

alarms during a device malfunction or an abnormal patient condition;

(ii) Reliabilities of the mechanical and electrical systems must be established through bench testing under simulated use conditions and matched by appropriate maintenance schedules;

(iii) Software design and verification and validation must be appropriately documented;

(iv) The skin-contacting components of the device must be demonstrated to be biocompatible;

(v) Appropriate analysis and testing must be conducted to verify electrical safety and electromagnetic compatibility of the device; and

(vi) Labeling must bear all information required for the safe and effective use of the device, including a detailed summary of the device-related and procedure-related complications pertinent to use of the device.

(2) Class III (premarket approval) for the following intended uses: Unstable angina pectoris; acute myocardial infarction; cardiogenic shock; congestive heart failure; postoperative treatment of patients who have undergone coronary artery bypass surgery; peripheral arterial disease associated with ischemic ulcers rest pain or claudication, threatened gangrene, insufficient blood supply at an amputation site, persisting ischemia after embolectomy or bypass surgery, and/or pre- and post-arterial reconstruction to improve runoff; diabetes complicated by peripheral arterial disease or other conditions possibly related to arterial insufficiency including nocturnal leg cramps and/or necrobiosis diabeticorum; venous diseases, including phlebitis of deep vein thrombophlebitis, edema (e.g., chronic lymphedema) and/or induration (e.g., stasis dermatitis) associated with chronic venous stasis, venous stasis ulcers, and/or thrombophlebitis; athletic injuries, including Charley horses, pulled muscles and/or edematous muscles; necrotizing cellulitis.

(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with FDA on or before [A DATE WILL BE ADDED THAT WILL BE 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER IN THE **FEDERAL REGISTER**], for any external counter-pulsating device, with an intended use described in (b)(2) of this section, that was in commercial distribution before May 28, 1976, or that has, on or before [A DATE WILL BE ADDED THAT WILL BE 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL

ORDER IN THE FEDERAL REGISTER], been found to be substantially equivalent to any external counter-pulsating device, with an intended use described in (b)(2) of this section, that was in commercial distribution before May 28, 1976. Any other external counter-pulsating device with an intended use described in (b)(2) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: May 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-12122 Filed 5-20-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2013-0320]

RIN 1625-AA00

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

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend the Safety Zone for Chicago Harbor, Navy Pier Southeast, Chicago, IL. This Zone is intended to restrict vessels from a portion of Chicago Harbor during fireworks displays, races, and other marine events that occur throughout each calendar year. The safety zone established by this proposed rule is necessary to protect spectators, participants, and vessels from the hazards associated with these fireworks displays, boat races, and other events.

DATES: Comments and related materials must be received by the Coast Guard on or before June 20, 2013.

ADDRESSES: You may submit comments identified by docket number USCG-2013-0320 using any one of the following methods:

(1) *Federal eRulemaking Portal:* <http://www.regulations.gov>.

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

(3) *Mail:* 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.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

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

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Petty Officer Joseph McCollum, U.S. Coast Guard Sector Lake Michigan; telephone 414-747-7148, email Joseph.P.McCollum@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

CFR Code of Federal Regulations

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-2012-0320) 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–2012–0320) 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 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**.

B. Basis and Purpose

Each year dozens of fireworks displays are launched from barges in positions just south of the Navy Pier in Chicago. These fireworks displays, along with other marine events, take place on a monthly and sometimes weekly basis. The Captain of the Port, Lake Michigan, has determined that these fireworks displays and other

events such as races or air shows pose a significant risk to public safety and property. Such hazards include falling debris and collisions among spectator vessels. To address these hazards, the Coast Guard established a permanent safety zone for the protection of spectators during these displays and events in 33 CFR 165.931. This year, however, the Coast Guard was informed by Melrose Pyrotechnics that a new launch position will be used for some of the fireworks displays. This new position launches a display from a break wall south of the Navy Pier and would impact portions of Chicago Harbor hundreds of feet beyond the boundaries of the zone as it is currently listed. To address this new launch position, and to ensure safety of spectators and vessels, this rule proposes to extend the boundaries of the safety zone within 33 CFR 165.931.

C. Discussion of Proposed Rule

The Captain of the Port, Lake Michigan, has determined that a safety zone is necessary to mitigate the aforementioned safety risks. Thus, this rule proposes to amend 33 CFR 165.931 to establish the following area as a safety zone: The waters of Lake Michigan within Chicago Harbor bounded by coordinates beginning at 41°53′26.5″ N, 087°35′26.5″ W; then south to 41°53′7.6″ N, 087°35′26.3″ W; then west to 41°53′7.6″ N, 087°36′23.2″ W; then north to 41°53′26.5″ N, 087°36′24.6″ W; then east back to the point of origin (NAD 83).

This proposed rule will amend 33 CFR 165.931 and update the permanent safety zone on Lake Michigan within Chicago harbor. The Captain of the Port, Lake Michigan will notify the public when the safety zone in this proposed rule will be enforced. Consistent with 33 CFR 165.7(a), such means may include, among other things, publication in the **Federal Register**, Broadcast Notice to Mariners, Local Notice to Mariners, or, upon request, by facsimile (fax). Also, the Captain of the Port will issue a Broadcast Notice to Mariners notifying the public if enforcement these safety zones in this section are cancelled prematurely.

Entry into, transiting, or anchoring within the proposed safety zone during the period of enforcement is prohibited unless authorized by the Captain of the Port, Lake Michigan, or his designated representative. The Captain of the Port, Lake Michigan, or his designated representative may be contacted via VHF Channel 16.

