

### III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: June 16, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-15560 Filed 6-21-11; 8:45 am]

BILLING CODE 4160-01-P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[Docket No. USCG-2011-0540]

RIN 1625-AA08

#### Special Local Regulation for Marine Events; Temporary Change of dates for Recurring Marine Events in the Fifth Coast Guard District; Mill Creek, Hampton, VA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard will temporarily change the enforcement period of one special local regulation for recurring marine events in the Fifth Coast Guard District. This regulation applies a hydroplane speed boat race which was originally scheduled for August 12-14, 2011 will be on August 6-7, 2011. This regulation will restrict vessel traffic in portions of Mill Creek in Hampton, Virginia during the rescheduled event to protect mariners and the boating public from the potential hazards associated with hydroplane speed boats that will reach speeds in excess of 150 miles per hour.

**DATES:** This rule is effective from August 6, 2011, through August 15, 2011.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket USCG-2011-0540 and are available online by going to <http://www.regulations.gov>, inserting USCG-2011-0540 in the "Keyword" box, and then clicking "Search." They are also available for inspection or copying at the 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, 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 rule, call or e-mail LCDR Christopher A. O'Neal, Waterways Management Division Chief, Sector Hampton Roads, Coast Guard; telephone 757-668-5580, e-mail [Christopher.A.ONeal@uscg.mil](mailto:Christopher.A.ONeal@uscg.mil). If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

#### SUPPLEMENTARY INFORMATION:

##### Regulatory Information

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 delaying the effective date would be contrary to the public interest since immediate action is needed to ensure the safety of the event participants, patrol vessels, spectator craft and other vessels transiting the event area. The potential dangers posed by hydroplane speed boats, operating in speeds excess of 150 miles per hour, make special local regulations necessary. However, the Coast Guard will provide advance notifications to users of the effected waterways via marine information broadcasts, local notice to mariners, commercial radio stations and area newspapers. This regulation represents the re-scheduling of the event in order to de-conflict the event from another race that many competitors and a sponsor are involved in during the second weekend in August 2011 and to have the event take place close in time to the regularly scheduled dates of the event. In addition, publishing an NPRM is unnecessary because this event is an annual event which mariners should be aware of taking place, as it is noticed in the **Federal Register**. If mariners had concerns about this event taking place, they are on notice throughout the year of the event and can object to or comment about the event at any time. When the NPRM, including the table to § 100.501 listing all of the annual events, was made available for comment, there were no objections to this event.

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 would be contrary to the public interest since immediate action is needed to ensure the safety of the event participants, patrol vessels, spectator craft and other vessels transiting the event area. The potential dangers posed by hydroplane speed boats, operating in speeds excess of 150 miles per hour, make special local regulations necessary. However, the Coast Guard will provide advance notifications to users of the effected waterways via marine information broadcasts, local notice to mariners, commercial radio stations and area newspapers. This regulation represents the re-scheduling of the event in order to de-conflict the event from another race that many competitors and a sponsor are involved in during the second weekend in August 2011 and to have the event take place close in time to the regularly scheduled dates of the event. In addition, publishing an NPRM is unnecessary because this event is an annual event which mariners should be aware of taking place, as it is noticed in the **Federal Register**. If mariners had concerns about this event taking place, they are on notice throughout the year of the event and can object to or comment about the event at any time. When the NPRM, including the table to § 100.501 listing all of the annual events, was made available for comment, there were no objections to this event.

##### Background and Purpose

This event is annually held in August, scheduled to begin on the second Friday of August and anticipated to run through the Saturday and Sunday of that weekend. The regulation listing annual marine events within the Fifth Coast Guard District and their regulated dates is 33 CFR 100.501. A table to § 100.501 identifies marine events by Captain of the Port zone. This particular event, sponsored this year by the City of Hampton, Hampton Cup Regatta Racing Club and the Phoebus Civic Association, is listed at line No. 44.

