

(ii) A statement in the labeling that the safety and effectiveness of the device has not been evaluated for outcomes related to the treatment or prevention of cancer, including but not limited to risk reduction, overall survival, disease-free survival and local recurrence, unless FDA determines that it can be removed or modified based on clinical performance data submitted to FDA;

(iii) Identification of compatible devices;

(iv) The list of surgical procedures for which the device has been determined to be safe with clinical justification;

(v) Reprocessing instructions for reusable components;

(vi) A shelf life for any sterile components;

(vii) A description of the device-specific use training program;

(viii) A statement that the device is only for distribution to facilities that implement and maintain the device-specific use training program and ensure that users of the device have completed the device-specific use training program; and

(ix) A detailed summary of the post-market surveillance data collected under paragraph (b)(3) of this section and any necessary modifications to the labeling to accurately reflect outcomes based upon the post-market surveillance data collected under paragraph (b)(3) of this section.

(6) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use.

(7) Human factors validation testing must be performed and must demonstrate that the user interfaces of the system support safe use in an operating room environment.

(8) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must include:

(i) Device motion accuracy and precision;

(ii) System testing;

(iii) Instrument reliability;

(iv) Thermal effects on tissue;

(v) Human-device interface;

(vi) Mounting hardware testing;

(vii) Workspace access testing; and

(viii) Performance testing with

compatible devices.

(9) Software verification, validation, and hazard analysis must be performed. Software documentation must include an assessment of the impact of threats and vulnerabilities on device functionality and end users/patients as part of cybersecurity review.

(10) Electromagnetic compatibility and electrical, thermal, and mechanical safety testing must be performed.

(11) Performance data must demonstrate the sterility of all patient-contacting device components.

(12) Performance data must support the shelf life of the device components provided sterile by demonstrating continued sterility and package integrity over the labeled shelf life.

(13) Performance data must validate the reprocessing instructions for the reusable components of the device.

(14) Performance data must demonstrate that all patient-contacting components of the device are biocompatible.

(15) Performance data must demonstrate that all patient-contacting components of the device are non-pyrogenic.

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-09749 Filed 5-5-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2022-0227]

Special Local Regulation; Crystal Pier Outrigger Race, San Diego, CA

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

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Crystal Pier Outrigger Race special local regulations on the waters of Mission Bay, California, on May 7, 2022. These special local regulations are 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 regulations in 33 CFR 100.1101 will be enforced from 7 a.m. through 5 p.m. on May 7, 2022, for the locations described in Item No. 14 in Table 1 to § 100.1101.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander John Santorum, Waterways Management, U.S. Coast Guard Sector San Diego, CA;

telephone 619-278-7656, email MarineEventsSD@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in 33 CFR 100.1101 for the Crystal Pier Outrigger Race in Mission Bay, CA in 33 CFR 100.1101, for the locations described in Item No. 14 in Table 1 to that section from 7 a.m. until 5 p.m. on May 7, 2022. This enforcement action is being taken to provide for the safety of life on navigable waterways during the event. The Coast Guard's regulation for recurring marine events in the San Diego Captain of the Port Zone identifies the regulated entities and area for this event. Under the provisions of 33 CFR 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 document in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners, marine information broadcasts, and local advertising by the event sponsor.

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 Broadcast Notice to Mariners or other communications coordinated with the event sponsor to grant general permission to enter the regulated area.

Dated: May 2, 2022.

T.J. Barelli,

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

[FR Doc. 2022-09722 Filed 5-5-22; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2022-0190]

RIN 1625-AA00

Safety Zone; Sabine River, Orange, TX

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters of the Sabine

River, extending the entire width of the river, adjacent to the public boat ramp located in Orange, TX. The safety zone is necessary to protect persons and vessels from hazards associated with a high-speed boat race competition in Orange, TX. Entry of vessels or persons into this zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Port Arthur or a designated representative.

