

TABLE 1—HYDROPHILIC RE-COATING SOLUTION RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse events leading to eye irritation (redness, burning, stinging, discomfort, pain), infection, keratitis, corneal ulcer, loss of visual acuity, or allergic reaction.	Clinical performance testing, Human factors evaluation, and Labeling.
Adverse tissue reaction	Biocompatibility evaluation, Lens solution compatibility testing, Coating effectiveness testing, and Labeling.
Infection	Sterility testing and validation, Disinfection solution compatibility testing, Shelf life testing, and Labeling.
Use error/improper device use leading to eye irritation (redness, burning, stinging, discomfort, pain), infection, keratitis, corneal ulcer, loss of visual acuity.	Clinical performance testing, Human factors evaluation, Coating performance testing, and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These 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 part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in 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 part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.
Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 886 is amended as follows:

PART 886—OPHTHALMIC DEVICES

- 1. The authority citation for part 886 continues to read as follows:
Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.
- 2. Add § 886.5919 to subpart F to read as follows:

§ 886.5919 Hydrophilic re-coating solution.

- (a) *Identification.* A hydrophilic re-coating solution is a home use device intended to restore the hydrophilic coating of rigid gas permeable (RGP) contact lenses using reactive coating components.
- (b) *Classification.* Class II (special controls). The special controls for this device are:
 - (1) Clinical performance testing must evaluate device safety as assessed by adverse events, slit lamp findings, and maintenance of visual acuity.
 - (2) The patient contacting components of the device and packaging components must be demonstrated to be biocompatible.
 - (3) Performance testing must demonstrate the sterility of the device.
 - (4) Use-related risk analysis must be performed to determine if a self-selection study and human factors validation study must be conducted to demonstrate that users can correctly use the device based solely on reading the directions for use.
 - (5) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity,

- and device functionality over the identified shelf life.
- (6) Performance testing must demonstrate compatibility with each lens and solution labeled for use with the device.
- (7) Performance testing must demonstrate the ability of the device to restore the coating of compatible lenses.
- (8) Labeling must include the following:
 - (i) Instructions on how to correctly use the device, including instructions to use fresh components for each use;
 - (ii) Descriptions of compatible contact lenses;
 - (iii) Descriptions of compatible care solutions;
 - (iv) A warning that if patients are not sure of their lens material, they should contact their health care provider prior to use; and
 - (v) A precaution against use with lenses that have not been demonstrated to be compatible with the device.

Dated: August 29, 2024.
Lauren K. Roth,
Associate Commissioner for Policy.
[FR Doc. 2024–19882 Filed 9–4–24; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2024–0244]

RIN 1625–AA08

Special Local Regulations; Recurring Marine Events, Sector St. Petersburg

AGENCY: Coast Guard, DHS.
ACTION: Final rule.

SUMMARY: The Coast Guard is revising existing regulations by updating two dates of events in the Seventh Coast

Guard District Captain of the Port (COTP) St. Petersburg. This action is necessary to provide for the safety of life on these navigable waters in Sarasota and St. Petersburg, FL.

DATES: This rule is effective September 5, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2024–0244 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 Marine Science Technician First Class Mara J. Brown, Sector St. Petersburg Prevention Department, Coast Guard; telephone (813) 228–2191, email Mara.J.Brown@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 amending the Recurring Marine Events in the geographic boundaries of the Seventh Coast Guard District Captain of the Port (COTP) St. Petersburg Zone that are listed in 33 CFR 100.703, table 1 to 100.703. The rule will ensure that the public is informed of the most up to date recurring special local regulations. The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters, during and after the scheduled events. On July 3, 2024, the Coast Guard published a notice of proposed rulemaking (NPRM) titled, “Special Local Regulations; Recurring Marine Events, Sector St. Petersburg” (89 FR 55133). There we stated why we issued the NPRM and invited comments on our proposed regulatory action related to this fireworks display. During the comment period that ended August 2, 2024, 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**. Delaying the effective date of this rule would be impracticable because we must establish a special local regulation (SLR) for the safety of the event participants and the public for a high-speed boat race starting on September 13, 2024. The event

protected by the SLR in 33 CFR 100.703, table 1 to § 100.703, item 4, as amended by this rule, is scheduled to start on September 13, 2024. Therefore, it is impracticable to delay implementation of this final rule 30 days because we must establish this SLR for the protection of participants of the high-speed boat race and all others transiting nearby.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70041. The Captain of the Port Sector St. Petersburg (COTP) has determined that potential hazards associated with the events will be a safety concern for anyone within the safety zone. The purpose of this rule is to ensure safety of vessels and the navigable waters before, during, and after the scheduled events.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published July 3, 2024. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM. This rule makes the following changes in 33 CFR 100.703, table 1 to § 100.703:

1. Revise Line No. 4, to reflect a date and time change to “One weekend (Friday, Saturday, and Sunday) in September Time (Approximate): 8:00 a.m. to 6:00 p.m. Revise Line No. 5, to reflect a date and time change to “One weekend (Friday, Saturday, and Sunday) in October Time (Approximate): 8:00 a.m. to 6:00 p.m.”