This year, the Regatta was initially scheduled to take place on August 12-14, 2011. However, the event was rescheduled to take place one week earlier, on August 6-7, 2011. The date has changed due to participants and a sponsor being involved in another race during the second weekend in August. In order to deal with this conflict, the regatta date was pushed up one weekend in August 2011.

On August 6–7, 2011, the City of Hampton, Hampton Cup Regatta Racing Club and the Phoebus Civic Association will sponsor the “85th Hampton Cup Regatta” in the waters of Mill Creek, adjacent to Fort Monroe, Hampton, Virginia. The event will consist of approximately 75–100 hydroplane powerboats conducting high-speed competitive races in heats counter-clockwise around an oval racecourse on the water of the Mill Creek adjacent to Fort Monroe, Hampton, Virginia and Route 258 Mercury Highway Bridge. A fleet of spectator vessels is expected to gather near the event site to view the competition. Due to the need for vessel control during the event, the Coast Guard will temporarily restrict vessel traffic in the event area to provide for the safety of participants, spectators, and other transiting vessels. The special local regulation will be enforced from 11:30 a.m. to 5 p.m. August 6, 2011 and from 11:30 a.m. to 5 p.m. on August 7, 2011.

During this enforcement period, vessels may not enter the regulated area unless they receive permission from the Coast Guard Patrol Commander.

#### Discussion of Rule

The Coast Guard will temporarily suspend the regulation listed at line No. 44 in Table to § 100.501 and will insert this new temporary regulation at Table to § 100.501 line No. 44a, in order to reflect the change in date for this event this year. This change is needed to accommodate the conflict in races during the second weekend in August 2011; because there is another race that many participants and a sponsor are involved with during the second week of August 2011, it was determined to shift the “85th Hampton Cup Regatta” to the first weekend in August 2011. No other portion of the Table to § 100.501 shall be affected by this regulation.

This special local regulation will restrict navigation in the regulated area during the marine event, from 11:30 a.m. to 5 p.m. on August 6, 2011 and from 11:30 a.m. to 5 p.m. on August 7, 2011. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area during the effective period. The regulated area is needed to control vessel traffic during the event to enhance the safety of participants in and spectators to the 85th Hampton Cup Regatta.

The enforcement period for this special local regulation will be from 11:30 a.m. to 5 p.m. on August 6, 2011 and from 11:30 a.m. to 5 p.m. on August 7, 2011. The Coast Guard, at its

discretion, will allow the passage of vessels when races are not taking place. Except for participants and vessels authorized by the Captain of the Port or his Representative, no person or vessel may enter or remain in the regulated area.

In addition to notice in the **Federal Register**, the maritime community will be provided advance notification via the Local Notice to Mariners and marine information broadcasts.

#### Regulatory Analyses

We developed this 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 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 that Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under that those Orders. Although this 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.

#### Small Entities

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

The 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 this section of Mill Creek during the

event from 11:30 a.m. to 6 p.m. on August 6 and from 11:30 a.m. to 6 p.m. on August 7, 2011.

Although this regulation prevents traffic from transiting a portion of Mill Creek during the event, this rule would not have a significant economic impact on a substantial number of small entities for the following reasons. This rule would be in effect for only a limited period. Vessel traffic will be able to transit the regulated area between heats, when the Coast Guard Patrol Commander deems it is safe to do so. 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 offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

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.

#### Collection of Information

This rule calls 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 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 (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.

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.

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.

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.

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.

Energy Effects

We have analyzed this 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 rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

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 which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(h), of the Instruction. 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 checklist and a categorical exclusion determination will be available in the docket where indicated under ADDRESSES.

