

(A) The positive percent agreement for the device when testing for Influenza A and Influenza B must be at least at the 80 percent point estimate with a lower bound of the 95 percent confidence interval that is greater than or equal to 70 percent.

(B) The negative percent agreement estimate for the device when testing for Influenza A and Influenza B must be at least at the 95 percent point estimate with a lower bound of the 95 percent confidence interval that is greater than or equal to 90 percent.

(2) When performing testing to demonstrate the device meets the requirements in paragraph (b)(1) of this section, a currently appropriate and FDA accepted comparator method must be used to establish assay performance in clinical studies.

(3) Annual analytical reactivity testing of the device must be performed with contemporary influenza strains. This annual analytical reactivity testing must meet the following criteria:

(i) The appropriate strains to be tested will be identified by FDA in consultation with the Centers for Disease Control and Prevention (CDC) and sourced from CDC or a CDC-designated source. If the annual strains are not available from CDC, FDA will identify an alternative source for obtaining the requisite strains.

(ii) The testing must be conducted according to a standardized protocol considered and determined by FDA to be acceptable and appropriate.

(iii) By July 31 of each calendar year, the results of the last 3 years of annual analytical reactivity testing must be included as part of the device's labeling. If a device has not been on the market long enough for 3 years of annual reactivity testing since the device was given marketing authorization, then the results of every designated annual reactivity testing since the device was given marketing authorization by FDA, including the results of annual analytical reactivity testing performed on the viral strains provided that calendar year, must be included. The results must be presented as part of the device's labeling in a tabular format, which includes the detailed information for each virus tested as described in the certificate of authentication, either by:

(A) Placing the results directly in the device's § 809.10(b) of this chapter compliant labeling in a section of the labeling devoted to annual analytical reactivity testing; or

(B) Providing a hyperlink in a section of the device's labeling to the manufacturer's public Web site where the annual analytical reactivity testing data can be found. If this option is

chosen, the manufacturer's home page must publicly provide a hyperlink, which can easily be found and executed, to the annual analytical reactivity testing results and the Web page containing those annual analytical reactivity testing results must allow unrestricted viewing access. This includes being easy to locate the results from the primary part of the manufacturer's Web site that discusses the device.

(4) If an emergency, or a potential emergency, is declared by the Secretary of Health and Human Services (HHS) for an influenza viral strain:

(i) Within 30 days from the date that FDA notifies manufacturers that characterized viral samples are available for test evaluation, the manufacturer must have testing performed on the device with that viral strain according to a standardized protocol considered and determined by FDA to be acceptable and appropriate. The procedure and location of testing may depend on the nature of the emerging virus.

(ii) Within 60 days from the date that CDC first makes characterized viral samples available to manufacturers and continuing until the emergency, or potential emergency, is declared by the Secretary of HHS to be over, the results of the influenza emergency analytical reactivity testing, including the detailed information for the virus tested as described in the certificate of authentication, must be included as part of the device's labeling in a tabular format, either by:

(A) Placing the table directly in the device's § 809.10(b) of this chapter compliant labeling in the section of the labeling devoted to annual analytical reactivity testing and influenza emergency analytical reactivity testing but separate from the annual analytical reactivity testing tables; or

(B) Providing a hyperlink in a section of the device's labeling devoted to annual analytical reactivity testing and influenza emergency analytical reactivity testing to a part of the manufacturer's public Web site where the annual and the emergency analytical reactivity testing data can be found. If this option is chosen, the manufacturer's home page must publicly provide a hyperlink, which can easily be found and executed, to the analytical reactivity and emergency testing results and the Web page containing those annual analytical reactivity testing results must allow unrestricted viewing access.

Dated: May 14, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-11635 Filed 5-21-14; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2014-0324]

RIN 1625-AA08

#### Safety Zones; 9-11 Patriot Festival, Charleston Harbor, Charleston, SC

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to establish safety zone on the Charleston Harbor in Charleston, South Carolina during the International Outboard Grand Prix (IOGP) 9-11 Patriot Festival, a series of high-speed boat races. The event is scheduled to take place on Friday September 12 through Sunday September 14, 2014. Approximately 25 high-speed race boats are anticipated to participate in the races. This safety zone is necessary to provide for the safety of life and property on navigable waters of the United States during the event. This safety zone would temporarily restrict vessel traffic in a portion of Charleston Harbor. Persons and vessels that are not participating in the races would be prohibited from entering, transiting through, anchoring in, or remaining within the restricted area unless authorized by the Captain of the Port Charleston or a designated representative.

