

(6) Labeling must include:

(i) Specific instructions, contraindications, warnings, cautions, limitations, and the clinical training needed for the safe use of the device.

(ii) Statement of the maximum insert indwelling period.

(iii) Information on the patient education and support program prior to and during initial device use.

(iv) Information on the patient population for which the device has been demonstrated to be safe and effective.

(v) Information on how the device operates and the recommended treatment regimen.

(vi) A detailed summary of the device- and procedure-related complications or adverse events pertinent to use of the device.

(vii) An expiration date/shelf life.

(7) Patient labeling must be provided and must include:

(i) Relevant contraindications, warnings, precautions, and adverse events/complications.

(ii) Information on how the device operates and the recommended treatment regimen.

(iii) Information on the patient education and support program prior to and during initial device use.

(iv) Information on the patient population for which there is clinical evidence of safety and effectiveness.

(v) The potential risks and benefits associated with the use of the device.

(vi) Post-insertion care instructions.

(vii) Alternative treatments.

Dated: March 31, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-07815 Filed 4-3-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG-2015-0138]

RIN 1625-AA08

Special Local Regulation; San Salvador Launch and Procession; San Diego Bay, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule; request for comments.

SUMMARY: The Coast Guard is establishing a marine event special local regulation for the launch of the historic

vessel San Salvador located in the Captain of the Port San Diego Zone on San Diego Bay. This action is necessary to provide for the safety of life and property on navigable waters during this event. This special local regulation will establish restrictions upon, and control movement of, vessels in a portion of San Diego Bay during the initial launch and subsequent procession of the San Salvador around a portion of San Diego Bay. Unauthorized persons and vessels are prohibited from entering into, transiting through or anchoring within this regulated area unless authorized by the Captain of the Port, or his designated representative. The Coast Guard requests public comments on the temporary special local regulation.

DATES: This rule is effective from 8:00 a.m. to 1:00 p.m. on April 19, 2015.

Public comments must be received by April 15, 2015.

ADDRESSES: Submit comments using *one* of the listed methods, and see **SUPPLEMENTARY INFORMATION** for more information on public comments.

- *Online*—<http://www.regulations.gov> following Web site instructions.

- *Fax*—202-493-2251.

- *Mail or hand deliver*—Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001. Hand delivery hours: 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays (telephone 202-366-9329).

Documents mentioned in this preamble are part of docket [USCG-2015-0138]. To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Randolph Pahilanga, Waterways Management, U.S. Coast Guard Sector San Diego; telephone (619) 278-7656, email D11-PF-MarineEventsSanDiego@uscg.mil.

If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security

FR Federal Register

NPRM Notice of Proposed Rulemaking

A. Public Participation and Comments

We encourage you to submit comments (or related material) on this temporary final rule. We will consider all submissions and may adjust our final action based on your comments.

Comments should be marked with docket number USCG-2015-0138 and should provide a reason for each suggestion or recommendation. You should provide personal contact information so that we can contact you if we have questions regarding your comments; but please note that all comments will be posted to the online docket without change and that any personal information you include can be searchable online (see the **Federal Register** Privacy Act notice regarding our public dockets, 73 FR 3316, Jan. 17, 2008).

Mailed or hand-delivered comments should be in an unbound 8½ x 11 inch format suitable for reproduction. The Docket Management Facility will acknowledge receipt of mailed comments if you enclose a stamped, self-addressed postcard or envelope with your submission.

Documents mentioned in this notice and all public comments, are in our online docket at <http://www.regulations.gov> and can be viewed by following the Web site’s instructions. You can also view the docket at the Docket Management Facility (see the mailing address under **ADDRESSES**) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

B. Regulatory History and Information

The San Salvador Launch and Procession is a onetime marine event with no regulatory history. The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This 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.”

Under 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 publishing an NPRM would be impracticable since immediate action is needed to minimize potential danger to the participants and the

public during the event. The danger posed by the volume of commercial, public and private recreational marine traffic in San Diego Bay makes special local regulations necessary to provide for the safety of the crew, spectators, sponsor safety vessel, and other users of the waterway during both the launch and procession occurring immediately after the launch. Additionally, publishing an NPRM is unnecessary because the area covered by the marine event special local regulations should have negligible impact on vessel transits. Furthermore, the necessary information to determine whether the marine event poses a threat to persons and vessels was provided initially to the Coast Guard less than 135 days before the event, specifically 60 days, and as only a draft plan which is insufficient time to publish an NPRM. We wish to take immediate action to help protect the safety of the participants, crew, spectators, and participating vessels from other vessels during the one day event. For the information for all mariners, it is important to have these regulations in effect during the event and impracticable to delay the regulations. For these same reasons, the Coast Guard finds good cause for implementing this rule less than thirty days before the effective date.