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 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. Suspend line No. 44 in the Table to § 100.501.
- 3. Add line No. 44a in Table to § 100.501 to read as follows:  
§ 100.501. Special Local Regulations; Marine Events in the Fifth Coast Guard District.  
\* \* \* \* \*

TABLE TO § 100.501—ALL COORDINATES LISTED IN THE TABLE TO § 100.501 REFERENCE DATUM NAD 1983

Number	Date	Event	Sponsor	Location
*	*	*	*	*
Coast Guard Sector Hampton Roads—COTP Zone				

TABLE TO § 100.501—ALL COORDINATES LISTED IN THE TABLE TO § 100.501 REFERENCE DATUM NAD 1983—  
Continued

Number	Date	Event	Sponsor	Location
44a .....	August 6–7, 2011	Hampton Cup Regatta	City of Hampton, Hampton Cup Regatta Racing Club, and the Phoebus Civic Association.	The waters of Mill Creek, adjacent to Fort Monroe, Hampton, Virginia, enclosed by the following boundaries: to the north, a line drawn along latitude 37°01'00" N, to the east a line drawn along longitude 076°18'30" W, to the south a line parallel with the shoreline adjacent to Fort Monroe, and the west boundary is parallel with the Route 258—Mercury Boulevard Bridge.
*	*	*	*	*

Dated: June 13, 2011.

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

[FR Doc. 2011–15619 Filed 6–21–11; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[Docket No. USCG–2011–0103]

**RIN 1625–AA08**

#### Special Local Regulation; Extreme Sailing Series Boston; Boston Harbor, Boston, MA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is establishing a temporary special local regulation in Boston Harbor, Boston, Massachusetts, within the Captain of the Port (COTP) Boston Zone. This special local regulation is necessary to provide for the safety of life on navigable waters during the Extreme Sailing Series Boston regatta. The special local regulation will temporarily restrict vessel traffic in a portion of Boston Harbor, and prohibit vessels not participating in the Extreme Sailing Series event from entering the designated race area.

**DATES:** This rule is effective from 1 p.m. on June 30, 2011, to 6 p.m. on July 4, 2011. This regulation will also be enforced daily from 1 p.m. until 6 p.m., June 30, 2011 through July 4, 2011.

**ADDRESSES:** Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2011–0103 and are

available online by going to <http://www.regulations.gov>, inserting USCG–2011–0103 in the “Keyword” box, and then clicking “Search.” This material is also available for inspection or copying at the 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, 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 e-mail MST1 David Labadie of the Waterways Management Division, U.S. Coast Guard Sector Boston; telephone 617–223–3010, e-mail [david.j.labadie@uscg.mil](mailto:david.j.labadie@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:

##### Regulatory Information

On April 13, 2011, we published a notice of proposed rulemaking (NPRM) entitled: Special Local Regulation; Extreme Sailing Series Boston; Boston Harbor, Boston, Massachusetts, in the **Federal Register** (76 FR 20595). We received one comment on the proposed rule. No public meeting was requested, and none was held.

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**. The Coast Guard completed the public comment period for this rule and only received one comment on the rule which was positive in nature. The sponsor is unable to reschedule this event due the vast number of participants, scheduling, and to other activities being held in conjunction with the event. Establishing a special local regulation for the event will help ensure

the safety of persons and property and minimize the associated risks by controlling vessel traffic and movement.

#### Basis and Purpose

The legal basis for this rule is 33 U.S.C. 1233, which authorizes the Coast Guard to define Special Local Regulations.

Establishing a special local regulation for the event will help ensure the safety of persons and property and minimize the associated risks by controlling vessel traffic and movement.

#### Background

This temporary special local regulation is necessary to ensure the safety of vessels, participants, and the public during the Extreme Sailing Series Boston regatta. The event will take place over the course of five days in Boston Harbor in the vicinity of Fan Pier. There will be two regulated areas associated with this event and they will be enforced immediately before, during, and after the regatta, from June 30th through July 4th, 2011, from 1 p.m. to 6 p.m. daily.

This rule is necessary to ensure the safety of vessels and spectators from the hazards associated with competitive sailing regattas. Without the rule, the combination of a large number of recreational vessels due to spectators, sailboats traveling at high speeds on the race course, and large numbers of spectators on the adjacent Fan Pier in close proximity to the water and in a small area of water, could easily result in serious injuries or fatalities.

All persons and vessels shall comply with the instructions of the COTP Boston or the designated on-scene representative. Entering into, transiting through, mooring or anchoring within the special local regulation area is prohibited unless authorized by the COTP Boston or the designated on-scene representative.