

proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we also are publishing this notice of the proposed collection of information set forth in this document and seeking public comment.

**II. Significance of Guidance**

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food). It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

**III. Paperwork Reduction Act of 1995**

The draft guidance entitled “Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food)” contains

information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the associated annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

*Title:* Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food).

*Description:* This draft guidance describes FDA procedures regarding the submission of attestations as established under both the Preventive Controls for Human Food Rule and Preventive Controls for Animal Food Rule. Proposed forms FDA 3942a and FDA 3942b have been developed for use by a business in reporting its status as a “qualified facility” under the applicable regulations.

*Description of Respondents:* Respondents to the collection of information are owners, operators or agents in charge of domestic or foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States asserting that a facility is a “qualified facility” under applicable FDA regulations.

We estimate the burden for this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Guidance section	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Section II; Human Food .....	3942a	37,134	0.5	18,567	0.5 (30 minutes) .....	9,284
Section III; Animal Food .....	3942b	1,120	0.5	560	0.5 (30 minutes) .....	280
<b>Total .....</b>						<b>9,564</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Consistent with the estimates found in our Preventive Controls for Human Food Rule, we calculate that approximately 37,134 human food facilities will spend approximately 30 minutes (0.5 hour) reporting their status as such to FDA every 2 years. Thus, dividing this figure by 2 to determine the annual burden, we estimate there will be a total of 18,567 responses and a total of 9,284 burden hours associated with this collection element.

Similarly, and consistent with the estimates found in our Preventive Controls for Animal Food Rule, we estimate that approximately 1,120 animal food facilities will spend approximately 30 minutes (0.5 hour) reporting their status as such to FDA every 2 years. Thus, dividing this figure by 2 to determine an annual burden, we estimate there will be a total of 560 responses and a total of 280 burden hours associated with this information collection element.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in part 117 have been approved under OMB control number 0910–0751. The collections of information in part 507 have been approved under OMB control number 0910–0789.

**IV. Electronic Access**

Persons with access to the Internet may obtain the draft guidance, including its appendices containing instructions for filling out Forms FDA 3942a and 3942b and the proposed Forms FDA 3942a and 3942b, at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: May 10, 2016.

**Leslie Kux,**  
Associate Commissioner for Policy.  
[FR Doc. 2016–11439 Filed 5–13–16; 8:45 am]  
BILLING CODE 4164–01–P

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 100**

[Docket Number USCG–2016–0185]

RIN 1625–AA08

**Special Local Regulation; Beaufort Water Festival, Beaufort, SC**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to establish a special local regulation on the waters of the Beaufort River, Beaufort, South Carolina, during the

Beaufort Water Festival on July 23, 2016. This action is necessary to ensure safety of life on navigable waters of the United States during the Beaufort Water Festival Air Show. This proposed rulemaking would prohibit persons and vessels from being in the regulated 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 15, 2016.

**ADDRESSES:** You may submit comments identified by docket number USCG–2016–0185 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 Lieutenant John Downing, Sector Charleston Office of Waterways Management, Coast Guard; telephone (843) 740–3184, email [John.Z.Downing@uscg.mil](mailto:John.Z.Downing@uscg.mil).

**SUPPLEMENTARY INFORMATION:**

**I. Table of Abbreviations**

CFR Code of Federal Regulations  
 DHS Department of Homeland Security  
 E.O. Executive order  
 FR Federal Register  
 NPRM Notice of proposed rulemaking  
 Pub. L. Public Law  
 § Section  
 U.S.C. United States Code  
 COTP Captain of the Port

**II. Background, Purpose, and Legal Basis**

On March 3, 2016, the Coast Guard received a marine event application for the 2016 Beaufort Water Festival Air Show that will take place from noon to 5 p.m. on July 23, 2016. The purpose of the proposed rule is to ensure safety of life on the navigable waters of the United States during the Beaufort Water Festival Air Show. The legal basis for the proposed rule is the Coast Guard’s Authority to establish special local regulations: 33 U.S.C. 1233.

**III. Discussion of Proposed Rule**

The COTP proposes to establish a special local regulation on the waters of the Beaufort River, Beaufort, South Carolina during the Beaufort Water Festival Air Show. The event is scheduled to take place on July 23, 2016 from noon to 5 p.m. Approximately 100 spectator vessels are expected to attend the event. 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. 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.

