

PART 14 [AMENDED]

■ 2. Part 14 is amended by removing the words “the Board of Tea Experts” wherever they appear; by removing the word “chairman” wherever it appears and adding in its place “Chairperson”; by removing the word “chairman’s” wherever it appears and adding in its place “Chairperson’s”; by removing the phrase “the act” and adding in its place “the FD&C Act”; and by removing the word “executive secretary” wherever it appears and adding in its place “Designated Federal Officer.”

■ 3. Amend § 14.1 by revising paragraphs (a) introductory text, (a)(2)(vii), and (f) to read as follows:

§ 14.1 Scope.

(a) This part governs the procedures when any of the following applies:

* * * * *

(2) * * *

(vii) Section 514(b)(5) of the FD&C Act on establishment, amendment, or revocation of a device performance standard;

* * * * *

(f) This part applies to all FDA advisory committees, except to the extent that specific statutes require otherwise for a particular committee, for example, TEPRSSC and advisory committees established under the Medical Device Amendments of 1976.

■ 4. Amend § 14.22 by revising paragraphs (b)(6) and (i)(4) to read as follows:

§ 14.22 Meetings of an advisory committee.

* * * * *

(b) * * *

(6) The committee is concerned with matters that functionally or historically occur in some other location, e.g., the Science Advisory Board of the National Center for Toxicological Research will generally hold meetings in the Little Rock, AR, vicinity.

* * * * *

(i) * * *

(4) Notes or minutes kept or reports prepared by a committee member have no status or effect unless adopted into the official minutes or report by the committee.

■ 5. Amend § 14.55 by removing paragraph (d); redesignating paragraphs (e) and (f) as paragraphs (d) and (e), respectively; and revising paragraph (c) and newly redesignated paragraph (d) to read as follows:

§ 14.55 Termination of advisory committees.

* * * * *

(c) TEPRSSC is a permanent statutory advisory committee established by section 358(f)(1)(A) of the Public Health Service Act, as added by the Radiation Control for Health and Safety Act of 1968, transferred to the FD&C Act (21 U.S.C. 360kk(f)(1)(A)), and is not subject to termination and renewal under paragraph (a) of this section, except that a new charter is prepared and filed at the end of each 2-year period as provided in § 14.40(c). Also, the statutory medical device classification panels established under section 513(b)(1) of the FD&C Act (21 U.S.C. 360c(b)(1)) and part 860, and the statutory medical device good manufacturing practice advisory committees established under section 520(f)(3) of the FD&C Act (21 U.S.C. 360j(f)(3)), are specifically exempted from the normal 2-year duration period.

(d) Color additive advisory committees are required to be established under the circumstances specified in sections 721(b)(5)(C) and (D) of the FD&C Act (21 U.S.C. 379e(b)(5)(C) and (D)). A color additive advisory committee is subject to the termination and renewal requirements of the Federal Advisory Committee Act and of this part.

* * * * *

■ 6. Amend § 14.65 by revising paragraph (a) to read as follows:

§ 14.65 Public inquiries and requests for advisory committee records.

(a) Public inquiries on general committee matters, except requests for records, are to be directed to the Committee Management Officer in the Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993.

* * * * *

§ 14.120 [Amended]

■ 7. Amend § 14.120 by removing “Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f(f)(1)(A))” and adding in its place “Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360kk(f)(1)(A)).”

§ 14.122 [Amended]

■ 8. Amend § 14.122 by removing “42 U.S.C. 263f” and adding in its place “21 U.S.C. 360kk” in paragraphs (a)(2) and (b).

§ 14.125 [Amended]

■ 9. Amend § 14.125 by removing “42 U.S.C. 263f (f)(1)(A)” and adding in its place “21 U.S.C. 360kk(f)(1)(A)” in paragraph (c).

§ 14.130 [Amended]

■ 10. Amend § 14.130 by removing “42 U.S.C. 263f (f)(1)(B)” and adding in its place “21 U.S.C. 360kk(f)(1)(B)” in paragraph (a).

Dated: March 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-06354 Filed 3-19-13; 8:45 am]

BILLING CODE 4160-01-P

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

[Docket No. USCG-2013-0047]

RIN 1625-AA08

Special Local Regulation; New River Raft Race, New River; Fort Lauderdale, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a special local regulation on the New River in Fort Lauderdale, Florida during the Rotary Club of Fort Lauderdale New River Raft Race, on Saturday, March 23, 2013. The special local regulation is necessary to ensure the safety of the participants, participant vessels, and the general public during the event. Persons and vessels, except those participating in the event, are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Miami or a designated representative.