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 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, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not “significant” under the regulatory policies and procedures of the Department of Homeland Security. We conclude that this proposed rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone established by this proposed rule will be enforced in short periods immediately before, during, and after the time the displays and events occur. Also, the safety zone is designed to minimize its impact on navigable waters and has been designed to allow vessels to transit unrestricted to portions of the waterways not affected by the safety zones. Thus, restrictions on vessel movements within any particular area are expected to be minimal. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by the Captain of the Port. On the whole, the Coast Guard expects insignificant adverse impact to mariners from the enforcement of this safety zone.

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 would affect the following entities, some of which might be small entities: the owners and

operators of vessels intending to transit or anchor in portions of Chicago Harbor when this safety zone is being enforced.

This proposed safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons discussed in the above Regulatory Planning and Review section. If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed 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**, 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 would call for no 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 proposed rule elsewhere in this preamble.

8. Taking of Private Property

This proposed rule would not affect 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 proposed 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 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 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 the establishment of safety zones and thus, is categorically excluded under paragraph (34)(g) of the Instruction. An environmental analysis checklist 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.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record keeping 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; 46 U.S.C. Chapters 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 165.931 to read as follows:

§ 165.931 Safety Zone; Chicago Harbor, Navy Pier Southeast, Chicago, IL.

(a) *Location.* The following area is a safety zone: The waters of Lake Michigan within Chicago Harbor bounded by coordinates beginning at 41°53′26.5″ N, 087°35′26.5″ W; then south to 41°53′7.6″ N, 087°35′26.3″ W; then west to 41°53′7.6″ N, 087°36′23.2″ W; then north to 41°53′26.5″ N, 087°36′24.6″ W then east back to the point of origin (NAD 83).

(b) *Definitions.* The following definitions apply to this section:

(1) “Designated representative” means any Coast Guard Commissioned, warrant, or petty officer designated by the Captain of the Port, Lake Michigan to monitor a safety zone, permit entry

into the zone, give legally enforceable orders to persons or vessels within the zone, and take other actions authorized by the Captain of the Port.

(2) “Public vessel” means vessels owned, chartered, or operated by the United States, or by a State or political subdivision thereof.

(c) *Regulations.* (1) In accordance with the general regulations in 33 CFR 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port, Lake Michigan, or his designated representative.

(2) This safety zone is closed to all vessel traffic, excepted as may be permitted by the Captain of the Port, Lake Michigan or his designated representative. All persons and vessels must comply with the instructions of the Coast Guard Captain of the Port or his designated representative. Upon being hailed by the U.S. Coast Guard by siren, radio, flashing light or other means, the operator of a vessel shall proceed as directed.

(3) All vessels must obtain permission from the Captain of the Port or his designated representative to enter, move within, or exit the safety zone established in this section when this safety zone is enforced. Vessels and persons granted permission to enter the safety zone must obey all lawful orders or directions of the Captain of the Port or a designated representative. While within a safety zone, all vessels must operate at the minimum speed necessary to maintain a safe course.

(d) *Notice of enforcement or suspension of enforcement.* The safety zone established by this section will be enforced only upon notice of the Captain of the Port. The Captain of the Port will cause notice of enforcement of the safety zone established by this section to be made by all appropriate means to the affected segments of the public including publication in the **Federal Register** as practicable, in accordance with 33 CFR 165.7(a). Such means of notification may also include, but are not limited to Broadcast Notice to Mariners or Local Notice to Mariners.

(e) *Exemption.* Public vessels, as defined in paragraph (b) of this section, are exempt from the requirements in this section.

(f) *Waiver.* For any vessel, the Captain of the Port Lake Michigan or his designated representative may waive any of the requirements of this section, upon finding that operational conditions or other circumstances are such that application of this section is unnecessary or impractical for the purposes of public or environmental safety.

Dated: May 3, 2013.

M.W. Sibley,

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

[FR Doc. 2013-12030 Filed 5-20-13; 8:45 am]

BILLING CODE 9110-04-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R04-OAR-2013-0272; FRL-9816-1]

Approval and Promulgation of Implementation Plans; Kentucky; Approval of Revisions to the Jefferson County Portion of the Kentucky SIP; Emissions During Startups, Shutdowns, and Malfunctions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve part of a revision to the Kentucky State Implementation Plan (SIP), submitted by the Commonwealth of Kentucky, through the Kentucky Division for Air Quality (KDAQ), on March 22, 2011. The proposed revision was submitted by KDAQ on behalf of the Louisville Metro Air Pollution Control District (District), which has jurisdiction over Jefferson County, Kentucky. The portion of the revision that EPA is proposing for approval modifies the Regulation entitled, “Emissions During Startups, Shutdowns, Malfunctions and Emergencies” in the Jefferson County portion of the Kentucky SIP. EPA is proposing approval of this portion of the March 22, 2011, SIP revision because the Agency has determined that it is in accordance with the requirements for SIP provisions under the Clean Air Act (CAA or Act). EPA will act on the other portions of KDAQ’s March 22, 2011, submittal, which are severable and unrelated, in a separate action.

DATES: Comments must be received on or before June 20, 2013.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R04-OAR-2013-0272, by one of the following methods:

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

2. *Email:* R4-RDS@epa.gov.

3. *Fax:* (404) 562-9019.

4. *Mail:* EPA-R04-OAR-2013-0272, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960.

5. *Hand Delivery or Courier:* Lynora Benjamin, Chief, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. 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 to 4:30, excluding federal holidays.

Instructions: Direct your comments to Docket ID No. “EPA-R04-OAR-2013-0272.” EPA’s policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an “anonymous access” system, which means 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 EPA without going through *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, 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 EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, 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 EPA’s public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. 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