

**§ 1.94 Hearing on refusal of admission or destruction.**

(a) If it appears that the article may be subject to refusal of admission, or that the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the district director shall give the owner or consignee a written notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony. Upon timely request giving reasonable grounds therefor, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility or destruction of the article, and may be introduced orally or in writing.

(b) If such owner or consignee submits or indicates his or her intention to submit an application for authorization to relabel or perform other action to bring the article into compliance with the Federal Food, Drug, and Cosmetic Act or to render it other than a food, drug, device, or cosmetic, such testimony shall include evidence in support of such application. If such application is not submitted at or prior to the hearing on refusal of admission, the district director shall specify a time limit, reasonable in the light of the circumstances, for filing such application.

(c) If the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the district director may give the owner or consignee a single written notice that provides the notice on refusal of admission and the notice on destruction of an article described in paragraph (a) of this section. The district director may also combine the hearing on refusal of admission with the hearing on destruction of the article described in paragraph (a) of this section into a single proceeding.

Dated: April 30, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-10304 Filed 5-5-14; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****33 CFR Part 165**

[Docket Number USCG-2014-0165]

RIN 1625-AA00

**Safety Zones; July 4th Fireworks Displays Within the Captain of the Port Miami Zone; FL**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of Proposed Rulemaking.

**SUMMARY:** The Coast Guard proposes to establish three temporary safety zones during Fourth of July fireworks events on navigable waterways in the vicinity of Stuart, West Palm Beach, and Miami, Florida. These safety zones are necessary to protect the public from hazards associated with launching fireworks over the navigable waters of the United States. Non-participant persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within any of the safety zones unless authorized by the Captain of the Port Miami or a designated representative.

**DATES:** Comments and related material must be received by the Coast Guard on or before June 20, 2014.

Requests for public meetings must be received by the Coast Guard on or before June 5, 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 if you have questions on this rule, call or email Petty Officer John K. Jennings, Sector Miami Prevention Department, Coast Guard; telephone

(305) 535-4317, email [John.K.Jennings@uscg.mil](mailto:John.K.Jennings@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-2014-0165 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-2014-0165) 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 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. Regulatory History and Information

Previously, a rule regarding these maritime events was published in the Code of Federal Regulations at 33 CFR 165. No final rule has been published in regards to these events.

## C. Basis and Purpose

The legal basis for the rule is the Coast Guard's authority to establish regulated navigation areas and other limited access areas: 33 U.S.C. 1231; 33 CFR 1.05-1(g), and 160.5; Department of Homeland Security Delegation No. 0170.1. The purpose of the proposed rule is to provide for the safety of life on navigable waters of the United States.

## D. Discussion of Proposed Rule

Multiple fireworks display events are planned for Fourth of July celebrations throughout the Captain of the Port Miami Zone. For some events, the fireworks will explode over navigable waters of the United States.

The Coast Guard is establishing three temporary safety zones for fireworks displays on July 4, 2014 on navigable waters of the United States within the Captain of the Port Miami Zone based on the location and/or size of the events. The safety zones are listed below.

The first safety zone is in Stuart, Florida. The safety zone encompasses all waters within a 400 yard radius around the barge from which the fireworks will be launched, located on the St. Lucie River north of City Hall. This safety zone will be enforced from 8:30 p.m. until 9:45 p.m.

The second safety zone is in West Palm Beach, Florida. The safety zone encompasses all waters within a 300 yard radius around the barge from which the fireworks will be launched, located on the Intracoastal Waterway north of the Royal Palm Bridge. This safety zone will be enforced from 9 p.m. until 10:15 p.m.

The third safety zone is located at Bayfront Park, Miami, Florida. The safety zone encompasses all waters within a 400 yard radius around the barge from which the fireworks will be launched, located on the waters of Biscayne Bay east of Bayfront Park. This safety zone will be enforced from 8:30 p.m. until 9:45 p.m.

Non-participant persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within any of the safety zones unless authorized by the Captain of the Port Miami or a designated representative. Non-participant persons and vessels may request authorization to enter the safety zones by contacting the Captain of the Port Miami by telephone at 305-535-4472, or a designated representative via VHF radio on channel 16. If authorization to enter, transit through, anchor in, or remain within the safety zones is granted by the Captain of the Port Miami or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Miami or a designated representative. The Coast Guard will provide notice of the safety zones by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

## E. 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) Each safety zone will be enforced for less than two hours; (2) although non-participant persons and vessels will not be able to enter, transit through, anchor in, or remain within the safety zones without authorization from the Captain of the Port Miami or a designated representative, they may operate in the surrounding area during the enforcement period; (3) non-participant persons and vessels may still enter, transit through, anchor in, or remain within the safety zones during the enforcement period if authorized by the Captain of the Port Miami or a designated representative; and (4) the Coast Guard will provide advance notification of the safety zones to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

## 2. Impact on Small Entities

The Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered the impact of this proposed rule on small entities. 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 any of the safety zones described in this regulation during the respective enforcement period. For the reasons discussed in the Regulatory Planning and Review section above, this proposed 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 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 proposed rule would economically affect it.