DATES: This rule will be effective from 12 p.m. until 1:30 p.m. on March 23, 2013.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG-2013-0047. 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 Lieutenant Junior Grade Mike H. Wu, Sector Miami Prevention

Department, U.S. Coast Guard; telephone (305) 535-7576, email *Mike.H.Wu@uscg.mil*. If you have questions on viewing or submitting material to the docket, call Barbara Hairston, 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

The Coast Guard is issuing this 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 it is impracticable. The Coast Guard did not receive necessary event information in regards to the event location until January 22, 2013.

Under 5 U.S.C. 553(d)(3), for the same reasons as above, the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Any delay in the effective date of this rule would be impracticable and contrary to the public interest because immediate action is needed to minimize potential danger to the race participants, participant vessels, spectators and the general public.

B. Basis and Purpose

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 ensure the safety of life and property on a navigable waterway of the United States during the Rotary Club of Fort Lauderdale New River Raft Race.

On March 23, 2013, Fort Lauderdale Rotary Club is sponsoring the Rotary Club of Fort Lauderdale New River Raft Race. The race will be held on the waters of the New River in Fort Lauderdale, Florida. Approximately 20–25 participants are expected to attend the race. No spectator vessels are expected.

This special local regulation is necessary to ensure the safety of the

participants, participant vessels, and the general public during the event.

C. Discussion of the Final Rule

This special local regulation encompasses certain navigable waters of the New River in Fort Lauderdale, Florida. The special local regulation will be effective from 12 p.m. until 1:30 p.m. on March 23, 2013. All persons and vessels, except those participating in the races, are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Miami or a designated representative.

Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Miami by telephone at (305) 535-4472, 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 Miami or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Miami or a designated representative. The Coast Guard will provide notice of the special local regulation by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

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 special local regulation will be enforced for a maximum of one and a half hours; (2) non-participant persons and vessels may enter, transit through, anchor in, or remain within the regulated area during the respective enforcement period if authorized by the

Captain of the Port Miami or a designated representative; (3) non-participant persons and vessels not authorized to enter, transit through, anchor in, or remain within the regulated area may operate in the surrounding areas during the respective enforcement period; and (4) 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.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule would affect the following entities, some of which may be small entities: the owners or operators of vessels intending to enter, transit through, anchor in, or remain within any of the regulated areas during the respective enforcement period. 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 (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**, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–

888-REG-FAIR (1-888-734-3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

4. Collection of Information

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

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. Unfunded Mandates Reform Act

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

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of

Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

11. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

12. Energy Effects

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

13. Technical Standards

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

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a special local regulation issued in conjunction with a regatta or marine parade to ensure the safety of race participants, participant vessels, spectators, and the general public during the event. This rule is categorically excluded from further review under paragraph 34(h) and 35(b) 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.

List of Subjects in 33 CFR Part 100

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping

requirements, Security Measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 2. Add a temporary § 100.35T07-0047 to read as follows:

§ 100.35T07-0047 Special Local Regulation; Rotary Club of Fort Lauderdale New River Raft Race, New River, Fort Lauderdale, FL.

(a) *Regulated Area.* All waters of the New River contained within the following points: starting at Point 1 in position 26°07'11" N, 80°08'52" W; thence southeast along the shoreline to Point 2 in position 26°07'05" N, 80°08'34" W; thence southwest across the river to Point 3 in position 26°07'04" N, 80°08'35" W thence northwest along the shoreline to Point 4 in position 26°07'08" N, 80°08'52" W; thence north back across the river to origin. 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 Miami 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 participating in the event.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Miami via telephone at 305-535-4472, or a designated representative via VHF radio on channel 16, to seek authorization. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the Captain of the Port Miami or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Miami or a designated representative.

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

(d) *Effective Date.* This rule is effective from 12:00 p.m. until 1:30 p.m. on March 23, 2013.

Dated: March 7, 2013.

C.P. Scraba,
Captain, U.S. Coast Guard, Captain of the Port Miami.

