

(C) The method comparison study must include predefined maximum acceptable differences between the test and comparator method across all primary outcome measures in the clinical study protocol.

(D) The final release test results for each lot used in the clinical study.

Dated: September 17, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–21616 Filed 9–20–24; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG–2024–0820]

RIN 1625–AA00

#### **Safety Zone; Kernwood Avenue Bridge Repairs—Danvers River, Salem, MA, and Beverly, MA**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary Interim Rule and request for comments.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone on the navigable waters at mile 1.0 Danvers River, within a 100-yard radius of the center point of the Kernwood Avenue Bridge between Salem, MA and Beverly, MA. The temporary safety zone is necessary to protect personnel, vessels and the marine environment from potential hazards created during bridge repairs. When enforced, entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Boston or a designated representative.

**DATES:**

*Effective date:* This rule is effective without actual notice from September 23, 2024 through 11:59 p.m. on December 31, 2024. For the purposes of enforcement, actual notice will be used from September 15, 2024, until September 23, 2024.

*Comments due date:* Comments and related material must be received by the Coast Guard on or before October 23, 2024.

**ADDRESSES:** You may submit comments identified by docket number USCG–2024–0820 using the Federal e-Rulemaking Portal at <http://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for

further instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this rulemaking, call or email Mr. Timothy Chase, Waterways Management Division, U.S. Coast Guard Sector Boston, telephone 617–447–1620, or email [Timothy.w.chase@uscg.mil](mailto:Timothy.w.chase@uscg.mil).

**SUPPLEMENTARY INFORMATION:**

**I. Table of Abbreviations**

CFR Code of Federal Regulations  
COTP Captain of the Port  
DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of proposed rulemaking  
NAD 83 North American Datum 1983  
§ Section  
U.S.C. United States Code  
MASSDOT Massachusetts Department of Transportation

**II. Background Information and Regulatory History**

On August 28, 2024, the Massachusetts Department of Transportation (MassDOT) bridge division notified the Waterways Management Division of U. S. Coast Guard Sector Boston that operations to make repairs to the Kernwood Avenue Bridge, spanning the Danvers River between Salem, MA, and Beverly, MA, will begin September 15, 2024.

The Coast Guard is issuing this temporary rule under the authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the construction schedule for Kernwood Avenue Bridge was only recently finalized and prompt action is needed to respond to the potential safety hazards associated with this project. It is impracticable and contrary to the public interest to publish an NPRM because prompt action is needed to establish this safety zone by September 15, 2024, to allow for the timely repairs to the Kernwood Avenue Bridge and ensure the safety of mariners transiting the area from the dangers associated with the operations associated with these repairs.

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

ensure public safety during repair operations to the Kernwood Avenue Bridge.

Although this regulation is published as an interim rule without prior notice, public comment is nevertheless desirable to ensure that the regulation is both workable and reasonable.

Accordingly, persons wishing to comment may do so by submitting written comments as set out under **ADDRESSES** in this preamble. Commenters should include their names and addresses, identify the docket number for the regulation, and give reasons for their comments. If the Coast Guard determines that changes to the temporary interim rule are necessary, we will publish a temporary final rule or other appropriate document.

**III. Legal Authority and Need for Rule**

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Boston (COTP) has determined that potential hazards associated with bridge repair operations starting September 15, 2024, will be a safety concern for anyone within a 100-yard radius of the center point of the Kernwood Avenue Bridge. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while bridge repair operations are taking place.

**IV. Discussion of Rule**

This rule establishes a safety zone from September 15, 2024, through 11:59 p.m. on December 31, 2024. While the safety zone will be effective through this period, it will only be enforced during active repair operations, when work barges and cranes will be placed in the narrow navigable channel, or other instances which may create a hazard to navigation. The active repair operations will take place during the overnight hours, from 9 p.m. through 5 a.m., Sunday through Thursday, when boating traffic is minimal.

The safety zone will cover all navigable waters within a 100-yard radius of the center point of the MassDOT Kernwood Avenue Bridge, at mile 1.0, spanning the Danvers River, between Salem, MA, and Beverly, MA, in approximate position 42°32'34.8" N 70°53'54.2" W (NAD 83). During times of enforcement, all persons or vessels will be prohibited from entering the safety zone without permission from the COTP or a designated representative.

The Coast Guard will make notice of the safety zone via the Local Notice to Mariners and issue a Broadcast Notice to Mariners via marine channel 16 (VHF–FM) as soon as practicable in

response to an emergency or hazardous condition. In addition, if the project is completed before 11:59 p.m. on December 31, 2024, enforcement of the safety zone will be suspended, and notice given via Local Notice to Mariners. The First Coast Guard District Local Notice to Mariners can be found at: <http://www.navcen.uscg.gov>.