Even though the normal comment process was shortened for this rule, we are providing an opportunity for public comment and, should public comment show the need for modifications to the regulated area during the event, we may make those modifications during the event and will provide actual notice of those modifications to the affected public.

C. Basis and Purpose

The legal basis the rule is the Coast Guard's authority to issue regulations to promote the safety of life on navigable waters during regattas or marine parades: 33 U.S.C. 1233.

The Coast Guard was notified by the San Diego Maritime Museum that the vessel *San Salvador*, a recreation of the original Spanish exploration sailing vessel used by the explorer, Juan Rodriguez Cabrillo, will be launched and towed to its final mooring space at the San Diego Maritime Museum on April 19, 2015. The launch and procession will require the immediate area adjacent to the downtown San Diego Embarcadero between Broadway and B Street Piers to be clear of all vessel traffic during the crane barge lift of the vessel, launch and subsequent parade. The parade route during the one-hour procession will go from the planned launch site at Broadway Pier

south along the Embarcadero and returning north to the Maritime Museum, roughly a two mile transit. This rule establishes a fifty-yard wide exclusion area for the safe transit of the vessel *San Salvador*.

If an alternate emergency launch site is required along the Embarcadero other than the Broadway Pier, the Coast Guard Captain of the Port will adjust the marine event special local regulations to ensure the safety of all participants, safety vessels and spectators during the launch and adjustment of the procession length. During the enforcement of the event, the Coast Guard will issue a broadcast notice to mariners (BNM) alert via VHF Channel 16 to notify the public of any course changes.

The Captain of the Port of San Diego has determined that establishing a temporary marine event special local regulation on the navigable waters of the San Diego Bay will ensure public safety for the launch and procession. This special local regulation is necessary to provide for the safety of the crew, spectators, sponsor safety vessel, and other users of the waterway.

D. Discussion of the Final Rule

The Coast Guard is establishing marine event special local regulations that will be enforced from 8:00 a.m. to 1:00 p.m. on April 19, 2015. This special local regulation is necessary to provide for the safety of the crew, event participants and spectators of the event and to protect other vessels and users of the waterway. Persons and vessels will be prohibited from entering into, transiting through, or anchoring within this regulated area unless authorized by the Captain of the Port, or his designated representative.

The special local regulation will encompass a portion of the navigable waters of San Diego Bay within twenty-five yards on either side of a predetermined course starting from the Broadway Pier, heading southeast past the Embarcadero, crossing the federal channel before buoy 24 at position (North American Datum of 1983, World Geodetic System, 1984) 32°41.55 N, 117°09.54 W, heading northwest past Coronado Landing, crossing the federal channel again before buoy 22 at position (North American Datum of 1983, World Geodetic System, 1984) 32°42.31 N, 117°10.43, then heading north and culminating at the Maritime Museum Pier. Entry into, transiting, or anchoring within the regulated area is prohibited unless authorized by the Captain of the Port San Diego or his designated on-scene representative.

If an alternate emergency launch site is required along the Embarcadero other

than the Broadway Pier, the Coast Guard Captain of the Port will adjust the marine event special local regulations to ensure the safety of all participants, safety vessels and spectators during the launch and adjustment of the procession length.

Before the effective period, the Coast Guard will publish a local notice to mariners (LNM). During the enforcement of the event, the Coast Guard will issue a broadcast notice to mariners (BNM) alert via VHF Channel 16.

E. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes and executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation is unnecessary. This determination is based on the size, location and limited duration of the regulated area. The special local regulation is designed in a way to limit impacts on vessel traffic while permitting vessels to navigate in other portions of the waterways not designated as a regulated area.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 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. This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit or anchor in the impacted portion of the San Diego

Bay from 8:00 a.m. through 1:00 p.m. on April 19, 2015.

This regulation will not have a significant economic impact on a substantial number of small entities for the following reasons. Vessel traffic can pass safely around the regulated area adjacent to the Embarcadero and the procession regatta. The Coast Guard will publish a local notice to mariners (LNM) and will issue broadcast notice to mariners (BNM) alerts via VHF Channel 16 before the special local regulation is enforced.

3. Assistance for Small Entities

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 contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

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.

4. 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).

5. Federalism

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 determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters.

Protesters are asked to contact 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.

7. 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.

8. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

11. Indian Tribal Governments

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.

12. Energy Effects

This action is not a “significant energy action” under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (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 the establishment of a special local regulation on the navigable waters of San Diego Bay. This rule is categorically excluded from further review under paragraphs 35(b) and 34(h) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek comments or information that may lead to the discovery of significant environmental impacts from this rule.

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: 33 U.S.C. 1233.

- 2. Add temporary § 100.35T11–690 to read as follows:

§ 100.35T11–690 Special Local Regulation for Marine Event; San Diego Bay, San Diego, CA.