[FR Doc. 2013-06451 Filed 3-19-13; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2012-0357]

RIN 1625-AA09

Drawbridge Operation Regulation; Elizabeth River, Eastern Branch, Norfolk, VA

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is adopting an interim drawbridge rule published in August 2012 as a final rule for the Berkley (I-264) Bridge, at mile 0.4, across the Eastern Branch of the Elizabeth River, Norfolk, VA. This rule, allowing only four scheduled bridge openings during the day, is necessary to alleviate heavy vehicular traffic delays throughout the day and secondary congestion during the afternoon rush hour, while still providing for the reasonable needs of navigation.

DATES: Effective April 19, 2013.

ADDRESSES: Comments and related materials received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2012-0357 and are available online by going to www.regulations.gov, and inserting USCG-2012-0357 in the “Search” 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

email Terrance A. Knowles, Bridge Administration Branch, Fifth Coast Guard District, telephone (757) 398-6587, email terrance.a.knowles@uscg.mil. If you have questions on viewing or submitting material to the docket, call Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

- CFR Code of Federal Regulations
- DHS Department of Homeland Security
- FR Federal Register
- U.S.C. United States Code
- VDOT Virginia Department of Transportation
- VMA Virginia Maritime Association

A. Regulatory History and Information

On August 30, 2012, we published an interim rule (IR) entitled, “Drawbridge Operation Regulations; Elizabeth River, Eastern Branch, Norfolk, VA” in the **Federal Register** (77 FR 52599). We received 545 comments on the proposed rule. No public meeting was requested, and none was held.

Other Related Regulatory Action: The following table describes regulatory actions related to this bridge. A discussion of those actions follows.

TABLE 1—RULEMAKINGS

Date	Action	FR Cite	Drawbridge operation regs. (Docket No.)
10/09/2009	Temporary Deviation	74 FR 52143	USCG-2009-0754.
10/09/2009	Proposed Rulemaking (NPRM)	74 FR 52158	USCG-2009-0754.
03/03/2010	Temporary Deviation	75 FR 9521	USCG-2010-0083.
03/03/2010	Supplemental NPRM	75 FR 9557	USCG-2009-0754.
08/06/2010	Temporary Final Rule	75 FR 47461	USCG-2009-0754.
08/30/2012	Interim Rule	77 FR 52599	USCG-2012-0357.

On October 9, 2009, we published a notice of temporary deviation request for comments entitled; “Drawbridge Operation Regulations; Elizabeth River, Eastern Branch, Norfolk, VA” in the **Federal Register** (74 FR 52143) and a notice of proposed rulemaking (NPRM) entitled “Drawbridge Operation Regulation; Elizabeth River, Eastern Branch, Norfolk, VA” in the **Federal Register** (74 FR 52158). We received 861 comments for both the temporary deviation and NPRM. No public meeting was requested then, and none was held.

On March 3, 2010, we published a notice of temporary deviation request for comments entitled; “Drawbridge Operation Regulations; Elizabeth River, Eastern Branch, VA” in the **Federal Register** (75 FR 9521) and a supplemental notice of proposed

rulemaking (SNPRM) entitled “Drawbridge Operation Regulations; Elizabeth River, Eastern Branch, Norfolk, VA” in the **Federal Register** (75 FR 9557). That time we received four comments on the published deviation and SNPRM. No public meeting was requested then, and none was held.

On August 6, 2010, we published a temporary final rule entitled “Drawbridge Operation Regulations; Elizabeth River, Eastern Branch, Norfolk, VA” in the **Federal Register** (75 FR 47461) that temporarily changed the drawbridge operation regulations effective from 9 a.m. on September 4, 2010, until 2:30 p.m. on October 5, 2012.

The establishment of the recent interim rule, effective since October 6, 2012, and the previous temporary final

rule, with its similar operating rules/provisions, which was in effect since September 4, 2010, did not place any additional constraints on the waterway users because mariners already used the temporary schedule for almost two years and could still plan their trips in accordance with the scheduled bridge openings. Any operating schedule that would revert back to the previous on-demand operation of the drawbridge would produce a tremendous amount of delay. Prior to these four scheduled daytime openings, delays for motorists were unpredictable and were expected to increase with population growth and any increase in associated traffic.

B. Basis and Purpose

VDOT, which owns and operates the bascule-type Berkley Bridge, requested a