## V. Regulatory Analyses

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

### A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, location, duration, and time of year of the safety zone. Vessel traffic will not be able to safely transit around this safety zone when enforced. As a result, enforcement of the safety zone will be limited in duration during active repair operations, in the overnight hours, Sunday through Thursday, during the winter months when vessel traffic is minimal. Additionally, the Salem, Beverly, and Danvers Harbor Masters will be on scene during work hours to inform any potential vessels of the safety zone. The Coast Guard will make notice of this safety zone via the Local Notice to Mariners and issue a Broadcast Notice to Mariners via marine channel 16 (VHF-FM) as soon as practicable in response to an emergency or hazardous condition. This rule also allows vessels to seek permission to enter the zone.

### B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions

with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator because they are able to transit with permission from COTP or the COTP’s designated representative.

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

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

### C. Collection of Information

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

### D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination

with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

### E. Unfunded Mandates Reform Act

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

### F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of a temporary safety zone for the navigable waters within 100-yard radius of the center point of the MassDOT Kernwood Avenue Bridge, at mile 1.0, spanning the Danvers River between Salem, MA, and Beverly, MA, from September 15, 2024, through December 31, 2024, during active repair operation on the bridge. The safety zone will only be enforced from 9 p.m. to 5 a.m. Sunday through Thursday, when work barges and cranes will be placed in the narrow navigable channel, or in response to an emergency or hazardous condition. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

### G. Protest Activities

The Coast Guard respects the First Amendment rights of protestors. Protesters are asked to contact the person listed in the **FOR FURTHER**

**INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

## VI. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. If we determine that changes to the temporary interim rule are necessary, the Coast Guard will publish a temporary final rule or other appropriate document. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision-Making Portal at <https://www.regulations.gov>. To do so, go to <https://www.regulations.gov>, type USCG-2024-0303 in the search box and click "Search." Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using <https://www.regulations.gov>, call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this temporary interim rule as being available in the docket, find the docket as described in the previous paragraph, and then select "Supporting & Related Material" in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the <https://www.regulations.gov> Frequently Asked Questions web page. Also, if you click on the Dockets tab and then the temporary interim rule, you should see a "Subscribe" option for email alerts. The option will notify you when comments are posted, or a subsequent document is published.

We review all comments received, but we will only post comments that address the topic of the rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's

eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

### List of Subjects in 33 CFR Part 165

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

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

### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T01-0820 to read as follows:

#### § 165.T01-0820 Safety Zone; Kernwood Avenue Bridge Repairs—Danvers River, Salem, MA, and Beverly, MA.

(a) *Location.* The following area is a safety zone: all navigable waters within a 100-yard radius of the center point of the Massachusetts Department of Transportation (MassDOT) Kernwood Avenue Bridge, at mile 1.0 spanning the Danvers River between Salem, MA, and Beverly, MA, in approximate position 42°32'34.8" N 70°53'54.2" W.

(b) *Enforcement period.* The safety zone in paragraph (a) of this section is effective from September 15, 2024, through 11:59 p.m. on December 31, 2024. The section is subject to enforcement from 9 p.m. to 5 a.m. Sunday through Thursday, or in response to an emergency or hazardous condition during this period. The Coast Guard will make notice of this safety zone via the Local Notice to Mariners and issue a Broadcast Notice to Mariners via marine channel 16 (VHF-FM) as soon as practicable in response to an emergency or hazardous condition. In addition, if the project is completed before 11:59 p.m. on December 31, 2024, enforcement of the safety zone will be suspended, and notice given via Local Notice to Mariners. The First Coast Guard District Local Notice to Mariners can be found at: <http://www.navcen.uscg.gov>.

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

(1) *Designated representative* means any Coast Guard commissioned, warrant, petty officer, or any federal, state, or local law enforcement officer who has been designated by the Captain of the Port Boston (COTP) to act on his or her behalf. The designated representative may be on an official

patrol vessel or may be on shore and will communicate with vessels via VHF-FM radio or loudhailer. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

(2) *Official patrol vessels* mean any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP to enforce this section.

(d) *Regulations.* When this safety zone is enforced, the following regulations, along with those contained in 33 CFR 165.23 apply:

(1) No person or vessel may enter or remain in the safety zone described in paragraph (a) of this section without the permission of the COTP or the COTP's designated representatives. Any person or vessel permitted to enter the safety zone must comply with the lawful directions and orders of the COTP or the COTP's designated representatives.

(2) To seek permission to enter the safety zone, individuals may reach the COTP or a COTP-designated representative via Channel 16 (VHF-FM) or (857) 416-3015 (Sector Boston Command Center).

**J.J. Schock,**

*Commander, U.S. Coast Guard, Acting Captain of the Port Boston.*

[FR Doc. 2024-21688 Filed 9-20-24; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2024-0755]

RIN 1625-AA00

#### Safety Zone; Lake Erie, Hamburg, NY

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone within 656 yards of the Andrew D. Byers Water Circular DZ, adjacent to Hamburg Beach on Lake Erie. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a military exercise. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Eastern Great Lakes or a designated representative.

**DATES:** This rule is effective from 6 a.m. through 11:30 p.m. from September 26, 2024, through September 27, 2024.