions, 1,644 were 2-year institutions, and 1,718 were less-than-2-year institutions. Of those, 1,226 4-year institutions, 690 2-year institutions, and 1,650 less-than-2-year institutions met the Department's proposed definition of a ''small IHE.''

TABLE 1—NUMBER OF SMALL IHES, FALL 2020

	4-Year	2-Year	Less than 2-year	Total
Not Small	1,577	954	68	2,599
Small	1,226	690	1,650	3,566
Total	2,803	1,644	1,718	6,165

During the 2018–2019 school year, 6,518 of the 17,798 LEAs with available revenue data met the Department's proposed definition of a ''small LEA.''

TABLE 2—NUMBER OF SMALL LEAS, FALL 2018

	LEAs
Not Small	11,280
Small	6,518
Total	17,798

2.C. Estimate of the Projected Burden of the Proposed Regulation on Small Entities

Based on the assumptions described in the RIA, an IHE that reviews and revises its policies as a result of the proposed regulation would see a net increase in costs of approximately $560 per year (assuming a discount rate of 3 percent). The Department notes that this estimate assumes an IHE that offers single-sex athletic teams. The Department believes that smaller IHEs, such as many offering less-than-2-year programs, are less likely than other IHEs to offer athletic teams and therefore would experience no additional costs.

According to data from the Integrated Postsecondary Education Data System (IPEDS), in FY 2019, small IHEs had, on average, total revenues of approximately $10,349,540. Therefore, the Department estimates that the proposed regulation could generate a net cost for small IHEs equal to approximately 0.005 percent of annual revenue when they choose to review their policies. According to data from IPEDS, approximately 30 IHEs had total reported nonzero annual revenues of less than $56,000, for which the costs estimated above would potentially exceed 1 percent of total revenues. Three of these IHEs reported no enrollment data for the Fall 2020. The remaining IHEs enrolled, on average, 65 students in Fall 2020. None of these IHEs reported membership in a national athletic association. Twenty-three of the IHEs were vocational or technical schools and four were administrative units associated with larger college systems. The Department believes it is highly unlikely that these small IHEs offer athletic teams and, if they do, that they would regularly offer single-sex athletic teams.

Based on the assumptions described in the Cost Estimates (Section 2.B.3) discussion of the RIA, an LEA that engages in an intensive review and revision of its policies would see a net increase in costs of approximately $140 per year (assuming a discount rate of 3 percent). The Department notes that these estimates assume a small LEA that offers athletic teams. Many small LEAs may not be impacted by the proposed regulation, given that they may not offer athletic teams. The Department estimates that small LEAs that do not offer athletic teams would experience no additional costs.

In 2018–2019, small LEAs had an average total revenue of approximately $3,450,911. Therefore, the Department estimates that the proposed regulation could generate a net cost for small LEAs of approximately 0.004 percent of total revenues. According to data from the National Center for Education Statistics, in 2018–2019, six small LEAs reported nonzero total revenues of less than $14,000, for which the estimated costs would potentially exceed 1 percent of total revenues. Among those, four small LEAs had zero students enrolled during the 2018–2019 academic year and the reported revenues for the remaining two would result in calculated total revenues of less than $10 per student. Based on this analysis, the Department

believes that these are likely reporting errors and, therefore, the Department does not believe the estimated costs would exceed 1 percent of total revenues for any affected small LEA.

As part of the 2017–2018 CRDC, respondents were asked about the number of male and female athletic teams offered at the high school level. In analyzing the data in conjunction with information from the National Center on Education Statistics, small LEAs that served students in high school were less likely than larger LEAs to report at least one male or female team (30 percent of small LEAs indicated that the item was not applicable, compared with only 12 percent among non-small LEAs). Further, among those that reported at least one male or female athletic team, small LEAs operated, on average, approximately one-fifth as many teams as non-small LEAs (8.7 teams on average compared to 39.4).

The Department requests comment on any additional burdens for small entities.

2.D. Discussion of Significant Alternatives

As discussed in section 3 above (Regulatory Alternatives Considered), the Department reviewed and assessed various alternatives prior to issuing the proposed regulation, drawing on stakeholder feedback OCR received. Specifically, the Department considered: (1) leaving the current regulations without amendment; (2) addressing the issue through guidance; (3) proposing amendments to the regulations to specify permissible eligibility requirements; or (4) proposing a regulatory standard that can be effectively implemented, consistent with Title IX, by recipients serving students at varying grade and education levels in a variety of team sports at varying levels of competition.