DATES: This rule is effective from 9 a.m. on May 21, 2022 through 6 p.m. on May 22, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2022–0190 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 Mr. Scott Whalen, Marine Safety Unit Port Arthur, U.S. Coast Guard; telephone 409–719–5086, email Scott.K.Whalen@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

On March 9, 2022, the City of Orange, TX notified the Coast Guard that it would be sponsoring high speed boat races from 9 a.m. through 6 p.m. on May 21 and 22, 2022, adjacent to the public boat ramp in Orange, TX. The Captain of the Port Marine Safety Unit Port Arthur (COTP) has determined that potential hazards associated with high speed boat races would be a safety concern for spectator craft and vessels in the vicinity of these race events. In response, on March 29, 2022, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Special Local Regulation, Sabine River, Orange, TX (87 FR 18338). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this marine event. During the comment period that ended April 29, 2022, we received no comments.

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**. High speed boat races are

scheduled to occur on the Sabine River on May 21 and 22, 2022. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with high speed boat races on a narrow waterway.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Port Arthur (COTP) has determined that potential hazards associated with high speed boat races will be a safety concern for spectator craft and vessels in the vicinity of these race events.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments regarding the establishment of this safety zone on our NPRM published March 29, 2022. We mistakenly referred to the rule as a special local regulation in some places in the NPRM. However, as we noted in the first sentence of the summary in the NPRM, we were proposing to establish a temporary safety zone. We made one change to the regulatory text to replace the reference to special local regulations with safety zone in paragraph (d)(4). There are no substantive changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from 9 a.m. through 6 p.m. daily on May 21, 2022 and May 22, 2022. The safety zone will cover all navigable waters of the Sabine River, extending the entire width of the river, adjacent to the public boat ramp located in Orange, TX bounded to the north by the Orange Public Wharf and latitude 30°05′50″ N and to the south at latitude 30°05′33″ N. The duration of the zone is intended to protect participants, spectators, and other persons and vessels, in the navigable waters of the Sabine River during high-speed boat races and will include breaks and opportunity for vessels to transit through the regulated area.

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. This rule has not been designated a “significant regulatory action,” under 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 proposed size, location and duration of the rule. The safety zone will encompass a less than half-mile stretch of the Sabine River for 8-hours on each of two days. The Coast Guard will notify the public by issuing Local Notice to Mariners (LNM), and/or Marine Safety Information Bulletin (MSIB) and Broadcast Notice to Mariners via VHF–FM radio and the rule will allow vessels to seek permission to enter the zone during scheduled breaks.

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 received no comments from the Small Business Administration on this rulemaking. 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 would 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 safety zone that will last 8-hours on each of two days and that would prohibit entry on less than a half-mile stretch of the Sabine River in Orange, TX. 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.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

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 AREA AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T08-0190 to read as follows:

§ 165.T08-0190 Safety Zone; Sabine River, Orange, Texas

(a) *Location.* The following area is a safety zone: All navigable waters of the Sabine River, extending the entire width of the river, adjacent to the public boat ramp located in Orange, TX bounded to the north by the Orange Public Wharf and latitude 30°05'50" N and to the south at latitude 30°05'33" N. The duration of the safety zone is intended to protect participants, spectators, and other persons and vessels, in the navigable waters of the Sabine River during high-speed boat races and will include breaks and opportunity for

vessels to transit through the regulated area.

(b) *Effective period.* This section is effective from 9 a.m. on May 21, 2022 through 6 p.m. on May 22, 2022.

(c) *Enforcement periods.* This section will be enforced from 9 a.m. through 6 p.m. daily.

(d) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry of vessels or persons into this zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Port Arthur (COTP) or a designated representative. They may be contacted on VHF-FM channel 13 or 16, or by phone at by telephone at 409-719-5070.

(2) The COTP or a designated representative may forbid and control the movement of all vessels in the regulated area. 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 area, citation for failure to comply, or both.

(3) The COTP or a designated representative may terminate the event or the operation of any vessel at any time it is deemed necessary for the protection of life or property.

(4) The COTP or a designated representative will terminate enforcement of the safety zone of this section at the conclusion of the event.

(e) *Informational broadcasts.* 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 Notices to Mariners (BNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

Dated: May 3, 2022.

Molly A. Wike,

Captain, U.S. Coast Guard, Captain of the Port, Marine Safety Zone Port Arthur.

[FR Doc. 2022-09753 Filed 5-5-22; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2022-0096]

Safety Zone; Four Seasons Hotel Fireworks Display Event, New Orleans, LA

AGENCY: Coast Guard, DHS.