**DATES:** Comments and related material must be received by the Coast Guard on or before June 23, 2014. Requests for public meetings must be received by the Coast Guard on or before June 1, 2014.

**ADDRESSES:** You may submit comments identified by docket number using any one of the following methods:

(1) *Federal eRulemaking Portal:*

<http://www.regulations.gov>.

(2) *Fax:* 202-493-2251.

(3) *Mail or Delivery:* 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. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202-366-9329.

See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Chief Warrant Officer Christopher Ruleman, Sector Charleston Office of Waterways Management, Coast Guard; telephone (843) 740-3184, email [Christopher.L.Ruleman@uscg.mil](mailto:Christopher.L.Ruleman@uscg.mil). If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone (202) 366-9826.

**SUPPLEMENTARY INFORMATION:**

**Table of Acronyms**

DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of Proposed Rulemaking

**A. 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.

**1. Submitting Comments**

If you submit a comment, please include the docket number for this rulemaking, 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 at <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, 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 email 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>, type the docket number [USCG-2014-0324] in the “SEARCH” box and click “SEARCH.” Click on “Submit a

Comment” on the line associated with this rulemaking.

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.

**2. 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>, type the docket number (USCG-2014-0324) 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.

**3. 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).

**4. Public Meeting**

We do not now plan to hold a public meeting, but you may submit a request for one on or before June 1, 2014 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**. For information on facilities or services for individuals with disabilities or to request special assistance at the public meeting, contact the person named in the **FOR FURTHER INFORMATION CONTACT** section, above.

**B. Basis and Purpose**

The legal basis for the proposed rule is the Coast Guard’s authority to establish a safety zone: 33 U.S.C. 1231; 33 U.S.C. 1225; 33 CFR 1.05-1, 33 CFR

6.04-1, 33 CFR 160.5; Department of Homeland Security Delegation No. 0170.1.

The purpose of the proposed rule is to protect the safety of spectator vessels and to ensure safety of life and property on the navigable waters of the United States during the IOGP 9-11 Patriot Festival boat races.

**C. Discussion of Proposed Rule**

On Friday September 12 through Sunday September 14, 2014 the International Outboard Grand Prix (IOGP) will host “9-11 Patriot Festival” a series of high-speed boat races. The event will be held on a portion of Charleston Harbor in Charleston, South Carolina. Approximately 25 high-speed race boats are anticipated to participate in the races.

The proposed rule would establish a safety zone that encompass certain waters of the Charleston Harbor in Charleston, South Carolina. The safety zone would be enforced daily from 2:30 p.m. through 5:30 p.m. on September 12, 10:30 a.m. through 6:30 p.m. on September 13, and 1:30 p.m. through 5:30 p.m. on September 14, 2014. The safety zone would consist of a regulated area around vessels participating in the event. The regulated area would be as follows: All waters of the Charleston Harbor encompassed within the following points; starting at point 1 in position 32°48’48” N 079°54’30” W; thence west to point 2 in position 32°48’48” N 079°54’54” W; thence south to point 3 in position 32°48’12” N 079°55’05” W; thence south to point 4 in position 32°47’20” N 079°55’01” W; thence east to point 5 in position 32°47’21” N 079°54’31” W; thence north along the bank back to origin. All coordinates are North American Datum 1983. Persons and vessels, except those participating in the race, would be prohibited from entering, transiting through, anchoring, or remaining within the safety zone unless specifically authorized by the Captain of the Port Charleston or a designated representative. Persons and vessels would be able to request authorization to enter, transit through, anchor in, or remain within the regulated area by contacting the Captain of the Port Charleston by telephone at: (843) 740-7050, or a designated representative via VHF radio on channel 16. 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 would be required to comply with the instructions of the Captain of the Port Charleston or

a designated representative. The Coast Guard would provide notice of the safety zone by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