Marine events listed in table 1 to § 100.703 are listed as recurring over a particular time, during each month and each year. Exact dates are intentionally omitted since calendar dates for specific events change from year to year. Once dates for a marine event are known, the Coast Guard notifies the public it intends to enforce the special local regulation through various means including a notice of enforcement published in the **Federal Register**, Local Notice to Mariners, and Broadcast Notice to Mariners.

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 section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location and duration of the special local regulations. These areas are limited in size and duration, and usually do not affect high vessel traffic areas. Moreover, the Coast Guard would provide advance notice of the regulated areas to the local maritime community by Local Notice to Mariners, Broadcast Notice to Mariners via VHF–FM marine channel 16, and the rule would allow vessels to seek permission to enter the regulated area.

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 revising an existing recurring event to reflect a date and time change for the event. Normally such actions are categorically excluded from further review under paragraphs L61 in table 3-1 of appendix A, table 1 of DHS Instruction Manual 023-01-001-01, Rev. 1, because it involves a revised special local regulation related to a

marine event permit for marine parades, regattas, and other marine events. A Memorandum for Record 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 100

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard is amending 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. In § 100.703, revise table 1 to read as follows:

§ 100.703 Special Local Regulations; Recurring Marine Events, Sector St. Petersburg.

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TABLE 1 TO § 100.703—SPECIAL LOCAL REGULATIONS; RECURRING MARINE EVENTS, SECTOR ST. PETERSBURG

Date/time	Event/sponsor	Location	Regulated area
1. One Saturday in January; Time (Approximate): 11:30 a.m. to 2 p.m.	Gasparilla Invasion and Parade/ Ye Mystic Krewe of Gasparilla.	Tapa, Florida	<p><i>Location:</i> A regulated area is established consisting of the following waters of Hillsborough Bay and its tributaries north of 27°51'18" N and south of the John F. Kennedy Bridge: Hillsborough Cut "D" Channel, Seddon Channel, Sparkman Channel and the Hillsborough River south of the John F. Kennedy Bridge.</p> <p><i>Additional Regulation:</i></p> <ol style="list-style-type: none"> (1) Entrance into the regulated area is prohibited to all commercial marine traffic from 9 a.m. to 6 p.m. EST on the day of the event. (2) The regulated area will include a 100 yard Safety Zone around the vessel JOSE GASPARGAR while docked at the Tampa Yacht Club until 6 p.m. EST on the day of the event. (3) The regulated area is a "no wake" zone. (4) All vessels within the regulated area shall stay 50 feet away from and give way to all officially entered vessels in parade formation in the Gasparilla Marine Parade. (5) When within the marked channels of the parade route, vessels participating in the Gasparilla Marine Parade may not exceed the minimum speed necessary to maintain steerage. (6) Jet skis and vessels without mechanical propulsion are prohibited from the parade route. (7) Vessels less than 10 feet in length are prohibited from the parade route unless capable of safely participating. (8) Vessels found to be unsafe to participate at the discretion of a present Law Enforcement Officer are prohibited from the parade route.

