

one clearance under any of those same three classification regulations;

- The manufacturer implemented “a robust post-market plan, transparency, and training measures” as described in the petition; and
- All existing “special controls, quality systems, establishment registration, and device listing requirements” remained in force.

On December 29, 2025, FDA published a notice of the petition in the **Federal Register** (90 FR 60730) and requested comments on it, in accordance with section 510(m)(2) of the FD&C Act. The comment period closed on February 27, 2026.

FDA considered the information available to the Agency, including comments from the public docket for the petition and **Federal Register** notice, and determined not to exempt devices classified under §§ 892.2060, 892.2070, 892.2080, and 892.2090 from the 510(k) requirements subject to the partial limitations of exemption proposed in the petition.¹ Accordingly, FDA responded to the petition by letter dated April 1, 2026, denying the petition within the 180-day timeframe under section 510(m)(2) of the FD&C Act.

IV. Order

As discussed in the petition response issued to the petitioner on April 1, 2026, based on FDA’s review of the petition’s proposed partial exemption, and in consideration of the comments submitted to the docket and FDA’s own assessment of each of the four factors for exemption described in the **Federal Register** notice (63 FR 3142) and the Class II 510(k) Exemption Guidance, FDA determined that the information presented in the petition does not demonstrate that premarket notification is not necessary to assure the safety and effectiveness of the Subject CAD and CADt Devices that may be covered by the petition’s proposed partial exemption. Therefore, FDA denied the petition request for partial exemption from premarket notification requirements for the Subject CAD and CADt Devices and is issuing this order setting forth the final determination. FDA’s response to the petition can be found in Docket No. FDA–2025–P–5560, available at <https://www.regulations.gov/docket/FDA-2025-P-5560>.

¹ In considering the petition and comments submitted to the docket, FDA has assumed that all elements of petitioner’s proposal were partial limitations on exemption that FDA may consider under section 510(m)(2) of the FD&C Act and we refer to them as partial limitations on exemption throughout this order.

Manufacturers of the Subject CAD and CADt Devices must continue to submit and receive FDA clearance of a 510(k) submission before marketing their devices, as well as comply with all other applicable requirements under the FD&C Act.

Although FDA determined that the proposal in the petition did not support a partial exemption from 510(k) requirements under section 510(m)(2) of the FD&C Act, the Agency has a longstanding commitment to develop and apply innovative approaches to the regulation of medical device software and other digital health devices to ensure their safety and effectiveness consistent with least burdensome principles. FDA supports the continued consideration of innovative and least burdensome approaches that may accelerate the availability of safe and effective devices.

V. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not normally 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

This final administrative order refers to previously approved collections of information found in FDA regulations. The previously approved 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 21 CFR part 820 (Quality Management System Regulation) have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 812 (Investigational Device Exemptions) have been approved under OMB control number 0910–0078; the collections of information in part 807, subpart E (Premarket Notification Procedures), have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 822 (Postmarket Surveillance) have been approved under OMB control number 0910–0449; and the collections of information under 21 CFR part 801 (Device Labeling) have been approved under OMB control number 0910–0485.

VII. References

The following reference is on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and is available for viewing by interested

persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. FDA Guidance, “Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,” February 19, 1998, available at <https://www.fda.gov/media/72685/download>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19074 Filed 9–16–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2026–1161]

RIN 1625–AA08

Special Local Regulation; Maumee River, Toledo, OH

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation (SLR) for certain navigable waters of the Maumee River near Toledo, OH. This action is necessary to provide for the safety of life on these navigable waters during the Glass City Regatta occurring on September 19, 2026. This regulation prohibits persons and vessels from entering the regulated area unless specifically authorized by the Captain of the Port, Sector Detroit or their designated representative.

DATES: This rule is effective from 7 a.m. through 4 p.m. on September 19, 2026.

ADDRESSES: To view available documents go to <https://www.regulations.gov> and search for USCG–2026–1161.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact MST2 Jacob Allen, Waterways Management Division, U.S. Coast Guard Marine Safety Unit Toledo; (419) 418–6050, D09-SMB-MSUToledo-WWM@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
§ Section
SLR Special Local Regulation
U.S.C. United States Code

II. Background and Authority

The Coast Guard received a Marine Event Application under 33 CFR 100.15 from the Toledo Rowing Foundation to host a rowing regatta. The event will be held from 7 a.m. through 4 p.m. on September 19, 2026, in Toledo, OH. The event will include approximately 30 rowing vessels.

The Captain of the Port Detroit (COTP) is issuing this Special Local Regulation (SLR) under the authority in 46 U.S.C. 70041. The COTP has determined that potential hazards associated with the rowing regatta include the participants rowing within the navigable channel, as well as the possibility that participants rowing within approaches to local public and private boat facilities might collide with or otherwise interfere with boaters near those facilities. The purpose of this rulemaking is to protect event participants, non-participants, and transiting vessels before, during, and after the scheduled event.

Because of these potential hazards, the Coast Guard is issuing this rule without prior notice and comment. As is authorized by 5 U.S.C. 553(b)(B), 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. On August 31, 2026, the Coast Guard became aware that the planned racecourse differed from the historical course used for this event, described in 33 CFR 100.911, Table 1, Event 14. We must establish this SLR by September 19, 2026, to protect personnel, vessels, and the marine environment. Therefore, we do not have enough time to solicit and respond to comments.

For the same reasons, the Coast Guard finds that under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Discussion of the Rule

This rule establishes a temporary SLR from 7 a.m. through 4 p.m. on September 19, 2026. The special local regulation will cover all navigable waters of the Maumee River from river mile 6.0 to river mile 3.2. No vessel or person will be permitted to enter the regulated area without obtaining permission from the COTP or their designated representative.

IV. 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. 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 that are not subject to notice and comment. Because 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), if this rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards by calling 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.

B. 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).

C. Federalism and Indian Tribal Governments

We have analyzed this rule under Executive Order 13132, Federalism, and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in that Order.

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.

D. Unfunded Mandates Reform Act

As required by The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Coast Guard certifies

that this rule will not result in an annual expenditure of \$100,000,000 or more (adjusted for inflation) by a State, local, or tribal government, in the aggregate, or by the private sector.

E. 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 *et seq.*), 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 is a special local regulation. 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.

List of Subjects in 33 CFR Part 100

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 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.T999–1161 to read as follows:

§ 100.T999–1161 Special Local Regulation; Maumee River, Toledo, OH.

(a) *Location*. This special local regulation applies to the following regulated area: All waters of the Maumee River, from surface to bottom, beginning at river mile 6.0, south of the Norfolk Southern Railroad Bridge, to river mile 3.2, northeast of the Craig Memorial Bridge.

(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 Detroit (COTP) in the enforcement of the regulated area. *Participant* means all persons and vessels registered with the event sponsor as a participant in the race.

(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 COTP or their designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative on VHF-FM channel 16. 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.

(d) *Enforcement period.* This section will be enforced from 7 a.m. to 4 p.m. on September 19, 2026.

Brett F. McCall,

Commander, U.S. Coast Guard, Acting Captain of the Port Sector Detroit.

[FR Doc. 2026-19056 Filed 9-16-26; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2026-1146]

RIN 1625-AA00

Safety Zone; Key West Main Ship Channel, and Fleming Key Cut, Key West, FL

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing two temporary safety zones to support U.S. military training operations. Zone 1 will encompass the navigable waters of Fleming Key Cut within a 500-foot radius of surface support vessels. Zone 2 will encompass the navigable waters of the Key West Main Ship Channel within a 500-foot radius of surface support vessels. The zones are needed to protect personnel, vessels, and the marine environment from hazards associated with military training operations. Entry into either zone is prohibited unless specifically authorized by the Captain of the Port, Sector Key West, or a designated representative.

DATES: This rule is effective without actual notice from September 17, 2026, through October 14, 2026. For the purposes of enforcement, actual notice will be used from September 10, 2026, until September 17, 2026.

ADDRESSES: To view available documents go to [https://](https://www.regulations.gov)

www.regulations.gov and search for USCG-2026-1146.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact MSTC Mathew Mason, Sector Key West Waterways Management Division, U.S. Coast Guard; telephone 305-292-8823, or email Mathew.R.Mason@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
§ Section
U.S.C. United States Code

II. Background and Authority

The Coast Guard received notification that U.S. military training operations will be conducted in and around the Port of Key West. The training operations will be held over multiple dates in September and October of 2026. The training operations will be conducted along the Key West Main Ship Channel, Man of War Harbor and around Fleming Key. The Captain of the Port (COTP) Key West has determined that potential hazards associated with the training operations are a safety concern for anyone within a 500-foot radius of the surface support vessels.

Therefore, the COTP is issuing this rule under the authority in 46 U.S.C. 70034, which is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zones.

Because of these potential hazards, the Coast Guard is issuing this rule without prior notice and comment. As is authorized by 5 U.S.C. 553(b)(B), 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. The Coast Guard was notified of this event on August 19, 2026, but we must establish this safety zone by September 10, 2026, to protect personnel, vessels, and the marine environment. Therefore, we do not have enough time to solicit and respond to comments.

For the same reason, the Coast Guard finds that under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Discussion of the Rule

This rule establishes two safety zones: Zone 1 and Zone 2. Zone 1 will be enforced daily from 8:00 a.m. until 11:59 p.m. on September 10-16, 2026, and from October 8-14, 2026. Zone 1

will encompass all navigable waters within a 500-foot radius of surface support vessels on Fleming Key Cut. Zone 2 will be enforced daily from 8:00 a.m. until 11:59 p.m. on September 15-October 13, 2026. Zone 2 will encompass all navigable waters within a 500-foot radius of surface support vessels on the Key West Main Ship Channel. Vessels and persons will not be allowed to enter either zone during this time, unless authorized by the Captain of the Port, or their designated representative.

IV. 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. 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 that are not subject to notice and comment. Because 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), if this rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards by calling 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.

B. 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).

C. Federalism and Indian Tribal Governments

We have analyzed this rule under Executive Order 13132, Federalism, and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in that Order.