

(b) *Classification*. Class II (special controls). The special controls for this device are:

(1) Design verification and validation must include:

(i) A detailed description of the image analysis algorithm, including a description of the algorithm inputs and outputs, each major component or block, how the algorithm and output affects or relates to clinical practice or patient care, and any algorithm limitations.

(ii) A detailed description of pre-specified performance testing protocols and dataset(s) used to assess whether the device will provide improved assisted-read detection and diagnostic performance as intended in the indicated user population(s), and to characterize the standalone device performance for labeling. Performance testing includes standalone test(s), side-by-side comparison(s), and/or a reader study, as applicable.

(iii) Results from standalone performance testing used to characterize the independent performance of the device separate from aided user performance. The performance assessment must be based on appropriate diagnostic accuracy measures (*e.g.*, receiver operator characteristic plot, sensitivity, specificity, positive and negative predictive values, and diagnostic likelihood ratio). Devices with localization output must include localization accuracy testing as a component of standalone testing. The test dataset must be representative of the typical patient population with enrichment made only to ensure that the test dataset contains a sufficient number of cases from important cohorts (*e.g.*, subsets defined by clinically relevant confounders, effect modifiers, concomitant disease, and subsets defined by image acquisition characteristics) such that the performance estimates and confidence intervals of the device for these individual subsets can be characterized for the intended use population and imaging equipment.

(iv) Results from performance testing that demonstrate that the device provides improved assisted-read detection and/or diagnostic performance as intended in the indicated user population(s) when used in accordance with the instructions for use. The reader population must be comprised of the intended user population in terms of clinical training, certification, and years of experience. The performance assessment must be based on appropriate diagnostic accuracy measures (*e.g.*, receiver operator

characteristic plot, sensitivity, specificity, positive and negative predictive values, and diagnostic likelihood ratio). Test datasets must meet the requirements described in paragraph (b)(1)(iii) of this section.

(v) Appropriate software documentation, including device hazard analysis, software requirements specification document, software design specification document, traceability analysis, system level test protocol, pass/fail criteria, testing results, and cybersecurity measures.

(2) Labeling must include the following:

(i) A detailed description of the patient population for which the device is indicated for use.

(ii) A detailed description of the device instructions for use, including the intended reading protocol and how the user should interpret the device output.

(iii) A detailed description of the intended user, and any user training materials or programs that address appropriate reading protocols for the device, to ensure that the end user is fully aware of how to interpret and apply the device output.

(iv) A detailed description of the device inputs and outputs.

(v) A detailed description of compatible imaging hardware and imaging protocols.

(vi) Warnings, precautions, and limitations must include situations in which the device may fail or may not operate at its expected performance level (*e.g.*, poor image quality or for certain subpopulations), as applicable.

(vii) A detailed summary of the performance testing, including test methods, dataset characteristics, results, and a summary of sub-analyses on case distributions stratified by relevant confounders, such as anatomical characteristics, patient demographics and medical history, user experience, and imaging equipment.

Dated: June 9, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025–10789 Filed 6–12–25; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[Docket Number USCG–2025–0257]

RIN 1625–AA08

#### **Special Local Regulation; 4th of July Fireworks, Lower East River & Upper New York Bay, Manhattan and Brooklyn, NY**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a special local regulation on the navigable waters of the Lower East River and New York Harbor, NY, for a 4th of July fireworks display. This special local regulation allows the Coast Guard to control vessel movement and prohibit all vessel traffic from entering the fireworks barge buffer zone and establish four separate viewing areas. This rule is necessary to provide for the safety of life on the navigable waters immediately before, during, and after a fireworks display on a highly congested waterway.

**DATES:** This rule is effective from 5:30 p.m. on July 4 through 11:30 p.m. on July 5, 2025. It will only be subject to enforcement, however, during the hours of 5:30 p.m. to 11:30 p.m. on July 4, or, in the event the fireworks display is postponed due to inclement weather or other causes, from 5:30 p.m. to 11:30 p.m. on July 5, 2025.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2025–0257 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this rule, call or email Lieutenant Junior Grade Rebecca Fitzgerald-Smith, Waterways Management Division, U.S. Coast Guard; telephone 718–801–2932, email [Rebecca.R.Fitzgerald-Smith@uscg.mil](mailto:Rebecca.R.Fitzgerald-Smith@uscg.mil).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Table of Abbreviations**

