

intended to stabilize microbial nucleic acids in human specimens for subsequent isolation and purification of nucleic acids for further molecular testing. The device is not intended for preserving morphology or viability of microorganisms. FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—MICROBIAL NUCLEIC ACID STORAGE AND STABILIZATION DEVICE RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Failure to stabilize pathogen nucleic acid resulting in a false negative result.	General Controls and Special Controls (1) (21 CFR 866.2950(b)(1)), (2) (21 CFR 866.2950(b)(2)), and (3) (21 CFR 866.2950(b)(3)).
Failure to inactivate the specimen .....	General Controls and Special Controls (1) (21 CFR 866.2950(b)(1)); (2)(i) (21 CFR 866.2950(b)(2)(i)), (2)(ii) (21 CFR 866.2950(b)(2)(ii)), and (2)(iv) (21 CFR 866.2950(b)(2)(iv)); and (3)(i) (21 CFR 866.2950(b)(3)(i)), (3)(ii) (21 CFR 866.2950(b)(3)(ii)), and (3)(iv) (21 CFR 866.2950(b)(3)(iv)).

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

**III. Analysis of Environmental Impact**

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**IV. Paperwork Reduction Act of 1995**

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo Classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under

OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

**List of Subjects in 21 CFR Part 866**

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

**PART 866—IMMUNOLOGY AND MICORBIOLOGY DEVICES**

- 1. The authority citation for part 866 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

- 2. Add § 866.2950 to subpart C to read as follows:

**§ 866.2950 Microbial nucleic acid storage and stabilization device.**

(a) *Identification.* A microbial nucleic acid storage and stabilization device is a device that consists of a container and reagents intended to stabilize microbial nucleic acids in human specimens for subsequent isolation and purification of nucleic acids for further molecular testing. The device is not intended for preserving morphology or viability of microorganisms.

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

(1) The intended use for the labeling required under § 809.10 of this chapter must include a detailed description of microorganisms and types of human specimens intended to be preserved.

(2) The labeling required under § 809.10(b) of this chapter must include the following:

- (i) A detailed device description, including all device components;
- (ii) Performance characteristics from applicable analytical studies, including

nucleic acid stability and microorganism inactivation;

(iii) A limiting statement that erroneous results may occur when the transport device is not compatible with molecular testing; and

(iv) A limiting statement that the device has only been validated to preserve the representative microorganisms used in the analytical studies.

(3) Design verification and validation must include the following:

- (i) Overall device design, including all device components and all control elements incorporated into the analytical validation procedures;
- (ii) Thorough description of the microorganisms and methodology used in the validation of the device including, extraction platforms and assays used for the detection of preserved nucleic acids; and
- (iii) The limit of detection (LoD) of the molecular test used to establish microorganism nucleic acid stability.

Dated: May 5, 2025.

**Grace R. Graham,**  
*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025–08145 Filed 5–8–25; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 100**

[Docket Number USCG–2025–0218]

RIN 1625–AA08

**Special Local Regulation; Ohio River, Cincinnati, OH**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary special local

regulation on the navigable waters of the Ohio River, extending the entire width of the river, between mile marker (MM) 469.6–470.2 in Cincinnati, OH. This special local regulation is necessary to provide for the safety of life on these navigable waters near Cincinnati, OH, during the Queen City Triathlon on June 22, 2025.

**DATES:** This rule is effective from 6:30 a.m. through 9:30 a.m. on June 22, 2025.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2025–0218 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 MST1 Jean Jimenez Sosa, Marine Safety Detachment Cincinnati, U.S. Coast Guard; telephone 513–921–9033, email [MSDCincinnati@uscg.mil](mailto:MSDCincinnati@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

#### I. Table of Abbreviations

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

#### II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule under the authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. This action is necessary to publish an NPRM because the Coast Guard must establish this special local regulation by June 22, 2025, and lacks sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

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 contrary to public interest in ensuring the safety of participants and vessels during the event because immediate action is necessary to prevent possible loss of life

and property on June 22, 2025. The Coast Guard will issue Broadcast Notice to Mariners (BNM) to update mariners of the restrictions and enforcement times during this event.