### 3. Assistance for Small Entities

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**, 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

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 that do not individually or cumulatively have a significant effect on the human environment. This proposed

rule involves establishing three temporary safety zones during Fourth of July fireworks events on navigable waterways in the vicinity of Stuart, West Palm Beach, and Miami, Florida. This proposed rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. A prior environmental analysis checklist and a Categorical Exclusion Determination were completed for a regulation (USCG–2013–0429) issued for these same events in 2013. The previously completed environmental analysis checklist and Categorical Exclusion Determination can be found in the docket folder for USCG–2013–0429 at [www.regulations.gov](http://www.regulations.gov). Because this proposed rule is substantially unchanged from the regulation issued when the prior determination was made and there have been no new developments relevant to that determination, we have not completed a new environmental analysis checklist and Categorical Exclusion Determination for this proposed rule. We have made a preliminary determination this proposed rule will not have any of the following: Significant cumulative impacts on the human environment; substantial controversy or substantial change to existing environmental conditions; or inconsistencies with any Federal, state, or local laws or administrative determinations relating to the environment. 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, and 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. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add a temporary § 165.T07–0165 to read as follows:

**§ 165.T07–0165 Safety Zones; July 4th Fireworks Displays within the Captain of the Port Miami Zone, FL.**

(a) *Regulated Areas.* The following regulated areas are safety zones. All coordinates are North American Datum 1983.

(1) *Stuart, FL.* All waters within a 400 yard radius around the barge from which the fireworks will be launched, located on the St. Lucie River north of City Hall at approximate position 27°12'09" N, 80°14'20" W.

(2) *West Palm Beach, FL.* All waters within a 300 yard radius around the barge from which the fireworks will be launched, located on the Intracoastal Waterway north of the Royal Palm Bridge at approximate position 26°42'36" N, 80°02'45" W.

(3) *Miami, FL.* All waters within a 400 yard radius around the barge from which the fireworks will be launched, located on the waters of Biscayne Bay east of Bayfront Park at approximate position 25°46'30" N, 80°10'56" W.

(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 Miami in the enforcement of the regulated areas.

(c) *Regulations.*

(1) All non-participant persons and vessels are prohibited from entering, transiting through, anchoring in or remaining within the safety zones unless authorized by the Captain of the Port Miami or a designated representative.

(2) Non-participant persons and vessels desiring to enter, transit through, anchor in, or remain within a regulated area may contact the Captain of the Port Miami by telephone at 305–535–4472, or a designated representative via VHF radio on channel 16. If authorization to enter, transit through, anchor in, or remain within a regulated area is granted by the Captain of the Port Miami or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Miami or a designated representative.

(3) The Coast Guard will provide notice of the safety zones by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

(d) *Effective Date.* This rule is effective on July 4, 2014. This rule will be enforced from 8:30 p.m. until 10:15 p.m. on July 4, 2014.

Dated: April 10, 2014.

A.J. Gould,

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

[FR Doc. 2014–10270 Filed 5–5–14; 8:45 am]

**BILLING CODE 9110–04–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 88**

**World Trade Center Health Program; Petition 004—Cardiovascular Disease; Finding of Insufficient Evidence**

**AGENCY:** Centers for Disease Control and Prevention, HHS.

**ACTION:** Denial of petition for addition of a health condition.

**SUMMARY:** On March 7, 2014, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 004) to add “heart attack,” which the Administrator has interpreted to mean “cardiovascular disease,” to the List of WTC-Related Health Conditions (List). Upon reviewing the scientific and medical literature, including information provided by the petitioner, the Administrator has determined that the available evidence does not have the potential to provide a basis for a decision on whether to add cardiovascular disease to the List. The Administrator finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (STAC), to publish a proposed rule, or to publish a determination not to publish a proposed rule.

**DATES:** The Administrator of the WTC Health Program is denying this petition for the addition of a health condition as of May 6, 2014.

**FOR FURTHER INFORMATION CONTACT:** Rachel Weiss, Program Analyst, 4674 Columbia Parkway, MS: C–46, Cincinnati, OH 45226; telephone (855) 818–1629 (this is a toll-free number); email [NIOSHregs@cdc.gov](mailto:NIOSHregs@cdc.gov).

**SUPPLEMENTARY INFORMATION:**

**A. WTC Health Program Statutory Authority**

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347), amended the Public Health Service Act (PHS Act) to add Title XXXIII<sup>1</sup> establishing the WTC

<sup>1</sup> Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm-61. Those portions of the Zadroga Act found in Titles II and III of Public Law

Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers (responders) who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania, and to eligible persons (survivors) who were present in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area.

All references to the Administrator of the WTC Health Program (Administrator) in this notice mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his or her designee.

Pursuant to section 3312(a)(6)(B) of the PHS Act, interested parties may petition the Administrator to add a health condition to the List in 42 CFR 88.1. Within 60 calendar days after receipt of a petition to add a condition to the List, the Administrator must take one of the following four actions described in section 3312(a)(6)(B) and 42 CFR 88.17: (i) Request a recommendation of the STAC; (ii) publish a proposed rule in the **Federal Register** to add such health condition; (iii) publish in the **Federal Register** the Administrator’s determination not to publish such a proposed rule and the basis for such determination; or (iv) publish in the **Federal Register** a determination that insufficient evidence exists to take action under (i) through (iii) above.

**B. Petition 004**

On March 7, 2014, the Administrator received a petition to add “heart attack” to the List (Petition 004).<sup>2</sup> The petition was submitted by a WTC Health Program member who responded to the September 11, 2001 terrorist attacks in New York City. The petitioner indicated that he has been diagnosed with a number of WTC-related health conditions, and has suffered a heart attack. Also included in his petition was a press release published by the New York City Department of Health and Mental Hygiene describing a WTC Health Registry study authored by Hannah T. Jordan *et al.* and published

111–347 do not pertain to the WTC Health Program and are codified elsewhere.

<sup>2</sup> See Petition 004. WTC Health Program: Petitions Received. <http://www.cdc.gov/wtc/received.html>.