

requirements of this part, part 50, or part 56 of this chapter, or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, the Commissioner will notify the investigator, the sponsor of any investigation in which the investigator has been named as a participant, and the reviewing investigational review boards (IRBs) that the investigator is not eligible to receive test articles under this part. The notification to the investigator, sponsor and IRBs will provide a statement of the basis for such determination. The notification also will explain that an investigator determined to be ineligible to receive test articles under this part will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

(c) Each application or submission to FDA under the provisions of this chapter containing data reported by an investigator who has been determined to be ineligible to receive FDA-regulated test articles is subject to examination to determine whether the investigator has submitted unreliable data that are essential to the continuation of an investigation or essential to the clearance or approval of a marketing application, or essential to the continued marketing of an FDA-regulated product.

(d) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, the Commissioner will notify the sponsor, who shall have an opportunity for a regulatory hearing under part 16 of this chapter. If a danger to the public health exists, however, the Commissioner shall terminate the investigational device exemption (IDE) immediately and notify the sponsor and the reviewing IRBs of the termination. In such case, the sponsor shall have an opportunity for a regulatory hearing before FDA under part 16 of this chapter on the question of whether the IDE should be reinstated. The determination that an investigation may not be considered in support of a research or marketing application or a notification or petition submission does not, however, relieve the sponsor of any obligation under any other applicable

regulation to submit to FDA the results of the investigation.

(e) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the continued clearance or approval of the product for which the data were submitted cannot be justified, the Commissioner will proceed to rescind clearance or withdraw approval of the product in accordance with the applicable provisions of the relevant statutes.

(f) An investigator who has been determined to be ineligible under paragraph (b) of this section may be reinstated as eligible when the Commissioner determines that the investigator has presented adequate assurances that the investigator will employ all test articles, and will conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, solely in compliance with the applicable provisions of this chapter.

Dated: April 24, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG-2012-0199]

RIN 1625-AA00

#### Safety Zone; Chicago Harbor, Navy Pier Southeast, Chicago, IL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce the Navy Pier Southeast Safety Zone in Chicago Harbor during various periods from July 4, 2012 through July 28, 2012. This action is necessary and intended to ensure safety of life on the navigable waters of the United States immediately prior to, during, and immediately after fireworks events. Enforcement of this safety zone will establish restrictions upon, and control movement of, vessels in a specified area immediately prior to, during, and immediately after various fireworks events. During the enforcement period, no person or vessel may enter the safety zones without permission of the Captain of the Port, Sector Lake Michigan.

**DATES:** The regulations in 33 CFR 165.931 will be enforced at various times between 9:00 p.m. on July 4, 2012 through 10:30 p.m. on July 28, 2012.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice, call or email MST2 Rebecca Stone, Prevention Department, Coast Guard Sector Lake Michigan, Milwaukee, WI at 414-747-7154, email [Rebecca.R.Stone@uscg.mil](mailto:Rebecca.R.Stone@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce the Safety Zone; Chicago Harbor, Navy Pier Southeast, Chicago, IL listed in 33 CFR 165.931 for the following events:

(1) *Navy Pier Fireworks*; on July 4, 2012 from 9:00 p.m. through 11:00 p.m.; on July 7, 2012 from 10:00 p.m. through 10:30 p.m.; on July 11, 2012 from 9:15 p.m. through 9:45 p.m.; on July 14, 2012 from 10:00 p.m. through 10:30 p.m.; on July 18, 2012 from 9:15 p.m. through 9:45 p.m.; on July 21, 2012 from 10:00 p.m. through 10:30 p.m.; on July 25, 2012 from 9:15 p.m. through 9:45 p.m.; and on July 28, 2012 from 10 through 10:30.

All vessels must obtain permission from the Captain of the Port, Sector Lake Michigan, or his or her on-scene representative to enter, move within or exit the safety zone. Vessels and persons granted permission to enter the safety zone shall obey all lawful orders or directions of the Captain of the Port, Sector Lake Michigan, or his or her on-scene representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

This notice is issued under authority of 33 CFR 165.931 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of these enforcement periods via broadcast Notice to Mariners or Local Notice to Mariners. The Captain of the Port, Sector Lake Michigan, will issue a Broadcast Notice to Mariners notifying the public when enforcement of the safety zone established by this section is suspended. If the Captain of the Port, Sector Lake Michigan, determines that the safety zone need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the safety zone. The Captain of the Port, Sector Lake Michigan, or his or her on-scene representative may be contacted via VHF Channel 16.

Dated: April 9, 2012.

