

SDV. New product code SDW, which represents clinical electronic thermometers with telethermographic functions, has been named “Stationary Infrared Thermometer.” Clinical electronic thermometers with continuous temperature measurement functions continue to fall under product code FLL. As such, FDA has revised the name of product code FLL from “Thermometer, Electronic, Clinical” to “Continuous Measurement Thermometer” to more accurately reflect the devices that fall within this product code. New product code SDV, which represents the class II exempt clinical electronic thermometers and reflects the partial exemption limitations, has been named “Clinical Electronic Thermometer.” This ensures that the non-exempt devices can be identified distinctly from devices that fall within the partial exemption limitation (*i.e.*, exempt and non-exempt devices have distinct product codes).

#### V. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(h) 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.

#### VI. Paperwork Reduction Act of 1995

FDA concludes that this final order contains no new collection of information. This final order refers to previously approved collections of information. These collections of information are subject to review by the OMB under the PRA. 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 parts 800, 801, and 830, regarding labeling have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR part 820 regarding quality system regulation have been approved under OMB control number 0910–0073.

#### List of Subjects in 21 CFR Part 880

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 880 is amended as follows:

#### PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 1. The authority citation for part 880 continues to read as follows:

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

■ 2. In § 880.2910, revise paragraph (b) to read as follows:

##### § 880.2910 Clinical electronic thermometer.

\* \* \* \* \*

(b) *Classification.* Class II (performance standards). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter, subject to the limitations in § 880.9 and the following conditions for exemption:

(1) Device is not a clinical thermometer with telethermographic functions;

(2) Device is not a clinical thermometer with continuous temperature measurement functions; and

(3) Appropriate analysis and testing (such as that outlined in the currently FDA-recognized editions, as appropriate, of ISO 80601–2–56, “Medical electrical equipment—Part 2–56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement,” or ASTM E1965, “Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature,” or ASTM E1112, “Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature,” or ASTM E1104, “Standard Specification for Clinical Thermometer Probe Covers and Sheaths”) must validate specifications and performance of the device.

Dated: June 13, 2025.

**Grace R. Graham,**

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

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**BILLING CODE 4164–01–P**

#### DEPARTMENT OF HOMELAND SECURITY

##### Coast Guard

##### 33 CFR Part 165

[Docket Number USCG–2025–0427]

RIN 1625–AA00

##### Safety Zone; Monongahela River MM 122–122.5, Rivesville, WV

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for the Monongahela River on June 28, 2025, from mile marker 122 to mile marker 122.5, to provide for the safety of life on the navigable waters during a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Pittsburgh, or a designated representative.

**DATES:** This rule is effective on June 28, 2025, from 9 p.m. through 11 p.m.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2025–0427 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 Petty Officer Brett Lanzel, MSU Pittsburgh, U.S. Coast Guard; telephone 206–815–6624, email [Brett.J.Lanzel@uscg.mil](mailto:Brett.J.Lanzel@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

##### 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. We must establish this

safety zone by June 28, 2025 to ensure public safety during a fireworks display, and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this 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 impracticable and contrary to the public interest because action is needed by June 28, 2025, to ensure the safety of life on the navigable waters during the firework display.

### 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 Pittsburgh (COTP) has determined that potential hazards associated with a firework show on June 28, 2025, will be a safety concern for anyone on the Monongahela River from mile marker 122 to mile marks 122.5 from 9 p.m. to 11 p.m. This rule is needed to protect participants, vessels, and the navigable waters in the safety zone, before, during, and after the scheduled event.

### IV. Discussion of the Rule

This rule establishes a safety zone from 9 p.m. until 11 p.m. on June 28, 2025. The safety zone will cover all navigable waters between mile marker 122 to 122.5 on the Monongahela River. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during a firework display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. To seek permission to enter, contact the COTP or designated representative via VHF-FM channel 16, or through Marine Safety Unit Pittsburgh at 412-221-0807. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative. The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement through Local Notice to Mariners (LNMs), Broadcast Notice to Mariners (BNMs), and/or Marine Safety Information Bulletins (MSIBs), as appropriate.

