

in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the

guidance. Submit written requests for a single hard copy of the SECG entitled “Mammography Quality Standards Act and Regulation Amendments: Small Entity Compliance Guide” to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Preetham Sudhaker, Division of Mammography Quality Standards, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993, 301-796-5911.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of March 10, 2023 (88 FR 15126), FDA issued a final rule to update the mammography regulations that were issued under the MQSA and the Federal Food, Drug, and Cosmetic Act.<sup>1</sup> The final rule, amending

21 CFR 900.1 through 900.25, becomes effective September 10, 2024. FDA has prepared this SECG to assist small entities in complying with the requirements established in FDA regulations as they apply to mammography facilities.

This level 2 guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**II. Paperwork Reduction Act of 1995**

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. 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 (PRA) (44 U.S.C. 3501-3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB Control No.
900; Form FDA 3422 .....	Mammography Quality Standards .....	0910-0309

**III. Electronic Access**

Persons interested in obtaining a copy of the SECG may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov> and <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Persons unable to download an electronic copy of “Mammography Quality Standards Act and Regulation Amendments: Small Entity Compliance Guide” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number GUI00007024 and complete title to identify the guidance you are requesting.

Dated: August 20, 2024.  
**Lauren K. Roth,**  
*Associate Commissioner for Policy.*  
 [FR Doc. 2024-19059 Filed 8-23-24; 8:45 am]  
**BILLING CODE 4164-01-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 100**

[Docket No. USCG-2024-0712]

**Special Local Regulation; Marine Events Within the Eleventh Coast Guard District-San Diego Bayfair**

**AGENCY:** Coast Guard, DHS.  
**ACTION:** Notification of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce the San Diego Bayfair special local regulation on the waters of Mission Bay, California from September 13, 2024, through September 15, 2024. This

special local regulation is necessary to provide for the safety of the participants, crew, spectators, sponsor vessels, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from anchoring, blocking, loitering, or impeding within this regulated area unless authorized by the Captain of the Port, or his designated representative.

**DATES:** The regulation in 33 CFR 100.1101, Table 1 to § 100.1101, Item No. 9, will be enforced from 6 a.m. until 6 p.m., each day from September 13, 2024, through September 15, 2024.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notification of enforcement, call or email Lieutenant Shelley Turner, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone (619) 278-7656, email [D11MarineEventsSD@uscg.mil](mailto:D11MarineEventsSD@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce the special local regulation in 33 CFR 100.1101, Table 1

<sup>1</sup> The Office of the Federal Register has published this document under the category “Rules and Regulations” pursuant to 1 CFR 5.9(b). The Office

of the Federal Register’s categorization is solely for purposes of publication in the **Federal Register** and does not change the nature of the document and is

not intended to affect its validity, content, or intent. See 1 CFR 5.1(c).

to § 100.1101, Item No. 9, for the San Diego Bayfair race regulated area daily from 6 a.m. to 6 p.m., on September 13, 2024, through September 15, 2024. This action is being taken to provide for the safety of life on navigable waterways during this 3-day event. Our regulation for marine events within the Eleventh Coast Guard District, § 100.1101, Table 1 to § 100.1101, Item No. 9, specifies the location of the regulated area for the San Diego Bayfair which encompasses the waters of Mission Bay to include Fiesta Bay, the east side of Vacation Isle, and Crown Point shores. Under the provisions of § 100.1101, persons and vessels are prohibited from anchoring, blocking, loitering, or impeding within this regulated area unless authorized by the Captain of the Port, or his designated representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and Marine Safety Information Broadcasting.

If the Captain of the Port Sector San Diego or his designated representative determines that the regulated area need not be enforced for the full duration stated on this document, he or she may use a Safety Marine Information Broadcast or other communications coordinated with the event sponsor to grant general permission to enter the regulated area.

**J.W. Spitzer,**

*Captain, U.S. Coast Guard, Captain of the Port San Diego.*

[FR Doc. 2024-19023 Filed 8-23-24; 8:45 am]

**BILLING CODE 9110-04-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 165**

[Docket Number USCG-2024-0770]

RIN 1625-AA00

**Safety Zone; West River Entrance, Shady Side, MD**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for waters near the West River Entrance near Shady Side, Maryland within 200 yards of the sunken recreational vessel LOVEBUG and salvage operations. The

safety zone is needed to protect the public and vessels from potential hazards created by an obstruction to the West River and to ensure a safe working environment for the first responders and dive teams from passing traffic. This rule will prohibit persons or vessels from entering this zone unless specifically authorized by the Captain of the Port (COTP) Sector Maryland-National Capital Region (NCR) or a designated representative.

**DATES:** For purposes of enforcement, actual notice will be used from August 20, 2024, through August 26, 2024. This rule is effective and enforceable without actual notice from August 26, 2024 to August 30, 2024.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2024-0770 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 on this rule, call or email LCDR Kate Newkirk, Sector Maryland-NCR, Waterways Management Branch, U.S. Coast Guard; 410-365-8141, [MDNCRWaterways@uscg.mil](mailto:MDNCRWaterways@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 Information and Regulatory History**

The yacht "Lovebug" ran aground a half-mile offshore of Maryland, between Beverly Beach and Curtis Point, on August 16, 2024. Salvage is currently underway. The Coast Guard is issuing this temporary rule under 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 salvage operations are occurring now, and immediate action is necessary to respond to the potential safety hazards associated with these emergency salvage operations. It is impracticable to publish an NPRM because we must establish this safety zone as soon as possible.

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 immediate action is necessary to ensure the safety of vessels and persons on these navigable waters during the emergency vessel salvage operation.

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

The Coast Guard is issuing this rule under the authority in 46 U.S.C. 70034. The COTP Sector Maryland-NCR has determined that potential hazards associated with this vessel salvage operation starting on August 20, 2024, will be a safety concern for anyone within a 200-yard radius of the vessel salvage operation in the West River Entrance. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the vessel salvage operations are being conducted.

**IV. Discussion of the Rule**

This rule establishes a safety zone from August 20, 2024, through August 30, 2024. The safety zone will cover all navigable waters within 200 yards of the vessel salvage operation near Shady Side, Maryland, located at -38° 51.660 N, 076° 29.600 W. This rule is necessary to ensure the safety of vessels and persons during the vessel salvage operation. This rule will prohibit persons or vessels from entering this zone unless specifically authorized by the COTP or a designated representative.

The COTP or a designated representative may forbid and control the movement of all vessels in the zone. When hailed or signaled by an official patrol vessel, a vessel shall come to an immediate stop and comply with the directions given. Failure to do so may result in expulsion from the zone, citation for failure to comply, or both.

**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.