

§ 56.120 Lesser administrative actions.

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(b) On the basis of the IRB's or the institution's response, FDA may schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the IRB or the parent institution takes appropriate corrective action, the Agency may require the IRB to:

(1) Withhold approval of new studies subject to the requirements of this part that are conducted at the institution or reviewed by the IRB;

(2) Direct that no new subjects be added to ongoing studies subject to this part; or

(3) Terminate ongoing studies subject to this part when doing so would not endanger the subjects.

(c) When the apparent noncompliance creates a significant threat to the rights and welfare of human subjects, FDA may notify relevant State and Federal regulatory agencies and other parties with a direct interest in the Agency's action of the deficiencies in the operation of the IRB.

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Dated: March 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-07523 Filed 4-1-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY
Coast Guard
33 CFR Part 100

[Docket Number USCG-2015-1055]

RIN 1625-AA08

Special Local Regulation; Charleston Race Week, Charleston Harbor, Charleston, SC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a special local regulation on the waters of Charleston Harbor in Charleston, SC during the Charleston Race Week from April 15, 2016 through April 17, 2016. This special local regulation is necessary to ensure the safety of participants, spectators, and the general public during the event. This regulation prohibits persons and vessels from being in the regulated area unless authorized by the Captain of the Port Charleston or a designated representative.

DATES: This rule is effective from April 15, 2016 through April 17, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2015-1055 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Lieutenant John Downing, Sector Charleston Office of Waterways Management, Coast Guard; telephone(843)740-3184, email John.Z.Downing@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
 DHS Department of Homeland Security
 NPRM Notice of proposed rulemaking
 § Section
 U.S.C. United States Code

II. Background Information and Regulatory History

On November 18, 2015, the Charleston Ocean Racing Association notified the Coast Guard that it will sponsor a series of sailboat races in the Charleston Harbor, Charleston, SC. from 8:30 a.m. to 5 p.m. April 15, 2016 through April 17, 2016. In response, on February 5, 2016, the Coast Guard published a notice of proposed rulemaking titled Charleston Race Week. There we stated why we issued the NPRM and invited comments on our proposed regulatory action related to this special local regulation. During the comment period that ended March 7, 2016, we received no comments.

Under good cause provisions in 5 U.S.C. 553(d)(3), we are making this rule effective less than 30 days after its publication in the **Federal Register**. The Coast Guard finds that good cause exists for making this rule effective starting April 15, 2016 because this special local regulation is necessary to ensure the safety of life and property during this high speed boat race and it would be contrary to public interest not to make this rule effective by April 15, 2016. Also, this regulation will have a limited impact on the waterway for a limited time and designated representatives will be on scene to assist the public with compliance.

III. Legal Authority and Need for Rule

The legal basis for the rule is the Coast Guard's authority to establish special local regulations: 33 U.S.C. 1233. The purpose of the rule is to insure safety of life on navigable waters of the United States during three Charleston Race Week sailboat races. It was determined that potential hazards

are associated with the areas used in the Charleston Race Week sailboat races that can be alleviated by prohibiting access to the regulated areas.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published February 5, 2016. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

From April 15, 2016 through April 17, 2016, Charleston Ocean Racing Association will host three sailboat races on Charleston Harbor in Charleston, South Carolina during Charleston Race Week. Approximately 300 sailboats will participate in the three races. This rule establishes a special local regulation on certain waters of Charleston Harbor in Charleston, South Carolina. The special local regulation will be enforced daily from 8:30 a.m. until 5 p.m. on April 15, 2016 through April 17, 2016. The special local regulation consists of the following three race areas.

1. *Race Area #1.* All waters encompassed within a 700 yard radius of position 32°46'10" N. 79°55'15" W.
2. *Race Area #2.* All waters encompassed within a 700 yard radius of position 32°46'02" N. 79°54'15" W.
3. *Race Area #3.* All waters encompassed within a 700 yard radius of position 32°45'55" N. 79°53'39" W.

Except for those persons and vessels participating in the sailboat races, persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within any of the race areas unless specifically authorized by the Captain of the Port Charleston or a designated representative. Persons and vessels desiring to enter, transit through, anchor in, or remain within any of the race areas 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 race areas 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. The Coast Guard will provide notice of the regulated areas by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget. 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) Non-participant persons and vessels may enter, transit through, anchor in, or remain within the regulated area during the enforcement periods if authorized by the Captain of the Port Charleston or a designated representative; (2) vessels not able to enter, transit through, anchor in, or remain within the regulated area without authorization from the Captain of the Port Charleston or a designated representative may operate in the surrounding areas during the enforcement period; and (3) the Coast Guard will provide advance notification of the special local regulation to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners; (4) the safety zone will impact only 3 small designated areas of Charleston Harbor for less than 9 hours per day for 3 days over the weekend of April 15, to 17, 2016, and thus is limited in time and scope.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider

the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule may affect the following entities, some of which may be small entities: The owner or operators of vessels intending to enter, transit through, anchor in, or remain within the regulated area during the enforcement period. For the reasons discussed in Regulatory Planning and Review section above, this rule will not have a significant economic impact on a substantial number of small entities.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 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.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship

between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a special local regulation issued in conjunction with a regatta or marine parade. This rule is categorically excluded from further review under paragraph 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 any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. 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.

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. Add a temporary § 100.35T07–1055 to read as follows:

§ 100.35T07–1055 Special Local Regulation; Charleston Race Week, Charleston Harbor, Charleston, SC.

(a) *Regulated Area.* A special local regulation is established on waters of Charleston Harbor in Charleston, South Carolina. The special local regulations will be enforced daily from 8:30 a.m. until 5 p.m. from April 15, 2016 through April 17, 2016. The special local regulations consist of the following three race areas.

(1) *Race Area #1.* All waters encompassed within a 700 yard radius of position 32°46'10" N. 79°55'15" W.

(2) *Race Area #2.* All waters encompassed within a 700 yard radius of position 32°46'02" N. 79°54'15" W.

(3) *Race Area #3.* All waters encompassed within a 700 yard radius of position 32°45'55" N. 79°53'39" W.

(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 areas.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area, except persons and vessels participating in Charleston Race Week or serving as safety vessels. 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.

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

(d) *Enforcement Date.* This rule will be enforced daily from 8:30 a.m. until 5 p.m. from April 15 through April 17, 2016.

Dated: March 29, 2016.

G.L. Tomasulo,

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

[FR Doc. 2016–07589 Filed 4–1–16; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2016–0009]

RIN 1625–AA08

Special Local Regulation; Bucksport/Lake Murray Drag Boat Spring Nationals, Atlantic Intracoastal Waterway; Bucksport, SC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a special local regulation on the Atlantic Intracoastal Waterway in Bucksport, South Carolina during the Bucksport/Lake Murray Drag Boat Spring Nationals, on June 4 and June 5, 2016. This special local regulation is necessary to ensure the safety of participants, spectators, and the general public during the event. This regulation prohibits persons and vessels from being in the regulated area unless authorized by the Captain of the Port Charleston or a designated representative.

DATES: This rule is effective from June 4, 2016 through June 5, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG–2016–0009 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

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FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Lieutenant John Downing, Sector Charleston Office of Waterways Management, Coast Guard; telephone (843) 740–3184, email John.Z.Downing@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On December 27, 2015, the Bucksport Marina notified the Coast Guard that it will sponsor a series of drag boat races from 1 p.m. to 7 p.m. on June 4 and June 5, 2016. In response, on February 5, 2016, the Coast Guard published a notice of proposed rulemaking titled Bucksport/Lake Murray Drag Boat Spring Nationals, Atlantic Intracoastal Waterway; Bucksport, SC. There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this special local regulation. During the comment period that ended March 7, 2016, we received no comments.

III. Legal Authority and Need for Rule

The legal basis for the rule is the Coast Guard’s authority to establish special local regulations: 33 U.S.C. 1233. The purpose of the rule is to insure safety of life on navigable waters of the United States during the two days of drag boat races.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published February 5, 2016. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM. From June 4, 2016 through June 5, 2016, Bucksport Marina will host a series of drag boat races on the Atlantic Intracoastal Waterway in Bucksport, South Carolina during the Bucksport/Lake Murray Drag Boat Spring Nationals. Approximately 50 powerboats are anticipated to participate in the races and approximately 35 spectator vessels are expected to attend the event. This rule establishes a special local regulation on certain waters on the Atlantic