CFR Code of Federal Regulations  
COTP Captain of the Port New York  
DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of proposed rulemaking  
§ Section  
SLR Special Local Regulation  
U.S.C. United States Code

## II. Background Information and Regulatory History

July 4, 2025, marks the 49th anniversary of the annual Macy's 4th of July fireworks. The firework launch barges have changed location throughout the years between the Hudson River, East River, and the Lower East River. Three years ago on June 21, 2022, the Captain of the Port, Sector New York (COTP) created a Final Rule titled, "Special Local Regulation; East River 4th of July Fireworks, New York, NY" which was published in the **Federal Register** (87 FR 36763) June 21, 2022. That rule, codified at 33 CFR 100.110, established a special local regulation on the navigable waters of the East River and New York Harbor, New York, NY for vessel management in the vicinity of the Macy's 4th of July fireworks barges. The 2022 Macy's 4th of July Fireworks occurred without incident.

On February 18, 2025, Macy's Inc. notified the Coast Guard that it desires to conduct their 4th of July fireworks display in 2025 at a different location on the Lower East River and Upper Bay. Because of the location change this year, we are promulgating this temporary rule rather than using the permanent rule at 33 CFR 100.110, which will not be subject to enforcement this year.

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 it is impractical to do so due to insufficient time to publish a final rule by July 4.

33 CFR 100.110, titled "East River 4th of July Fireworks, East River, Manhattan, NY" establishes a permanent special local regulation, which is enforced annually on July 4, from 5:30 p.m. through 11:30 p.m. In the event the fireworks display is postponed due to inclement weather or other causes, it would be enforced on July 5, from 5:30 p.m. to 11:30 p.m. 33 CFR 100.110 is suspended from 5:30 p.m. on July 4, 2025, until 11:30 p.m. on July 5, 2025, due to this special local regulation.

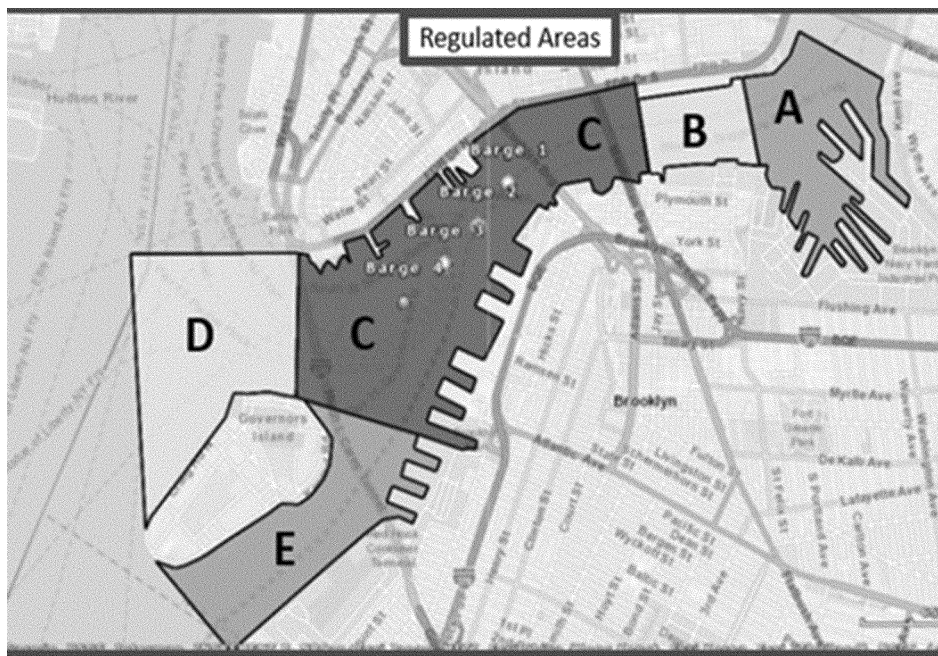
## III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector New York (COTP) has determined that this rule is

needed to protect personnel, vessels, and the marine environment in the navigable waters within the regulated areas to ensure the safety of spectators and vessels from hazards associated with the fireworks display.

## IV. Discussion of the Rule

The Coast Guard is establishing a special local regulation subject to enforcement from 5:30 p.m. through 11:30 p.m. on July 4, 2025, with July 5, 2025, from 5:30 p.m. through 11:30 p.m. being a contingency date. This special local regulation creates five regulated areas: a buffer zone around each firework display barge and four viewing areas. As shown in the illustration below, the buffer zone, area "C," will exclude all nonparticipating vessels from the area surrounding the barges immediately before, during, and after the display. The four separate viewing areas, areas "A," "B," "D," and "E," will separate vessels based on the vessels' length and timing of entry into each zone. Vessels desiring to utilize ALPHA ("A"), BRAVO ("B"), or ECHO ("E") limited access areas must enter the area by 7:30 p.m. Vessels desiring to utilize DELTA ("D") may begin entering the designated viewing area at 8:00 p.m. and must be in a holding position no later than 9:00 p.m.



(Illustration showing locations of regulated areas)

The duration of the enforcement times is intended to ensure the safety of vessels, participants, spectators, and

those transiting the area during the fireworks display. Navigation rules, 33 CFR part 83, will apply at all times within the areas. The Coast Guard will provide notice of the special local

regulation by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

## 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.

### 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. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the special local regulation’s size, location, and duration. In addition, although this rule restricts access to the waters encompassed by the special local regulation, the effect of this rule will not be significant because the local waterway users will be notified in advance via a public Broadcast Notice to Mariners and Local Notice to Mariners. The entities most likely affected are commercial vessels and pleasure crafts engaged in recreational activities.

### B. Impact on Small Entities

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), 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 would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

### D. Federalism and Indian Tribal Governments

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

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

### E. Unfunded Mandates Reform Act

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

### F. Environment

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

individually or cumulatively have a significant effect on the human environment. This rule involves a temporary regulated area lasting six hours or less that would limit persons or vessels from transiting a portion of the Lower East River and portions of the Upper Bay during the scheduled event. It is categorically excluded from further review under paragraph L61 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.

### List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

## PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

**Authority:** 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add § 100.T01–0257 to read as follows:

### § 100.T01–0257 Special Local Regulation; 4th of July Fireworks, Lower East River & New York Harbor, Manhattan, NY

(a) *Regulated areas.* The regulations in this section apply to the following areas:

(1) *Area ALPHA (“A”):* All navigable waters of the East River bound by a line connecting the following coordinates: from 40°42′46″ N 73°58′34″ W (near Grand St. Manhattan), thence to 40°42′38″ N 73°58′12″ W, along the shore to 40°42′22″ N, 073°58′45″ W (near Little Street, Brooklyn, NY), thence to 40°42′37″ N, 073°58′50″ W (the corner of Pier 42, Manhattan, NY), then along the shoreline back to the point of origin.

(2) *Area BRAVO (“B”):* All navigable waters of the East River bound by a line connecting the following points: from 40°42′37″ N, 073°58′50″ W (near Pier 42, Manhattan, NY), thence to 40°42′22″ N, 073°58′45″ W (near Little Street, Brooklyn, NY), along the shore to 40°42′19″ N 73°59′15″ W (near Pearl Street, Brooklyn, NY), thence to 40°42′33″ N 73°59′18″ W (near Jefferson Street, Manhattan, NY) then along the shoreline to the point of origin.

(3) *Area CHARLIE (“C”):* All navigable waters of the East River bound by a line connecting the following

points: beginning at 40°42'33" N 73°59'18" W (near Jefferson Street, Manhattan, NY), thence to 40°42'19" N 73°59'15" W (near Pearl Street, Brooklyn, NY), along the shore thence to 40°41'28" N 74°00'19" W (Pier 8, Brooklyn, NY), thence to 40°41'34.728" N 74°00'54" W (near Governors Island Ferry Slip), thence to 40°42'03" N 74°00'55" W (near Battery Park, Manhattan, NY), then along the shoreline back to the point of origin.

(4) *Area DELTA ("D")*: All navigable waters of the Upper Bay bound by a line connecting the following points from 40°42'03" N 74°00'55" W (near Battery Park, Manhattan, NY), thence to 40°41'35" N 74°00'54" W (near the Governors Island Ferry Slip), along the shoreline of Governors Island thence to 40°41'09" N 74°01'36" W, then north thence to 40°42'03" N, 074°01'40" W, then back to the point of origin.

(5) *Area ECHO ("E")*: All navigable waters of the Upper Bay bound by a line connecting the following points beginning at 40°41'34" N, 74°0'51" W (near Governors Island) thence to 40°41'28" N 74°00'19" W (Pier 8, Brooklyn, NY), thence to 40°40'44" N 74°01'10" W (Red Hook), thence to 40°41'03" N 74°01'32" W, then along the shore back to the point of origin.