TABLE 1 TO § 100.703—SPECIAL LOCAL REGULATIONS; RECURRING MARINE EVENTS, SECTOR ST. PETERSBURG—Continued

Date/time	Event/sponsor	Location	Regulated area
2. One Saturday in February; Time (Approximate): 9:00 a.m. to 9:00 p.m.	Bradenton Area River Regatta/ City of Bradenton.	Bradenton, FL	<p>(9) Northbound vessels in excess of 65 feet in length without mooring arrangement made prior to the date of the event are prohibited from entering Seddon Channel unless the vessel is officially entered in the Gasparilla Marine Parade.</p> <p>(10) Vessels not officially entered in the Gasparilla Marine Parade may not enter the parade staging area box within the following coordinates: 27°53'53" N, 082°27'47" W; 27°53'22" N, 082°27'10" W; 27°52'36" N, 082°27'55" W; 27°53'02" N, 082°28'31" W.</p> <p><i>Location(s) Enforcement Area #1.</i> All waters of the Manatee River between the Green Bridge and the CSX Train Trestle contained within the following points: 27°30'43" N, 082°34'20" W, thence to position 27°30'44" N, 082°34'09" W, thence to position 27°30'00" N, 082°34'04" W, thence to position 27°29'58" N, 082°34'15" W, thence back to the original position, 27°30'43" N, 082°34'20" W.</p> <p><i>Enforcement Area #2.</i> All waters of the Manatee River contained within the following points: 27°30'35" N, 082°34'37" W, thence to position 27°30'35" N, 082°34'26" W, thence to position 27°30'26" N, 082°34'26" W, thence to position 27°30'26" N, 082°34'37" W, thence back to the original position, 27°30'35" N, 082°34'37" W.</p>
3. One weekend (Friday, Saturday, and Sunday) in March; Time (Approximate): 8:00 a.m. to 5:00 p.m.	Gulfport Grand Prix/Gulfport Grand Prix LLC.	Gulfport, FL	<p><i>Location(s): (1) Race Area.</i> All waters of Boca de Ciego contained within the following points: 27°44'10" N, 082°42'29" W, thence to position 27°44'07" N, 082°42'40" W, thence to position 27°44'06" N, 082°42'40" W, thence to position 27°44'04" N, 082°42'29" W, thence to position 27°44'07" N, 082°42'19" W, thence to position 27°44'08" N, 082°42'19" W, thence back to the original position, 27°44'10" N, 082°42'29" W.</p> <p>(2) <i>Buffer Zone.</i> All waters of Boca de Ciego encompassed within the following points: 27°44'10" N, 082°42'47" W, thence to position 27°44'01" N, 082°42'44" W, thence to position 27°44'01" N, 082°42'14" W, thence to position 27°44'15" N, 082°42'14" W.</p>
4. One weekend (Friday, Saturday, and Sunday) in September; Time (Approximate): 8:00 a.m. to 6:00 p.m.	Sarasota Powerboat Grand Prix/Powerboat P-1 USA, LLC.	Sarasota, FL	<p><i>Location:</i> All waters of the Gulf of Mexico contained within the following points: 27°18'44" N, 082°36'14" W, thence to position 27°19'09" N, 082°35'13" W, thence to position 27°17'42" N, 082°34'00" W, thence to position 27°16'43" N, 082°34'49" W, thence back to the original position, 27°18'44" N, 082°36'14" W.</p>
5. One weekend (Saturday and Sunday) in September; Time (Approximate): 8:00 a.m. to 4:00 p.m.	Clearwater Offshore Nationals/ Race World Offshore.	Clearwater, FL	<p>(1) <i>Race Area.</i> All waters of the Gulf of Mexico contained within the following points: 27°58'34" N, 82°50'09" W, thence to position 27°58'32" N, 82°50'02" W, thence to position 28°00'12" N, 82°50'10" W, thence to position 28°00'13" N, 82°50'10" W, thence back to the original position, 27°58'34" N, 82°50'09" W.</p> <p>(2) <i>Spectator Area.</i> All waters of Gulf of Mexico seaward no less than 150 yards from the race area and as agreed upon by the Coast Guard and race officials.</p> <p>(3) <i>Enforcement Area.</i> All waters of the Gulf of Mexico encompassed within the following points: 28°58'40" N, 82°50'37" W, thence to position 28°00'57" N, 82°49'45" W, thence to position 27°58'32" N, 82°50'32" W, thence to position 27°58'23" N, 82°49'53" W, thence back to position 28°58'40" N, 82°50'37" W.</p>
6. One weekend (Friday, Saturday and Sunday) in October; Time (Approximate): 8:00 a.m. to 6:00 p.m.	St.Petersburg Powerboat Grand Prix.	St. Petersburg, FL	<p><i>Location:</i> All waters of the Tampa Bay encompassed within the following points: 27°46'56.22" N, 082°36'55.50" W, thence to position 27°47'08.82" N, 082°34'33.24" W, thence to position 27°46'06.96" N, 082°34'29.04" W, thence to position 27°45'59.22" N, 082°37'02.88" W, thence back to the original position 27°46'24.24" N, 082°37'30.24" W.</p>
7. One Thursday, Friday, and Saturday in October; Time (Approximate): 10:00 a.m. to 5:00 p.m.	Roar Offshore/OPA Racing LLC	Fort Myers Beach, FL	<p><i>Locations:</i> All waters of the Gulf of Mexico west of Fort Myers Beach contained within the following points: 26°26'27" N, 081°55'55" W, thence to position 26°25'33" N, longitude 081°56'34" W, thence to position 26°26'38" N, 081°58'40" W, thence to position 26°27'25" N, 081°58'8" W, thence back to the original position 26°26'27" N, 081°55'55" W.</p>
8. One weekend (Friday, Saturday, and Sunday) in November; Time (Approximate): 8:00 a.m. to 6:00 p.m.	OPA World Championships/ Englewood Beach Waterfest.	Englewood Beach, FL	<p><i>Locations: (1) Race Area.</i> All waters of the Gulf of Mexico contained within the following points: 26°56'00" N, 082°22'11" W, thence to position 26°55'59" N, 082°22'16" W, thence to position 26°54'22" N, 082°21'20" W, thence to position 26°54'24" N, 082°21'16" W, thence to position 26°54'25" N, 082°21'17" W, thence back to the original position, 26°56'00" N, 082°21'11" W.</p>