### 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 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) 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. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

The Office of Management and Budget (OMB) has not designated this rule a “significant regulatory action,” under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it.

This regulatory action determination is based on size, location, and duration of the temporary safety zone. This safety zone only impacts a half-mile stretch on the Monongahela River for 2 hours on June 28, 2025. Moreover, the Coast Guard will issue Local Notice to Mariners and Broadcast Notice to Mariners via VHF-FM marine channel 16 about the zone and the rule allows vessels to seek permission from the COTP to transit the zone.

#### B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule 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 creates a safety zone for a fireworks display, lasting only 2 hours that will prohibit entry within mile marker 122 through 122.5 on the Monongahela River. 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.

### 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. 01.4.

■ 2. Add § 165.T08–0427 to read as follows:

### § 165.T08–0427 Safety Zone; Monongahela River Mile Marker 122 to 122.5, Rivesville, WV.

(a) *Location.* The following area is a safety zone: All navigable waters on the Monongahela River between mile marker 122 and mile marker 122.5.

(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 Pittsburgh (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of

this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VFH Channel 13 or 16, or through Marine Safety Unit Pittsburgh at 412–221–0807. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be subject to enforcement from 9 p.m. to 11 p.m. on June 28, 2025.

Dated: June 3, 2025.

**Justin R. Jolley,**

*Commander, U.S. Coast Guard, Captain of the Port, MSU Pittsburgh.*

[FR Doc. 2025–11202 Filed 6–17–25; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 165

[Docket Number USCG–2025–0135]

RIN 625–AA00

### Safety Zones; Erie, PA; Detroit, MI; Duluth, MN

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing temporary safety zones around each tall ship visiting the Great Lakes during the Tall Ships Challenge 2025 race series beginning on July 10, 2025 through October 1, 2025. These safety zones will provide for the regulation of vessel traffic in the vicinity of each tall ship in the navigable waters of the United States. The Coast Guard is taking this action to safeguard participants and spectators from the hazards associated with the limited maneuverability of these tall ships and to ensure public safety during tall ships events.

**DATES:** This rule is effective from July 10, 2025 through October 1, 2025.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2025–0135 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 LTJG Jonathan Tripi, Ninth District Waterways Management, U.S. Coast Guard; 216–902–6078, [jonathan.r.tripi@uscg.mil](mailto:jonathan.r.tripi@uscg.mil)

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#### II. Background Information and Regulatory History

On October 2, 2024, Tall Ships America notified the Coast Guard that from July 10, 2025 through October 1, 2025, it will be conducting maritime parades, training cruises, races, and mooring in the ports of Erie, PA, Detroit, MI, and Duluth, MN. In response, on May 1, 2025, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zones; Erie, PA; Detroit, MI; Duluth, MN (90 FR 18635). There we stated why we issued the NPRM and invited comments on our proposed regulatory action related to these Tall Ship events. During the comment period that ended June 2, 2025, we received zero comments.

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

The Coast Guard is issuing this rule under the authority in 46 U.S.C. 70034. The Captain of the Port (COTP) of the respective areas expect a large number of spectators in confined areas adjacent to the tall ships. The combination of large numbers of recreational boaters, congested waterways, boaters crossing commercially transited waterways, and low maneuverability of the tall ships could easily result in serious injuries or fatalities. Therefore, the Coast Guard will enforce safety zones around each ship to ensure the safety of both participants and spectators in these areas.

#### IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published May 1, 2025. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes safety zones from 12:01 a.m. on July 10, 2025 until 12:01 a.m. on October 1, 2025. The safety zones will cover all navigable waters within 100 yards of a tall ship in the Great Lakes. The duration of the zones are intended to ensure the safety of vessels and these navigable waters during the 2025 Tall Ships Challenge. No vessel or person would be permitted