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

(1) *Coast Guard Patrol Commander* means a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel.

(2) *Designated representative* means a Coast Guard Patrol Commander and a Federal, State, and local officer designated by or assisting the Captain of the Port New York (COTP) in the enforcement of the regulations in this section.

(3) *Official Patrol Vessel* means any Coast Guard, Coast Guard Auxiliary, Federal, State or local law enforcement vessel assigned or approved by the COTP New York to assist in the enforcement of this section.

(4) *Spectator* means a person or vessel not registered with the event sponsor as participants or official patrol vessels.

(5) *Participant* means all persons and vessels hired by the event sponsor as a participant in the event.

(c) *Regulations*. (1) All non-participants are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area described in paragraph (a) of this section unless authorized by the Captain of the Port New York (COTP) or their designated representative.

(2) All vessels that are authorized by the COTP or a designated representative to enter the regulated areas established

by this section must adhere to the following restrictions:

(i) Area ALPHA ("A") is limited to vessels over 20 meters (65.6ft) in length.

(ii) Area BRAVO ("B") is limited to vessels less-than or equal to 20 meters (65.6ft) in length.

(iii) All vessels are prohibited from entering area CHARLIE ("C") without permission from the COTP or a designated representative after 6:00 p.m. Commercial passenger vessels that need to transit through the Charlie Section enroute to their designated viewing areas, or designated facility must receive authorization from the Coast Guard Patrol Commander. Commercial passenger vessels must pass as close to the pierhead as possible and must transit through the zone no later than 7:30 p.m. Vessels must operate at the minimum speed necessary to maintain safe course while crossing through area CHARLIE and comply with all direction that may be provided by the Coast Guard.

(iv) Area DELTA ("D") is limited to vessels over 20 meters (65.6ft) in length.

(v) Area ECHO ("E") is limited to vessels less-than or equal to 20 meters (65.6ft) in length.

(vi) Vessels desiring to utilize ALPHA ("A"), BRAVO ("B"), or ECHO ("E") limited access areas must enter the area by 7:30 p.m.

(vii) Vessels desiring to utilize DELTA ("D") may begin entering the designated viewing area at 8 p.m. and must be in a holding position no later than 9 p.m.

(3) During periods of enforcement all persons and vessels in the limited access areas must comply with all lawful orders and directions from the COTP New York or the COTP New York's designated representative.

(4) Vessel operators desiring to enter or operate within a limited access area should contact the designated representative at 844-NYC-USCG or on VHF 16 to obtain permission.

(5) Spectators or other vessels must not anchor, block, loiter or impede the transit of event participants or official patrol vessels in the limited access area during the enforcement period and times unless authorized by COTP New York or designated representative.

(6) The COTP or a designated representative will inform the public through local notice to mariners. Broadcast Notices to Mariners, or both, of the enforcement period for the regulated area as well as any changes of the enforcement times.

(d) *Enforcement periods*. This section will be subject to enforcement from 5:30 p.m. through 11:30 p.m. on July 4, 2025. In the event the fireworks display is postponed due to inclement weather or

other causes, this section will be enforced from 5:30 p.m. to 11:30 p.m. on July 5, 2025.

**Jonathan Andrechik,**  
*Captain, U.S. Coast Guard, Captain of the Port, Sector New York.*

[FR Doc. 2025–10767 Filed 6–12–25; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[Docket Number USCG–2025–0023]

RIN 1625–AA08

### Special Local Regulation; Duluth Harbor, Duluth, MN

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary special local regulation for certain waters of the Duluth Harbor entrance to Superior Bay on Lake Superior. This action is necessary to provide for the safety of life on these navigable waters near Duluth, MN during the Festival of Sail 2025 event beginning on July 10, 2025, and ending the evening of July 13, 2025. This regulation prohibits persons and vessels from being in the safety zone unless authorized by the Captain of the Port Duluth or a designated representative.

**DATES:** This rule is effective from 9 a.m. on July 10, 2025, through 9 p.m. on July 13, 2025.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2025–0023 in the search box and click "Search." Next, in the Document Type column, select "Supporting & Related Material."

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this rule, call or email Lieutenant Zachary Fedak, Marine Safety Unit Duluth, U.S. Coast Guard; telephone 218–522–0708, email [Zachary.A.Fedak@uscg.mil](mailto:Zachary.A.Fedak@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### I. Table of Abbreviations

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