C.W. Tenney,

*Commander, U.S. Coast Guard, Captain of the Port, Lake Michigan, Acting.*

[FR Doc. 2012-10316 Filed 4-27-12; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R01-OAR-2012-0008; A-1-FRL-9664-8]

#### Approval and Promulgation of Air Quality Implementation Plans; Massachusetts; Determination of Attainment of the One-Hour Ozone Standard for the Springfield Area

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

**ACTION:** Final rule.

**SUMMARY:** The EPA is making two separate and independent determinations. First, EPA is determining that the Springfield (Western Massachusetts) serious one-hour ozone nonattainment area did not meet the applicable deadline of December 31, 2003, for attaining the one-hour National Ambient Air Quality Standard (NAAQS) for ozone. This final determination is based upon complete, quality-assured, certified ambient air monitoring data that show the area had an expected ozone exceedance rate above the level of the now revoked one-hour ozone NAAQS for the 2001–2003 monitoring period. Second, EPA is determining that the Springfield (Western Massachusetts) serious one-hour ozone nonattainment area currently attains the now revoked one-hour NAAQS for ozone, based upon complete, quality-assured, certified ambient air monitoring data for 2009–2011. The area first attained the one-hour NAAQS during the 2007–2009 monitoring period, and continued in attainment during the 2008–2010, and 2009–2011 monitoring periods.

**DATES:** *Effective Date:* This rule is effective on May 30, 2012.

**ADDRESSES:** EPA has established a docket for this action under Docket Identification No. EPA-R01-OAR-2012-0008. All documents in the docket are listed on the [www.regulations.gov](http://www.regulations.gov) web site. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly

available only in hard copy form. Publicly available docket materials are available either electronically through [www.regulations.gov](http://www.regulations.gov) or in hard copy at the Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:** Richard P. Burkhart, Air Quality Planning Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100, Boston, MA 02109-3912, telephone number (617) 918-1664, fax number (617) 918-0664, email [Burkhart.Richard@epa.gov](mailto:Burkhart.Richard@epa.gov).

**SUPPLEMENTARY INFORMATION:** Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA.

*Organization of this document.* The following outline is provided to aid in locating information in this preamble.

- I. What actions is EPA taking?
- II. What is the effect of these actions?
- III. Final Actions
- IV. Statutory and Executive Order Reviews

#### I. What Actions is EPA Taking?

EPA is making two separate and independent final determinations for the Springfield (Western Massachusetts) one-hour ozone serious nonattainment area (hereafter, “the Western Massachusetts area”).

##### A. Determination of Failure To Attain by Applicable Attainment Date

EPA is determining that the Western Massachusetts area did not attain the one-hour ozone National Ambient Air Quality Standard (NAAQS) by the applicable attainment date, December 31, 2003. This determination is based upon complete, quality-assured and certified air quality monitoring data for the 2001 through 2003 ozone seasons.

##### B. Determination of Current Attainment

In addition, EPA is determining that the Western Massachusetts area is currently attaining the one-hour ozone NAAQS based upon complete, quality-assured and certified ambient air monitoring data for 2009–2011 showing the area has attained the one-hour ozone NAAQS, and that it has done so continuously since the 2007–2009 monitoring period.

Additional information related to these determinations and the rationale for them are set forth in the Notice of Proposed Rulemaking (NPR) published on January 24, 2012 (77 FR 3417) and will not be restated here. EPA received no comments on the NPR.

#### II. What is the Effect of These Actions?

After revocation of the one-hour ozone standard, EPA must continue to provide a mechanism to give effect to one-hour ozone anti-backsliding requirements. See *SCAQMD v. EPA*, 472 F.3d 882, at 903 (DC Cir. 2006). In keeping with this responsibility, EPA has determined that the Western Massachusetts area failed to attain the one-hour ozone standard by its applicable attainment date. Consistent with 40 CFR 51.905(e)(2), and the South Coast decision, upon revocation of the one-hour ozone NAAQS for an area, EPA is no longer obligated to determine whether an area has attained the one-hour NAAQS, except insofar as it relates to effectuating the anti-backsliding requirements that are specifically retained. EPA's determination here is linked solely to required one-hour anti-backsliding, contingency measures. A final determination of failure to attain will not result in reclassification of the area under the revoked one-hour standard, nor is EPA identifying or determining any new one-hour reclassification for the area. EPA is no longer required to reclassify an area to a higher classification for the one-hour ozone NAAQS based upon a determination that the area failed to attain that NAAQS by its attainment date. See 40 CFR 51.905(e)(2)(i)(B). Moreover, EPA has previously approved the one-hour ozone attainment demonstration and Reasonable Further Progress (ROP) plans for this area, and in doing so noted that although there were no state implementation plan contingency measure reductions applicable to the Western Massachusetts area for failure to attain, there were federal measures the state had not accounted for in its attainment demonstration that provided more reductions than necessary to serve the purpose of contingency measures for this area. See 66 FR 666, January 3, 2001. In addition, EPA has also determined that the Western Massachusetts area attained the one-hour ozone standard in 2009, and continues to attain this standard. In this context, EPA has also determined that there are not any additional obligations, including those relating to one-hour ozone contingency measures, for the Western Massachusetts area under the one-hour ozone standard.