

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 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 892 is amended as follows:

#### PART 892—RADIOLOGY DEVICES

- 1. The authority citation for part 892 continues to read as follows:

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

- 2. Add § 892.2100 to subpart B to read as follows:

##### § 892.2100 Radiological acquisition and/or optimization guidance system.

(a) *Identification.* A radiological acquisition and/or optimization guidance system is a device that is intended to aid in the acquisition and/or optimization of images and/or diagnostic signals. The device interfaces with the acquisition system, analyzes its output, and provides guidance and/or feedback to the operator for improving image and/or signal quality.

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

(1) Design verification and validation must include:

(i) A detailed, technical device description, including a detailed description of the impact of any software and hardware on the device's functions, the associated capabilities and limitations of each part, and the associated inputs and outputs.

(ii) A detailed, technical report on the non-clinical performance testing of the subject device in the intended use environments, using relevant consensus standards when applicable.

(iii) A detailed report on the clinical performance testing, obtained from either clinical testing, accepted virtual/physical systems designed to capture clinical variability, comparison to a closely-related device with established clinical performance, or other sources that are justified appropriately. The

choice of the method must be justified given the risk of the device and the general acceptance of the test methods. The report must include the following:

(A) A thorough description of the testing protocol(s).

(B) A thorough, quantitative evaluation of the diagnostic utility and quality of images/data acquired, or optimized, using the device.

(C) A thorough, quantitative evaluation of the performance in a representative user population and patient population, under anticipated conditions and environments of use.

(D) A thorough discussion on the generalizability of the clinical performance testing results.

(E) A thorough discussion on use-related risk analysis/human factors data.

(iv) A detailed protocol that describes, in the event of a future change, the level of change in the device technical specifications or indications for use at which the change or changes could significantly affect the safety or effectiveness of the device and the risks posed by these changes. The assessment metrics, acceptance criteria, and analytical methods used for the performance testing of changes that are within the scope of the protocol must be included.

(v) Documentation of an appropriate training program, including instructions on how to acquire and process quality images and video clips, and a report on usability testing demonstrating the effectiveness of that training program on user performance, including acquiring and processing quality images.

(2) The labeling required under § 801.109(c) of this chapter must include:

(i) A detailed description of the device, including information on all required and/or compatible parts.

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

(iii) A detailed description of the intended user population, and the recommended user training.

(iv) Detailed instructions for use, including the information provided in the training program used to meet the requirements of paragraph (b)(1)(iv) of this section.

(v) A warning that the images and data acquired using the device are to be interpreted only by qualified medical professionals.

(vi) A detailed summary of the reports required under paragraphs (b)(1)(ii) and (iii) of this section.

(vii) A statement on upholding the As Low As Reasonably Achievable (ALARA) principle with a discussion on the associated device controls/options.

Dated: May 22, 2025.

**Grace R. Graham,**

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

[FR Doc. 2025–09837 Filed 5–30–25; 8:45 am]

**BILLING CODE 4164–01–P**

#### DEPARTMENT OF HOMELAND SECURITY

##### Coast Guard

##### 33 CFR Part 165

[USCG–2025–0435]

RIN 1625–AA00

##### Safety Zone; Gulf of America, Pass A Loutre State Wildlife Management Area

**AGENCY:** Coast Guard, Department of Homeland Security (DHS).

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone one nautical mile in all directions around well #59 at approximate position 29°04'28.919" N, 089°10'48.720" W, near the Pass A Loutre State Wildlife Management Area. The safety zone is needed to protect persons and critical infrastructure from the potential contamination due to an oil spill in the Gulf of America. Entry of vessels or persons into this zone, or movement of vessels within this zone is prohibited unless specifically authorized by the Captain of the Port or a designated representative.

**DATES:** This rule is effective without actual notice from June 2, 2025, through July 2, 2025. For the purposes of enforcement, actual notice will be used from May 22, 2025, until June 2, 2025.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2025–0435 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 Commander Xiaobin Tuo, Sector New Orleans, U.S. Coast Guard; 504–365–2246, email [Xiaobin.Tuo@uscg.mil](mailto:Xiaobin.Tuo@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 previously established a temporary safety zone in this area from April 30 through May 19, 2025, following the discovery of an ongoing oil spill from a leaking pipeline (90 FR 19124, May 6, 2025, docket number USCG–2025–0014). While the source of the oil spill is currently under control, response and clean-up operations are expected to continue for several more weeks. Therefore, this new temporary rule is needed to continue the safety zone until response operations are complete.