**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.

*A. Regulatory Planning and Review*

E.O.s 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. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a “significant regulatory action,” under E.O. 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget. 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) The special local regulations would be enforced for only five hours (2) although persons and vessels would not be able to enter, transit through, anchor, 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; (3) 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 (4) 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.

*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” 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. We have considered the impact of this proposed rule on 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.

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 E.O. 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 E.O. 13132.

Also, this proposed rule does not have tribal implications under E.O. 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 above.

#### 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 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 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 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. 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.

#### 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, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

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 Web site'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 100

Marine Safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 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 § 100.35T07–0185 to read as follows:

#### § 100.35T07–0185 Special Local Regulations; Beaufort Water Festival, Beaufort, SC.

(a) Regulated Area. This rule establishes a special local regulation on certain waters of the Beaufort River, Beaufort, South Carolina. The special local regulation would create a regulated area that will encompass a portion of the waterway that is 700 ft wide by 2600 ft in length on waters of the Beaufort River encompassed within the following points:

32°25'47" N./080°40'44" W.,

32°25'41" N./080°40'14" W.,

32°25'35" N./080°40'16" W.,

32°25'40" N./080°40'46" W.,

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 Charleston in the enforcement of the regulated areas.

(c) *Regulations*.

(1) All persons and vessels, except those participating in the Beaufort Water Festival Airshow, or serving as safety vessels, are prohibited from entering, transiting through, anchoring, 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 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 Period*. This rule will be enforced July 23, 2016 from noon until 5 p.m.

Dated: May 6, 2016.

**G.L. Tomasulo,**

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

[FR Doc. 2016-11471 Filed 5-13-16; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 58

[EPA-HQ-OAR-2015-0486, FRL-9946-34-OAR]

RIN 2060-AS71

### Revision to the Near-Road NO<sub>2</sub> Minimum Monitoring Requirements

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

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to revise the minimum monitoring requirements for near-road nitrogen dioxide (NO<sub>2</sub>) monitoring by removing the existing requirements for near-road NO<sub>2</sub> monitoring stations in Core Based Statistical Areas (CBSAs) having populations between 500,000 and 1,000,000 persons, that are due by January 1, 2017. Current near-road NO<sub>2</sub> monitoring data indicate air quality levels in the near-road environment are well below the National Ambient Air Quality Standards (NAAQS) for the oxides of nitrogen. In light of this information, and due to the relationship between population, traffic, and expected NO<sub>2</sub> concentrations in the near-road environment, it is anticipated that measured near-road NO<sub>2</sub> concentrations in relatively smaller CBSAs (e.g., CBSAs with populations less than 1,000,000 persons) would exhibit similar, and more likely, lower concentrations, than what is being measured in larger urban areas.

**DATES:** Comments must be received on or before June 30, 2016.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2015-0486, at <http://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 made 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>.

**Instructions:** Direct your comments to Docket ID No. EPA-HQ-OAR-2015-0486. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or email. The [www.regulations.gov](http://www.regulations.gov) Web site is an "anonymous access" system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through <http://www.regulations.gov>, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

**Docket:** All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket

materials are available either electronically at [www.regulations.gov](http://www.regulations.gov) or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA William J. Clinton (WJC) West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744 and the telephone number for the Air and Radiation Docket and Information Center is (202) 566-1742.

**FOR FURTHER INFORMATION CONTACT:** Mr. Nealson Watkins, Air Quality Assessment Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C304-06, Research Triangle Park, NC 27711; telephone: (919) 541-5522; fax: (919) 541-1903; email: [watkins.nealson@epa.gov](mailto:watkins.nealson@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### A. Does this action apply to me?

This action applies to state, territorial, and local air quality management programs that are responsible for ambient air quality monitoring under 40 CFR part 58. Categories and entities potentially regulated by this action include:

Category	NAICS <sup>a</sup> code
State/territorial/local/tribal government .....	924110

<sup>a</sup>North American Industry Classification System.

##### B. What should I consider as I prepare my comments for the EPA?

1. **Submitting CBI.** Do not submit this information to the EPA through <http://www.regulations.gov> or email. Clearly mark any of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to the EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

2. **Tips for Preparing Your Comments.** When submitting comments, remember to: