

PART 890—PHYSICAL MEDICINE DEVICES

■ 1. The authority citation for 21 CFR part 890 continues to read as follows:

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

■ 2. Add § 890.5760 to subpart F to read as follows:

§ 890.5760 Nonpowered lower extremity pressure wrap.

(a) *Identification.* A nonpowered lower extremity pressure wrap is a prescription device that applies mechanical pressure by wrapping around the lower extremity, such as the leg or foot, and is intended for primary Restless Leg Syndrome.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

Dated: June 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15626 Filed 7–2–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 100**

[Docket No. USCG–2014–0360]

Special Local Regulation; Eleventh Coast Guard District Annual Marine Events

AGENCY: Coast Guard, DHS.

ACTION: Notice of Enforcement of Regulation.

SUMMARY: The Coast Guard will enforce the San Diego Maritime Museum Tall Ship Festival of Sail special local regulations during this year's event on August 29, 2014 through September 1, 2014. This event occurs on the navigable waters of the San Diego Bay in San Diego, CA. These special local regulations are necessary to provide for the safety of the participants, crew, spectators, sponsor vessels of the boat parade, and general users of the waterway. During the enforcement period, 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.

DATES: This rule is effective from 9 a.m. to 7 p.m. on August 29, 2014 through September 1, 2014.

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

SUPPLEMENTARY INFORMATION:

The Coast Guard will enforce the special local regulations in 33 CFR 100.1101 in support of San Diego Maritime Museum Tall Ship Festival of Sail (Item 15 on Table 1 of 33 CFR 100.1101), held on a weekend in September. The Coast Guard will enforce the special local regulations on the San Diego Bay in San Diego, CA on Friday August 29, 2014 through Monday September 1, 2014 from 9 a.m. to 7 p.m.

Under the provisions of 33 CFR 100.1101, 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 may be assisted by other Federal, State, or local law enforcement agencies in the patrol and notification of the regulation.

This document is issued under authority of 5 U.S.C. 552(a) and 33 CFR 100.1101. 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 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 notice, 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: June 5, 2014.

J.A. Janszen,

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

[FR Doc. 2014–15543 Filed 7–2–14; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165**

[Docket Number USCG–2014–0160]

RIN 1625–AA00

Safety Zone; Swim Around Charleston, Charleston, SC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary moving safety zone during the Swim Around Charleston, a swimming race occurring on waters of the Wando River, the Cooper River, Charleston Harbor, and the Ashley River, in Charleston, South Carolina. The Swim Around Charleston is scheduled to take place on September 21, 2014. The temporary safety zone is necessary for the safety of the swimmers, participant vessels, spectators, and the general public during the event. Persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port Charleston or a designated representative.

DATES: This rule will be effective from 11:30 a.m. until 6:30 p.m. on September 21, 2014.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2014–0160. 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 Chief Warrant Officer Christopher Ruleman, Sector Charleston Waterways Management, U.S. Coast Guard; telephone (843) 740–3184, email christopher.l.ruleman@uscg.mil. If you have questions on viewing 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. Regulatory History and Information

On April 22, 2014, we published a notice of proposed rulemaking (NPRM) entitled *Safety Zone; Swim Around Charleston, Charleston, SC* in the **Federal Register**. We received no comments on the proposed rule. No public meeting was requested, and none was held.

B. Basis and Purpose

The legal basis for the rule is the Coast Guard's authority to establish regulated navigation areas and other limited access areas: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Public Law 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

The purpose of the rule is to ensure the safety of the swimmers, participant vessels, spectators, and the general public during the Swim Around Charleston.

C. Discussion of Comments, Changes and the Final Rule

The Coast Guard did not receive any comments to the proposed rule, and no changes were made to the regulatory text.

D. 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. The economic impact of this rule is not significant for the following reasons: (1) The safety zone will only be enforced for a total of seven hours; (2) the safety zone will move with the participant vessels so that once the swimmers clear a portion of the waterway, the safety zone will no longer be enforced in that portion of the waterway; (3) although persons and

vessels may not enter, transit through, anchor in, or remain within the safety zone without authorization from the Captain of the Port Charleston or a designated representative, they may operate in the surrounding area during the enforcement period; (4) persons and vessels may still enter, transit through, anchor in, or remain within the safety zone if authorized by the Captain of the Port Charleston or a designated representative; and (5) the Coast Guard will provide advance notification of the safety zone to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

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.

(1) This rule would affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit or anchor in a portion of the Wando River, the Cooper River, Charleston Harbor, or the Ashley River in Charleston, South Carolina from 11:30 a.m. until 6:30 p.m. on September 21, 2014.

(2) For the reasons discussed in the Regulatory Planning and Review section above, this rule will not have a significant economic impact on a substantial number of small entities.

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** section 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 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 concluded 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 special local regulation issued in conjunction with a regatta or marine parade. An environmental analysis checklist and a Categorical Exclusion Determination were completed for this event in previous years. Since this event has remained materially unchanged from the time of the prior determinations, a new environmental analysis checklist and Categorical Exclusion Determination were not completed for 2014. The previously completed environmental analysis checklist and Categorical Exclusion Determination can be found in docket folder for USCG-2013-0322 at

www.regulations.gov. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2-1 of the Commandant Instruction. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

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: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add a temporary § 165.T07-0160 to read as follows:

§ 165.T07-0160 Safety Zone; Swim Around Charleston, Charleston, SC.

(a) *Regulated area.* The following regulated area is a moving safety zone: All waters within a 75-yard radius around Swim Around Charleston participant vessels that are officially associated with the swim. The Swim Around Charleston swimming race consists of a 10-mile course that starts at Remley’s Point on the Wando River in approximate position 32°48’49” N, 79°54’27” W, crosses the main shipping channel of Charleston Harbor, and finishes at the General William B. Westmoreland Bridge on the Ashley River in approximate position 32°50’14” N, 80°01’23” W. All coordinates are North American Datum 1983.

(b) *Definition.* The term “designated representative” means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Charleston in the enforcement of the regulated area.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Charleston or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may

contact the Captain of the Port Charleston by telephone at 843-740-7050, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the Captain of the Port Charleston or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Charleston or a designated representative.

(3) The Coast Guard will provide notice of the regulated area by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

(d) *Effective date.* This rule is effective on September 21, 2014 and will be enforced from 11:30 a.m. until 6:30 p.m.

Dated: June 2, 2014.

R.R. Rodriguez,

Captain, U.S. Coast Guard, Captain of the Port Charleston.

[FR Doc. 2014-15545 Filed 7-2-14; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2013-1033]

Safety Zones; Annual Events Requiring Safety Zones in the Captain of the Port Lake Michigan Zone—Miesfeld’s Lakeshore Weekend Fireworks, Sheboygan, WI

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone on Lake Michigan in Sheboygan, WI, for the Miesfeld’s Lakeshore Weekend fireworks. This zone will be enforced from 8:30 p.m. until 9:45 p.m. on July 25, 2014. This action is necessary and intended to ensure the safety of life on navigable waters during a fireworks display.

DATES: The regulations in 33 CFR 165.929 will be enforced for safety zone (e)(49), Table 165.929, from 8:30 p.m. until 9:45 p.m. on July 25, 2014.

FOR FURTHER INFORMATION CONTACT: If you have questions on this document, call or email MST1 Joseph McCollum, Prevention Department, Coast Guard Sector Lake Michigan, Milwaukee, WI at (414) 747-7148, email joseph.p.mccollum@uscg.mil.