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 needed for an on-going emergency response to an oil spill from a leaking pipeline which began around April 27, 2025. Immediate action is needed to respond to the potential safety impacts associated with oil contamination and the clean-up operations. It is impracticable to publish an NPRM because we must establish this safety zone immediately.

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 the public interest because immediate action is needed to respond to the potential safety hazards associated with the oil spill.

## 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 Orleans (COTP) has determined that potential hazards associated with ongoing contamination and cleanup efforts due to an oil spill will be a safety concern to all persons and critical infrastructure within the vicinity of the oil spill.

## IV. Discussion of the Rule

This rule establishes a safety zone from May 22, 2025, through July 2, 2025. The safety zone encompasses all waters within one nautical mile in all directions around well #59, at

approximate position 29°04′28.919″ N, 089°10′48.720″ W, near the Pass A Loutre State Wildlife Management Area. The duration of the zone is intended to protect persons and critical infrastructure from the potential contamination due to an oil spill and active clean-up operations in the Gulf of America. No vessel or person will be permitted to enter the safety zone 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 (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. Executive Order 14192 (Unleashing Prosperity Through Deregulation) directs agencies to significantly reduce the private expenditures required to comply with Federal regulations and provides that “any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.”

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 rule is not an Executive Order 14192 regulatory action because this rule is not significant under Executive Order 12866. See OMB Memorandum M–25–20, “Guidance Implementing Section 3 of Executive Order 14192, titled ‘Unleashing Prosperity Through Deregulation’” (Mar. 26, 2025).

This regulatory action determination is based on the size, location, and duration of the safety zone. This safety zone will impact a relatively small, designated area of the Gulf of America that has been impacted by a significant oil spill, and within which active clean-up operations are occurring. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule

will allow vessels to seek permission to transit through the zone when it is safe to do so, and with the permission of the Captain of the Port.

### 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 involves an emergency safety zone that will prohibit entry one nautical mile in all directions around well #59 at approximate position 29°04′28.919″ N, 089°10′48.720″ W near the Pass A Loutre State Wildlife Management Area. It is categorically excluded from further review under paragraph L60(d) 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.T08–0435 to read as follows:

##### **§ 165.T08–0435 Safety Zone; Gulf of America, Pass A Loutre State Wildlife Management Area.**

(a) *Location.* The following area is a safety zone: all navigable waters within one nautical mile in all directions around well #59 at approximate position 29°04′28.919″ N, 089°10′48.720″ W, near the Pass A Loutre State Wildlife Management Area. These coordinates are based on World Geodetic System (WGS) 84.

(b) *Definition.* 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 New Orleans (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 via VHF–FM Channel 16 or 67 or by telephone at (504) 365–2545. 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 enforced 24-hours per day from May 22, 2025, through July 2, 2025, unless cancelled earlier by the Captain of the Port. The COTP or a designated representative will inform the public of any changes to the enforcement times or dates for this safety zone through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

Dated: May 22, 2025.

**G.A. Callaghan,**

*Captain, U.S. Coast Guard, Captain of the Port New Orleans.*

[FR Doc. 2025–09928 Filed 5–30–25; 8:45 am]

**BILLING CODE 9110–04–P**

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

##### **Coast Guard**

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

[Docket No. USCG–2025–0417]

##### **Safety Zone; City of Duluth Fourth Fest, Duluth, MN**

**AGENCY:** Coast Guard, DHS.

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

**SUMMARY:** The Coast Guard will enforce a safety zone for the Duluth Fourth Fest Fireworks Display from 9:30 p.m. to 11 p.m. on July 4, 2025 to provide for the safety of life on navigable waterways during this event in the vicinity of Bayfront Park. During the enforcement period, entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port (COTP) Marine Safety Unit Duluth or a designated representative.

**DATES:** The regulations in 33 CFR 165.943 will be enforced for the Duluth 4th Fest Fireworks regulated area listed in item 5 in Table 1 to § 165.943 from 9:30 p.m. to 11 p.m., on July 4, 2025.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notification of enforcement, call or email LT 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:** The Coast Guard will enforce a safety zone regulation in 33 CFR 165.943 for the Duluth 4th Fest Fireworks listed in item 5 in Table 1 to § 165.943 from 9:30 p.m. to 11 p.m., on July 4, 2025. This action is being taken to provide for the safety of life on navigable waterways during this event. The regulation for recurring marine events within the COTP Duluth Zone, Table 1 to § 165.943, item 5, specifies the location of the regulated area for the Duluth 4th Fest Fireworks event. During the enforcement period, no vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP Marine Safety Unit Duluth or his or her on-scene representative.