the phase duration expressed in milliseconds and measured at 50 percent of the phase amplitude);

(ii) A maximum average current that does not exceed 10 milliamperes (average absolute value);

(iii) A maximum primary (depolarizing) phase duration that does not exceed 500 microseconds;

- (iv) An average direct current (dc) that does not exceed 100 microamperes when no pulses are being applied, or if the device fails;
- (v) A maximum current density that does not exceed 2 milliamperes root mean square (rms) per square centimeter of electrode conductive surface area;
- (vi) A maximum average power density that does not exceed 0.25 watts per square centimeter of electrode conductive surface area.
- (2) Classification. Class II (special controls). The special controls for this device are:
- (i) The FDA guidance document entitled "Class II Special Controls Guidance Document: Powered Muscle Stimulator with Limited Output for Rehabilitation." See § 890.1(e) for the availability of this guidance document; and
- (ii) Sale, distribution, and use are restricted to prescription use in accordance with the prescription device requirements in § 801.109 of this chapter. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations of exemptions in § 890.9, when it follows the recommendations of the special controls guidance and its sale, distribution, and use are restricted to prescription use in accordance with the prescription device requirements in § 801.109 of this chapter.
- (c) Powered muscle stimulator for muscle conditioning—(1) Identification. A powered muscle stimulator for muscle conditioning is an electrically powered device that repeatedly contracts muscles by passing pulsed electrical current through cutaneous electrodes and into the body, thereby temporarily affecting the stimulated muscles' contractile properties, force output, and/or fatigue resistance. This does not include the powered muscle stimulators classified in paragraphs (a), (b), and (d) of this section.
- (2) Classification. Class II (special controls.) The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Powered Muscle Stimulator for Muscle Conditioning." See § 890.1(e) for the availability of this guidance document.

- (d) Powered muscle stimulator with limited output for muscle conditioning—(1) Identification. A powered muscle stimulator with limited output for muscle conditioning is an electrically powered device that repeatedly contracts muscles by passing pulsed electrical current through cutaneous electrodes and into the body, thereby temporarily affecting the stimulated muscles' contractile properties, force output, and/or fatigue resistance. This does not include the powered muscle stimulators classified in paragraphs (a) through (c) of this section. The device utilizes a stimulus generator that delivers, into a resistive load, which represents the worse case of either 500 ohms or the typical load expected during normal conditions of use, the following:
- (i) A maximum charge per phase that does not exceed Q, where Q = 20 + (28)(t) microcoulombs (and where t is the phase duration expressed in milliseconds and measured at 50 percent of the phase amplitude);
- (ii) A maximum average current that does not exceed 10 milliamperes (average absolute value);
- (iii) A maximum primary (depolarizing) phase duration that does not exceed 500 microseconds;
- (iv) An average dc that does not exceed 100 microamperes when no pulses are being applied, or if the device fails;
- (v) A maximum current density that does not exceed 2 milliamperes rms per square centimeter of electrode conductive surface area; and
- (vi) A maximum average power density that does not exceed 0.25 watts per square centimeter of electrode conductive surface area.
- (2) Classification. Class II (special controls). The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Powered Muscle Stimulator with Limited Output for Muscle Conditioning." See § 890.1(e) for the availability of this guidance document. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations of exemptions in § 890.9, when it follows the recommendations of the special controls guidance.

Dated: March 24, 2010.

Jeffrey Shuren,

Director, Center for Devices and Radiological Health.

[FR Doc. 2010–7637 Filed 4–2–10; 8:45 am] BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2010-0180]

RIN 1625-AA08

Special Local Regulation for Marine Event; Temporary Change of Dates for Recurring Marine Event in Fifth Coast Guard District

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

summary: The Coast Guard proposes to temporarily change the enforcement period of special local regulations for recurring marine events in Fifth Coast Guard District. The regulation applies to one recurring marine event that establishes two spectator vessel anchorage areas and restricts vessel traffic. Special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in portions of the Hampton River, Hampton, VA, and Sunset Creek, Hampton, VA during the event.

DATES: Comments and related material must be received by the Coast Guard on or before May 5, 2010.