TABLE 1 TO § 100.703—SPECIAL LOCAL REGULATIONS; RECURRING MARINE EVENTS, SECTOR ST. PETERSBURG—Continued

Date/time	Event/sponsor	Location	Regulated area
			<p>(2) <i>Spectator Area</i>. All waters of the Gulf of Mexico contained with the following points: 26°55'33" N, 082°22'21" W, thence to position 26°54'14" N, 082°21'35" W, thence to position 26°54'11" N, 082°21'40" W, thence to position 26°55'31" N, 082°22'26" W, thence back to position 26°55'33" N, 082°22'21" W.</p> <p>(3) <i>Enforcement Area</i>. All waters of the Gulf of Mexico encompassed within the following points: 26°56'09" N, 082°22'12" W, thence to position 26°54'13" N, 082°21'03" W, thence to position 26°53'58" N, 082°21'43" W, thence to position 26°55'56" N, 082°22'48" W, thence back to position 26°56'09" N, 082°22'12" W.</p>

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Dated: August 26, 2024.

Michael P. Kahle,
Captain, U.S. Coast Guard, Captain of the Port Sector St. Petersburg.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG-2024-0766]

RIN 1625-AA08

Special Local Regulation; Galveston Channel, Galveston, TX

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a special local regulation for navigable waters within the Galveston Ship Channel. The special local regulation is needed to safely align and navigate vessels for the Texian Navy Day Parade. Entry of non-participants into the pre-staging and parade transit zones is prohibited unless specifically authorized by the Captain of the Port, Sector Houston-Galveston (COTP). Those in the regulated area must comply with all lawful orders or directions given to them by the COTP or the designated representative.

DATES: This rule is effective from 8 a.m. to 1 p.m. on September 21, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2024-0766 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 Ignacio J. Fernández-Cuervo, Marine Safety Unit Texas City, Waterways Management Division, U.S. Coast Guard; telephone (281) 309-1617, email MSUTexasCityWaterways@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 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 the final rule would not be completed prior to the event start date. Failure to establish these regulated areas would create a hazard to navigation for vessels transiting through the Galveston Channel during the event. It is impracticable to publish an NPRM because we must establish the regulated areas by September 21, 2024.

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 because prompt action is needed to ensure vessel traffic safety on the day of the event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70041. The

Captain of the Port Sector Houston-Galveston (COTP) has determined that potential hazards associated with the boat parade on September 21, 2024 will be a safety concern for anyone within a 200-yard radius of the parade in the Galveston Channel. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the regulated areas while the parade is ongoing.

IV. Discussion of the Rule

This rule establishes a special local regulation from 8 a.m. to 1 p.m. on September 21, 2024. The special local regulation will encompass three zones to include a Pre-Staging Zone, Spectator Zone, and Parade Transit Zone as described below:

Pre-Staging Zone: This area is the pre-staging area for participating vessels to line up. It will include all waters within a 200-yard radius of 29°20'23" N, 094°46'37" W.

Spectator Zone: All vessels that will be viewing the event will be required to stay within a designated area. The sponsor is responsible for marking the spectator zone with 4 buoys on the outer corners and ensuring that all vessels within the area are anchored and remain in the area during parade transit. The following coordinates are the approximate location of the Spectator Zone: 29°19'17" N, 094°46'36" W, thence to 29°19'37" N, 094°46'53" W, and both points connecting to the eastern shore.

Parade Transit Zone: This area is exclusive to vessels participating in the parade. It will include all waters within the following areas: 29°19'07.02" N, 094°47'10.98" W, thence to 29°18'55.43" N, 094°47'04.23" W, thence to 29°20'29.45" N, 094°46'14.18" W, thence to 29°20'32.68" N, 094°46'29.94" W, and along the shore line back to the beginning point.

All non-participants will be prohibited from entering the established pre-staging and parade transit zones