

Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 117 have been approved under OMB control number 0910–0751.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: October 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23005 Filed 10–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0948]

RIN 1625–AA00

Safety Zone; Delaware River; Camden, NJ; Fireworks Display

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone on a portion of the Delaware River in Camden, NJ. This action is necessary to protect the surrounding public and vessels on these navigable waters adjacent to the Battleship New Jersey Museum and Memorial, Camden, NJ, during a fireworks display on November 14, 2018. This proposed rulemaking would prohibit persons and vessels from entering, transiting, or remaining within the safety zone unless authorized by the Captain of the Port Delaware Bay or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before November 6, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0948 using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Petty Officer Thomas Welker, U.S. Coast Guard, Sector Delaware Bay, Waterways Management Division; telephone 215–271–4814, email Thomas.j.welker@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On September 14, 2018, Rexel, Inc notified the Coast Guard that it will be conducting a fireworks display from 8:35 p.m. to 8:55 p.m. on November 14, 2018. The fireworks are to be launched from a barge in the Delaware River adjacent to the Battleship New Jersey Museum and Memorial, Camden, NJ. Hazards from fireworks displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port Delaware Bay (COTP) has determined that potential hazards associated with the fireworks to be used in this display would be a safety concern for anyone within a 600-foot radius of the barge.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within a 600-foot radius of the fireworks barge before, during, and after the scheduled event. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The COTP is proposing to establish a safety zone from approximately 8:15 p.m. through 9:15 p.m. on November 14, 2018. The safety zone would cover all navigable waters within 600 feet of a fireworks barge in the Delaware River adjacent to the Battleship New Jersey Museum and Memorial, Camden, NJ. The barge will be anchored in approximate position 39°56′20″ N Latitude, 075°08′08″ W Longitude. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled 8:35 p.m. to 8:55 p.m. fireworks display. No vessel or person would be permitted to enter, transit, or remain within the safety zone without obtaining permission from the COTP or a designated representative.

The regulatory text we are proposing appears at the end of this document.

IV. 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 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 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic would be able to safely transit around this safety zone which would impact a small designated area of the Delaware River for one hour during the evening when vessel traffic is normally low. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

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 certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

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.

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

C. Collection of Information

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

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination 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 proposed rule involves a safety zone lasting one hour that would prohibit entry within 600 feet of a fireworks barge. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A preliminary Record of Environmental Consideration supporting this determination is 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 proposed 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.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. 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.

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, visit <http://www.regulations.gov/privacyNotice>.

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at <http://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

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; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

- 2. Add § 165.T05–0948 to read as follows:

§ 165.T05–0948 Safety Zone; Delaware River; Camden, NJ; Fireworks Display.

(a) *Location.* The following area is a safety zone: all waters of the Delaware River within a 600-foot radius of the fireworks barge, which will be anchored in approximate position 39°56'20" N Latitude 075°08'08" W Longitude. All coordinates are based on Datum NAD 1983.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard petty officer, warrant or commissioned officer on board a Coast Guard vessel or on board a federal, state, or local law enforcement vessel assisting the Captain of the Port, Delaware Bay in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part—

(i) You may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative; and

(ii) All persons and vessels in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(2) To request permission to enter the safety zone, contact the COTP or the COTP's representative on marine band radio VHF-FM channel 16 (156.8 MHz) or 215-271-4807.

(3) No vessel may take on bunkers or conduct lightering operations within the safety zone during the enforcement period.

(4) This section applies to all vessels except those engaged in law enforcement, aids to navigation servicing, and emergency response operations.

(d) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by federal, state, and local agencies.

(e) *Enforcement period.* This zone will be enforced from 8:15 p.m. through 9:15 p.m. on November 14, 2018.

Dated: October 15, 2018.

S.E. Anderson,

Captain, U.S. Coast Guard, Captain of the Port Delaware Bay.