ADDRESSES: You may submit comments identified by docket number USCG—2010–0180 using any one of the following methods:

- (1) Federal eRulemaking Portal: http://www.regulations.gov.
 - (2) Fax: 202–493–2251.
- (3) Mail: 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.
- (4) Hand Delivery: Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the

SUPPLEMENTARY INFORMATION section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail LT Tiffany Duffy, Project Manager, Sector Hampton Roads, Waterways Management Division, Coast Guard; telephone 757–668–5580, e-mail

Tiffany.A.Duffy@uscg.mil. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to http://www.regulations.gov and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG-2010-0180), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via http:// www.regulations.gov) or by fax, mail, or hand deliver, but please use only one of these means. If you submit a comment online via http://www.regulations.gov, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to http://www.regulations.gov, click on the "submit a comment" box, which will then become highlighted in blue. In the "Document Type" drop down menu select "Proposed Rule" and insert "USCG-2010-0180" in the "Keyword" box. Click "Search" then click on the balloon shape in the "Actions" column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to http://www.regulations.gov, click on the "read comments" box, which will then become highlighted in blue. In the "Keyword" box insert USCG-2010-0180 and click "Search." Click the "Open Docket Folder" in the "Actions" column. 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. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

Public Meeting

We do not now plan to hold a public meeting, but you may submit a request for one using one of the four methods specified under ADDRESSES. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the Federal Register.

Background and Purpose

Marine events are frequently held on the navigable waters within the boundary of Fifth Coast Guard District. The water activities that typically comprise marine events include sailing regattas, powerboat races, swim races and holiday parades. For a description of the geographical area of the Coast Guard Sector Hampton Roads Captain of the Port Zone, please see 33 CFR 3.25– 10.

This regulation proposes to temporarily change the enforcement period of special local regulations for recurring marine events within Fifth Coast Guard District. This proposed regulation applies to one marine event in 33 CFR 100.501, Table to § 100.501.

On July 9, 10, and 11, 2010, the City of Hampton and The Virginia Air and Space Museum will sponsor the "11th Hampton Blackbeard Festival," a historic festival on the waters of the

Hampton River near Hampton, Virginia. The regulation at 33 CFR 100.501 is effective annually for this marine event. The event will consist of three replica pirate ships conducting a simulated wartime demonstration on July 10, 2010 from 11:30 a.m. to 2:30 p.m. and July 11, 2010 from 12:30 p.m. to 1:30 p.m. on the Hampton River in the vicinity of Mill Point Park, Hampton, Virginia. The event will also consist of a fireworks display on July 10, 2010 from 9 p.m to 10 p.m over the Hampton River in the vicinity of Mill Point Park, Hampton, Virginia. A fleet of spectator vessels is expected to gather near the event site to view the simulated wartime demonstration and fireworks display. To provide for the safety of participants, spectators, support and transiting vessels, the Coast Guard will temporarily restrict vessel traffic in the event area during the demonstration and fireworks display. The regulation at 33 CFR 100.501 would be enforced for the duration of the event. Under provisions of 33 CFR 100.501, from 11:30 a.m. to 2:30 p.m. and 9 p.m. to 10 p.m. on July 10, 2010, and from 12:30 p.m. to 1:30 p.m. on July 11, 2010, vessels may not enter the regulated area unless they receive permission from the Coast Guard Patrol Commander.

Discussion of Proposed Rule

The Coast Guard proposes to temporarily suspend the regulations at 33 CFR 100.501 by changing the date of enforcement in the table to § 100.501. The Coast Guard proposes to temporarily change the enforcement period of special local regulations for recurring marine events within Fifth Coast Guard District. This regulation applies to only one marine event listed as number 36 in the Table to § 100.501.

Hampton River, Hampton, VA

The Table to § 100.501, event No. 36 establishes the enforcement date for the "11th Hampton Blackbeard Festival". This regulation proposes to temporarily change the enforcement date from "May—last Friday, Saturday and Sunday or June—1st Friday, Saturday, and Sunday" to the second Friday, Saturday and Sunday in July, holding the event on July 9, 10, and 11, 2010. The temporary special local regulations will be enforced from 11:30 a.m. to 2:30 p.m. and 9 p.m. to 10 p.m. on July 10, 2010, and from 12:30 p.m. to 1:30 p.m. on July 11, 2010 and will restrict general navigation in the regulated area during the event. The City of Hampton and The Virginia Air and Space Museum which is the sponsor for this event intends to hold this event annually; however, they have requested to change the date of the

event for 2010 so that it is outside the scope of the existing enforcement period. Except for participants and vessels authorized by the Coast Guard Patrol Commander, no person or vessel will be allowed to enter or remain in the regulated area. These regulations are needed to control vessel traffic during the event to enhance the safety of participants, spectators and transiting vessels.

Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Although this proposed rule prevents traffic from transiting a portion of certain waterways during specified events, the effect of this regulation will not be significant due to the limited duration that the regulated area will be in effect and the extensive advance notifications that will be made to the maritime community via marine information broadcasts, local radio stations and area newspapers so mariners can adjust their plans accordingly. Additionally, this rulemaking does not change the permanent regulated area that was published in 33 CFR 100.501, Table to § 100.501. In some cases vessel traffic may be able to transit the regulated area when the Coast Guard Patrol Commander deems it is safe to do so.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. 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 proposed rule would not have a significant economic impact on a substantial number of small entities. This rule would affect the

following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in the areas where marine events are being held. This regulation will not have a significant impact on a substantial number of small entities because it will be enforced only during marine events that have been permitted by the Coast Guard Captain of the Port. The Captain of the Port will ensure that small entities are able to operate in the areas where events are occurring when it is safe to do so. In some cases, vessels will be able to safely transit around the regulated area at various times, and, with the permission of the Patrol Commander, vessels may transit through the regulated area. Before the enforcement period, the Coast Guard will issue maritime advisories so mariners can adjust their plans accordingly.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see ADDRESSES) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

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 proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. 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 Sector Hampton Roads Project Officer listed under FOR FURTHER INFORMATION **CONTACT** at the beginning of this rule. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and

have determined that it does not have implications for federalism.

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 or more (adjusted for inflation) in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

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

Civil Justice Reform

This proposed 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.

Protection of Children

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

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

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

Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule involves implementation of regulations within 33 CFR Part 100 that apply to organized marine events on the navigable waters of the United States that may have potential for negative impact on the safety or other interest of waterway users and shore side activities in the event area. The category of water activities includes but is not limited to sail boat regattas, boat parades, power boat racing, swimming events, crew racing, and sail board racing. Under figure 2-1, paragraph (34)(h), of the Instruction, an "Environmental Analysis Check List" and a "Categorical Exclusion Determination" are not required for this rule. We seek any comments or information that may lead to the

discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 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. In § 100.501, suspend from July 1, 2010 until July 31, 2010, line No. 36 in the Table to § 100.501.
- 3. In § 100.501, from July 1, 2010 until July 31, 2010, add line No. 61 in Table to § 100.501; to read as follows:

§ 100.501–T05–0180 Special Local Regulations; Recurring Marine Event in the Fifth Coast Guard District.

Table To § 100.501.—All coordinates listed in the Table to § 100.501 reference Datum NAD 1983.

COAST GUARD SECTOR HAMPTON ROADS—COTP ZONE

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Dated: March 23, 2010.

M.S. Ogle,

Captain, U.S. Coast Guard, Captain of the Port, Hampton Roads.

[FR Doc. 2010-7571 Filed 4-2-10; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2010-0113]

RIN 1625-AA08

Special Local Regulation for Marine Event; Temporary Change of Dates for Recurring Marine Event in the Fifth Coast Guard District

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to temporarily change the enforcement period of special local regulations for recurring marine event in the Fifth Coast Guard District. These regulations apply to only one recurring marine event that conducts swimming competitions. Special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in a portion of the Chester River, near Chestertown, MD during the event.

DATES: Comments and related material must be received by the Coast Guard on or before May 5, 2010.

ADDRESSES: You may submit comments identified by docket number USCG—2010–0113 using any one of the following methods:

- (1) Federal eRulemaking Portal: http://www.regulations.gov.
 - (2) Fax: 202–493–2251.
- (3) Mail: 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.
- (4) Hand Delivery: Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the

SUPPLEMENTARY INFORMATION section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call Mr. Ronald L. Houck, Project Manager, Coast Guard Sector Baltimore Waterways Management Division, at 410–576–2674 or e-mail at Ronald.L.Houck@uscg.mil. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826. SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to http://www.regulations.gov and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG-2010-0113), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via http:// www.regulations.gov) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via http:// www.regulations.gov, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand delivery, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to http://www.regulations.gov, click on the "submit a comment" box, which will then become highlighted in blue. In the "Document Type" drop down menu select "Proposed Rule" and insert "USCG-2010-0113" in the "Keyword" box. Click "Search" then click on the balloon shape in the "Actions" column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 81/2 by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to http://www.regulations.gov, click on the "read comments" box, which will then become highlighted in blue. In the "Keyword" box insert USCG-2010-0113 and click "Search." Click the "Open Docket Folder" in the "Actions" column. 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. We have an agreement with the Department of Transportation to use the Docket Management Facility.

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Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one using one of the four methods specified under ADDRESSES. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the Federal Register.

Background and Purpose

Marine events are frequently held on the navigable waters within the boundary of the Fifth Coast Guard District. The on water activities that typically comprise marine events include sailing regattas, power boat races, swim races and holiday parades. For a description of the geographical area of each Coast Guard Sector—Captain of the Port Zone, please see 33 CFR 3.25.

This regulation proposes to temporarily change the enforcement period of special local regulations for recurring marine events within the Fifth Coast Guard District. This proposed regulation applies to one marine event