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

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70041. The Captain of the Port Sector Ohio Valley (COTP) has determined that this action is necessary to provide for the safety of life on these navigable waters near Cincinnati, OH during the Queen City Triathlon on June 22, 2025. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the special local regulation from MM 469.6–470.2 from 6:30 a.m. through 9:30 a.m.

#### IV. Discussion of the Rule

This rule establishes a temporary special local regulation from 6:30 a.m. until 9:30 a.m. on June 22, 2025. The regulation will prevent mariners and persons not participating in the triathlon from entering the Ohio River between MM 469.6–470.2. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the schedule event. No vessel or person will be permitted to enter the regulated area without obtaining permission from the COTP or a designated representative.

#### V. Regulatory Analyses

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

##### 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 size, location, duration, and time of year of the temporary special local regulation. The temporary special local regulation will be in effect for only three hours and will cover an area less than one mile in length on the Ohio River. The Coast Guard expects minimum adverse impact to mariners from the temporary special local

regulation activation as the event has been advertised to the public.

##### 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 regulated area may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule 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 will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

##### D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship

between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

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

#### *E. Unfunded Mandates Reform Act*

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

#### *F. Environment*

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a special local regulation that will prohibit entry from MM 469.6–470.2 of the Ohio River lasting from 6:30 a.m. through 9:30 a.m. It is categorically excluded from further review under paragraph L61of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Memorandum for the Record 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.T08–0218 to read as follows:

#### **§ 100.T08–0218 Special Local Regulation; Ohio River, Cincinnati, OH.**

(a) *Regulated area.* The regulations in this section apply to the following area: All navigable waters of the Ohio River extending from mile marker 469.6–470.2 in Cincinnati, OH.

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

*Designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Sector Ohio Valley (COTP) in the enforcement of the regulations in this section.

*Participant* means all persons and vessels registered with the event sponsor as participants in the event.

(c) *Regulations.* 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 Sector Ohio Valley or their designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative on VFH–FM radio channel 16 or phone at 1–800–253–7465. Those in the regulated area must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(3) The COTP will provide notice of the regulated area through advanced notice via broadcast notice to mariners and by on-scene designated representatives.

(d) *Enforcement period.* This temporary special local regulation will be enforced from 6:30 a.m. until 9:30 a.m. on June 22, 2025.

Dated: April 29, 2025.

#### **H.R. Mattern,**

*Captain, U.S. Coast Guard, Captain of the Port Sector Ohio Valley.*

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#### **DEPARTMENT OF HOMELAND SECURITY**

#### **Coast Guard**

#### **33 CFR Part 165**

[Docket No. USCG–2025–0391]

#### **Safety Zone; Fireworks Displays Within the Fifth Coast Guard District; The Wharf, Washington, DC**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notification of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce a safety zone for a fireworks display at “The Wharf DC,” in Washington, DC, to provide for the safety of life on navigable waterways during this event. Our regulation, “Safety Zones; Fireworks Displays within the Fifth Coast Guard District,” identifies the precise location. During the enforcement period, vessels may not enter, remain in, or transit through the safety zone unless authorized to do so by the COTP or his representative, and vessels in the vicinity must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

**DATES:** The regulation in 33 CFR 165.506 will be enforced for the location identified in line no. 1 of table 2 to 33 CFR 165.506(h)(2) from 8 p.m. until 10 p.m., on June 07, 2025.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notification of enforcement, call or email LCDR Kate M. Newkirk, Sector Maryland-NCR, Waterways Management Division, U.S. Coast Guard: telephone 410–576–2596, email [MDNCRMarineEvents@uscg.mil](mailto:MDNCRMarineEvents@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce the safety zone regulation for a fireworks display at The Wharf DC from 8 p.m. to 10 p.m. on June 07, 2025. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation, “Safety Zones; Fireworks Displays within the Fifth Coast Guard District,” § 165.506, specifies the location of the safety zone for the fireworks show, which encompasses portions of the Washington Channel in the Upper Potomac River. As reflected in 33 CFR 165.23, vessels in the vicinity of the safety zone may not enter, remain in, or transit through the safety zone during the enforcement period unless authorized to do so by the COTP or his representative, and they must comply with directions from the Patrol