[FR Doc. 2018-22911 Filed 10-19-18; 8:45 am]

BILLING CODE 9110-04-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R10-OAR-2017-0170; FRL-9985-39-Region 10]

Air Plan Approval; ID, West Silver Valley PM_{2.5} Clean Data Determination

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to determine that the West Silver Valley, Idaho nonattainment area has clean data for the 2012 annual fine particulate matter (PM_{2.5}) National Ambient Air Quality Standard (NAAQS). This proposed clean data determination (CDD) is based upon quality-assured, quality-controlled, and certified ambient air monitoring data showing the area has attained the 2012 PM_{2.5} NAAQS based

on the 2015–2017 data available in the EPA's Air Quality System (AQS) database. The EPA also proposes to take final agency action on the September 2017 wildfire exceptional event at the Pinehurst monitoring station, pursuant to EPA regulations, as having affected PM_{2.5} and PM₁₀ values. Based on the proposed clean data determination, the EPA is also proposing to determine that the obligation for Idaho to make submissions to meet certain Clean Air Act (CAA or the Act) requirements related to attainment of the NAAQS for this area are not applicable for as long as the area continues to attain the 2012 annual PM_{2.5} NAAQS.

DATES: Written comments must be received on or before November 21, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R10-OAR-2017-0170, at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Justin Spenillo, at 206-553-6125, or spenillo.justin@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document, wherever “we”, “us” or “our” are used, it is intended to refer to the EPA.

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- I. Background
- II. Clean Data Determination for the West Silver Valley, Idaho Nonattainment Area
- III. The EPA's Proposed Action
- IV. Statutory and Executive Order Reviews

I. Background

On December 14, 2012, the Environmental Protection Agency (EPA) promulgated a revised primary annual PM_{2.5} NAAQS to provide increased protection of public health from fine particle pollution (“2012 annual PM_{2.5} NAAQS”).¹ In that action, the EPA strengthened the primary annual PM_{2.5} standard, lowering the level from 15.0 micrograms per cubic meter (µg/m³) to 12.0 µg/m³. The 2012 annual PM_{2.5} NAAQS is attained when the 3-year average of the annual arithmetic means does not exceed 12.0 µg/m³. See 40 CFR 50.18 and 40 CFR part 50, appendix N. Effective April 15, 2015, the EPA made designation determinations, as required by section 107(d)(1) of the CAA, for the 2012 annual PM_{2.5} NAAQS.² In that action, the EPA designated the West Silver Valley area in Shoshone County, Idaho (WSV NAA) as moderate nonattainment for the 2012 annual PM_{2.5} NAAQS. See 40 CFR 81.313.

On March 26, 2018, the EPA issued a finding of failure to submit under section 110(k) of the CAA finding that several states, including Idaho, failed to submit specific moderate area SIP elements for the 2012 annual PM_{2.5} NAAQS required under subpart 4 of part D of Title I of the CAA.³ In particular, Idaho failed to submit the following specific moderate area SIP elements for the WSV NAA: An attainment demonstration; control strategies, including reasonably available control measures (“RACM”) and reasonably available control technologies (“RACT”); a reasonable further progress (RFP) plan; quantitative milestones; and contingency measures. This finding triggered the sanctions clock under Section 179 of the CAA, as well as an obligation under Section 110(c) of the CAA for EPA to promulgate a FIP no later than 2 years from the effective date of the finding, if Idaho does not submit, and the EPA has not approved, the required SIP submission.

On August 24, 2016, the EPA issued the Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements (“PM_{2.5} SIP Requirements Rule”).⁴ The PM_{2.5} SIP Requirements Rule is codified at 40 CFR part 51, subpart Z and provides rules for the implementation of current and future PM_{2.5} NAAQS.

Over the past 2 decades, the EPA has consistently applied its “Clean Data Policy” interpretation to attainment

¹ 78 FR 3086, January 15, 2013.

² 80 FR 2206.

³ 83 FR 14759.

⁴ 81 FR 58010, effective October 24, 2016.