As the Department described in the Regulatory Alternatives Considered (section 3) discussion of the RIA, it currently believes that alternative (4) is the best option, including that it is the Department's current view that the proposed regulation would better ensure fulfillment of Title IX's nondiscrimination guarantee and would provide more clarity as to how Title IX applies to sex-related criteria that would limit or deny students' eligibility to participate on male or female teams consistent with their gender identity.

After careful consideration of the four alternatives discussed above, the Department proposes that adopting option (4) would best clarify recipients' legal obligations and most appropriately implement Title IX's guarantee of nondiscrimination on the basis of sex by recipients of Federal funds in the unique context of athletic teams offered by schools. Specifically, the Department's preliminary conclusion is that alternative (4) would help ensure recipients understand the standard that would govern if they adopt or apply sex-related eligibility criteria for determining student participation on male or female athletic teams and thereby protect students' equal opportunity to participate on male and female teams consistent with Title IX. The Department's current view is that alternative (4) also strikes the appropriate balance between Title IX's guarantee that a recipient's education program or activity be free from sex discrimination and the unique considerations in the context of athletics.

The Department also considered whether proposing different requirements for smaller-sized recipients than for mid-sized or larger ones would reduce any potential burden on smaller entities. The Department rejects this alternative at this time because Title IX rights do not depend on the size of a recipient, and the proposed regulation is sufficiently adaptable so that small entities, along with other entities, can adopt the approach that works best for their particular educational environment.

Executive Order 12250 on Leadership and Coordination of Nondiscrimination Laws

Under Executive Order 12250, the Attorney General has the responsibility to ''review . . . proposed rules . . . of the Executive agencies'' implementing nondiscrimination statutes such as Title IX ''in order to identify those which are inadequate, unclear or unnecessarily inconsistent.'' [23] The Attorney General has delegated that function to the Assistant Attorney General for the Civil Rights Division for purposes of reviewing and approving proposed rules, 28 CFR 0.51, and the Assistant Attorney General has reviewed and approved this proposed rule.

Paperwork Reduction Act of 1995

This proposed regulation does not contain any information collection requirements.

Intergovernmental Review: This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79 because it is not a program or activity of the Department that provides Federal financial assistance.

Assessment of Educational Impact: In accordance with section 411 of the General Education Provisions Act, 20 U.S.C. 1221e–4, the Secretary particularly requests comments on whether the proposed regulation would require transmission of information that any other agency or authority of the United States gathers or makes available.

Federalism: Executive Order 13132 requires the Department to ensure meaningful and timely input by State and local elected officials in the development of regulatory policies that have federalism implications. ''Federalism implications'' means substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. The proposed regulation—§ 106.41(b)(2)—may have federalism implications. We encourage State and local elected officials to review and provide comments on this proposed regulation.

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[23] *Executive Order on Leadership and Coordination of Nondiscrimination Laws,* Exec. Order No. 12250, 45 FR 72995 (Nov. 4, 1980), *https://tile.loc.gov/storage-services/service/ll/fedreg/fr045/fr045215/fr045215.pdf.*

List of Subjects in 34 CFR Part 106

Civil rights, Education, Sex discrimination, Youth organizations.

Miguel A. Cardona,

Secretary of Education.

For the reasons discussed in the preamble, the Department of Education proposes to amend 34 CFR part 106 to read as follows:

PART 106—NONDISCRIMINATION ON THE BASIS OF SEX IN EDUCATION PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

■ 1. The authority citation for part 106 continues to read as follows:

Authority: 20 U.S.C. 1681 *et seq.,* unless otherwise noted.

■ 2. Section 106.41 is amended by:

■ a. Designating the text following the heading in paragraph (b) as paragraph (b)(1); and

■ b. Adding paragraph (b)(2).

The addition reads as follows:

§ 106.41 Athletics.

* * * * *

(b) * * *

(2) If a recipient adopts or applies sex-related criteria that would limit or deny a student's eligibility to participate on a male or female team consistent with their gender identity, such criteria must, for each sport, level of competition, and grade or education level:

(i) Be substantially related to the achievement of an important educational objective; and

(ii) Minimize harms to students whose opportunity to participate on a male or female team consistent with their gender identity would be limited or denied.

* * * * *

[FR Doc. 2023–07601 Filed 4–12–23; 8:45 am]

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