#### D. Regulatory Analyses

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

##### 1. 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, 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 proposed rule is not significant for the following reasons: (1) Although persons and vessels would not be 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, they would be able to operate in the surrounding area during the enforcement periods; (2) persons and vessels would still be able to enter, transit through, anchor in, or remain within the regulated area if authorized by the Captain of the Port Charleston or a designated representative; and (3) the Coast Guard would provide advance notification of the regulated area 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 proposed rule will not have a significant economic impact on a substantial number of small entities: This proposed rule may 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 that portion of the Charleston harbor encompassed within the safety zone from 2:30 p.m. through 5:30 p.m. on September 12; and from 10:30 a.m. through 6:30 p.m. on September 13; and from 1:30 p.m. through 5:30 p.m. on September 14, 2014. For the reasons discussed in the Regulatory Planning and Review section above, this proposed rule would not have a significant economic impact on a substantial number of small entities.

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.

##### 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 proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above. 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.

##### 4. Collection of Information

This proposed 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 proposed 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 proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

##### 8. Taking of Private Property

This proposed rule would 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 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.

##### 10. Protection of Children From Environmental Health Risks

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.

##### 11. 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.

##### 12. Energy Effects

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

### 14. Environment

We have analyzed this proposed 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 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 proposed rule involves establishing a safety zone issued in conjunction with a regatta or marine parade, that will be enforced from 2:30 p.m. through 5:30 p.m. on September 12, and from 10:30 a.m. through 6:30 p.m. on September 13; and from 1:30 p.m. through 5:30 p.m. on September 14, 2014. This proposed rule involves establishing a safety zone as described in figure 2-1, paragraph (34)(g), of the Instruction. 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 165

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

#### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 33 CFR 1.05-1, 6.04-1, 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add a temporary § 165.T07-0324 to read as follows:

#### § 165.T07-0324 Safety Zones; 9-11 Patriot Festival, Charleston Harbor, Charleston, SC.

(a) *Regulated area.* All waters of the Charleston Harbor encompassed within the following points; starting at point 1 in position 32°48'48" N 079°54'30" W; thence west to point 2 in position 32°48'48" N 079°54'54" W; thence south to point 3 in position 32°48'12" N 079°55'05" W; thence south to point 4 in position 32°47'20" N 079°55'01" W; thence east to point 5 in position

32°47'21" N 079°54'31" W; thence north along the bank back to origin. All coordinates are North American Datum 1983.

(b) *Enforcement Period.* The rule establishes a safety zone on certain waters of the Charleston harbor in Charleston, South Carolina. The safety zone will consist of a regulated area which will be enforced daily from 2:30 p.m. through 5:30 p.m. on September 12; and from 10:30 a.m. through 6:30 p.m. on September 13; and from 1:30 p.m. through 5:30 p.m. on September 14, 2014. The safety zone would consist of a regulated area around vessels participating in the event.

(c) *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 safety zone.

(d) *Regulations.* (1) All persons and vessels, except those participating in the 9-11 Patriot Festival, or serving as safety vessels, are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area. 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 safety zone 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.

Dated: May 1, 2014.

**R.R. Rodriguez,**

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

[FR Doc. 2014-11806 Filed 5-21-14; 8:45 am]

**BILLING CODE 9110-04-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R05-OAR-2014-0274; FRL-9910-91-Region 5]

### Approval and Promulgation of Air Quality Implementation Plans; Illinois; Revision to the Chicago 8-Hour Ozone Maintenance Plan

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve Illinois's March 28, 2014, State Implementation Plan (SIP) revision to the Chicago area's 1997 8-hour ozone maintenance plan. This maintenance plan revision establishes new transportation conformity Motor Vehicle Emissions Budgets (MVEB) for the year 2025. EPA is approving the allocation of a portion of the safety margin for the volatile organic compounds and oxides of nitrogen to the area's 2025 MVEBs for transportation conformity purposes. This allocation will still maintain the total emissions for the area below the attainment level required by the transportation conformity regulations.

**DATES:** Comments must be received on or before June 23, 2014.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R05-OAR-2014-0274, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *Email:* [blakley.pamela@epa.gov](mailto:blakley.pamela@epa.gov).

3. *Fax:* (312) 692-2450.

4. *Mail:* Pamela Blakley, Chief, Control Strategies Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery:* Pamela Blakley, Chief, Control Strategies Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.