(a) *Regulated area.* A regulated area is established to include all navigable waters of San Diego Bay within twenty-five yards of the vessel *San Salvador* and the predetermined course starting from the waters of the basin between B Street Pier and Broadway Pier upon the initial preparation and launch of the *San Salvador* vessel. Once the vessel is floated, the regulated area will include the waters heading southeast past the Embarcadero, crossing the federal

channel before buoy 24 at position (North American Datum of 1983, World Geodetic System, 1984) 32°41.55 N, 117°09.54 W, heading northwest past Coronado Landing, crossing the federal channel again before buoy 22 at position (North American Datum of 1983, World Geodetic System, 1984) 32°42.31 N, 117°10.43, then heading north and culminating at the Maritime Museum Pier, as part of the marine event procession. Before the effective period and during the enforcement of the event, the Coast Guard will issue a broadcast notice to mariners (BNM) alert via VHF Channel 16 if any course modifications are required due to emergency reasons.

(b) *Enforcement period.* This section will be enforced from 8:00 a.m. to 1:00 p.m. on April 19, 2015. If the event concludes prior to the schedule termination time, the COTP will cease enforcement of the special local regulation and will announce that fact via Broadcast Notice to Mariners or other communications coordinated with the event sponsor to grant general permission to enter the regulated area.

(c) *Definitions.* The following definition applies to this section: *Designated representative* means any commissioned, warrant, or petty officer of the Coast Guard on board Coast Guard, Coast Guard Auxiliary, or local, state, or federal law enforcement vessels who have been authorized to act on the behalf of the Captain of the Port.

(d) *Regulations.* (1) No vessel may enter, transit through, or anchor within this regulated area unless authorized by the Captain of the Port of San Diego or his designated representative.

(2) Commercial vessels operating solely within the San Diego Bay federal channel will have right-of-way over event participants. Vessels participating in the procession will stop for oncoming commercial deep draft traffic and will resume after the vessel has completed its passage through the regulated area.

(3) All persons and vessels shall comply with instructions from the Coast Guard Captain of the Port (COTP) or his designated representative. The COTP San Diego or his on-scene representative may be contacted via VHF Channel 16 or at 619-278-7033.

(4) Upon being hailed by U.S. Coast Guard or designated patrol personnel by siren, radio, flashing light or other means, the operator of a vessel shall proceed as directed.

(5) The Coast Guard may be assisted by other federal, state, or local agencies in patrol and notification of the regulation.

Dated: March 24, 2015.

J.S. Spaner,

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

[FR Doc. 2015-07859 Filed 4-3-15; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket Number USCG-2015-0150]

Drawbridge Operation Regulation; Upper Mississippi River, Rock Island, IL

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Rock Island Railroad and Highway Drawbridge across the Upper Mississippi River, mile 482.9, at Rock Island, Illinois. The deviation is necessary to allow the Bandits Race to Home 5K Marathon to cross the bridge. This deviation allows the bridge to be maintained in the closed-to-navigation position for two hours.

DATES: This deviation is effective from 8:30 a.m. to 10:30 a.m., April 11, 2015.

ADDRESSES: The docket for this deviation, [USCG-2015-0150] is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Eric A. Washburn, Bridge Administrator, Western Rivers, Coast Guard; telephone 314-269-2378, email Eric.Washburn@uscg.mil. If you have questions on viewing the docket, call Cheryl F. Collins, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION: The U.S. Army Rock Island Arsenal requested a temporary deviation for the Rock Island Railroad and Highway Drawbridge, across the Upper Mississippi River, mile

482.9, at Rock Island, Illinois to remain in the closed-to-navigation position for a two hour period from 8:30 a.m. to 10:30 a.m., April 11, 2015, while the Bandits Race to Home 5K Marathon is held between the cities of Davenport, IA and Rock Island, IL.

The Rock Island Railroad and Highway Drawbridge currently operates in accordance with 33 CFR 117.5, which states the general requirement that drawbridges shall open promptly and fully for the passage of vessels when a request to open is given in accordance with the subpart.

There are no alternate routes for vessels transiting this section of the Upper Mississippi River.

The Rock Island Railroad and Highway Drawbridge, in the closed-to-navigation position, provides a vertical clearance of 23.8 feet above normal pool. Navigation on the waterway consists primarily of commercial tows and recreational watercraft. This temporary deviation has been coordinated with waterway users. No objections were received.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: March 30, 2015.

Eric A. Washburn,

Bridge Administrator, Western Rivers.

[FR Doc. 2015-07730 Filed 4-3-15; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2015-0186]

RIN 1625-AA00

Safety Zone; Rock and Roll Hall of Fame and Museum Fireworks Display; Lake Erie, Cleveland, OH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on Lake Erie, Cleveland Harbor, Cleveland, OH. This safety zone is intended to restrict vessels from a portion of Lake Erie during the Rock and Roll Hall of Fame and Museum fireworks display. This temporary safety zone is necessary to protect mariners and vessels from the