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#### List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 876 be amended as follows:

#### PART 876—GASTROENTEROLOGY—UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 876.5540 is amended by revising paragraphs (a)(1), (a)(2), and (b)(1) and by removing paragraph (c) to read as follows:

##### § 876.5540 Blood access device and accessories.

(a) \* \* \*

(1) The implanted blood access device consists of various flexible or rigid tubes, such as catheters, or cannulae, which are surgically implanted in appropriate blood vessels, may come through the skin, and are intended to remain in the body for 30 days or more. This generic type of device includes: Single, double, and triple lumen catheters with cuffs, subcutaneous ports with catheters, shunts, cannula, vessel tips, and connectors specifically designed to provide access to blood.

(2) The nonimplanted blood access device consists of various flexible or rigid tubes, such as catheters, cannulae or hollow needles, which are inserted into appropriate blood vessels or a vascular graft prosthesis (§§ 870.3450 and 870.3460), and are intended to remain in the body for less than 30 days. This generic type of device includes noncuffed catheters, fistula needles, single dialysis needles (coaxial flow

needle), and the single needle dialysis set (alternating flow needle).

\* \* \* \* \*

(b) *Classification.* (1) Class II (special controls) for the implanted blood access device. The special control for this device is FDA's "Class II Special Controls Guidance Document: Implanted Blood Access Devices for Hemodialysis."

\* \* \* \* \*

Dated: June 15, 2012.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

[FR Doc. 2012–15024 Filed 6–19–12; 8:45 am]

**BILLING CODE 4160–01–P**

#### DEPARTMENT OF HOMELAND SECURITY

##### Coast Guard

##### 33 CFR Part 165

[Docket No. USCG–2011–0906]

RIN 1625–AA87

#### Security Zone; Cruise Ships, Santa Barbara Harbor, Santa Barbara, CA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to establish fixed security zones around and under any cruise ships visiting Santa Barbara Harbor, Santa Barbara, California. This proposed regulation is needed for national security reasons to protect cruise ships, vessels, users of the waterway and the port from potential terrorist acts. These security zones would encompass all navigable waters from the surface to the sea floor within a 100-yard radius of any cruise ship located within 3 nautical miles of the Santa Barbara Harbor Breakwater Light (Light List Number 3750). Entry into these zones would be prohibited unless specifically authorized by the Captain of the Port (COTP) Los Angeles—Long Beach (LA–LB), or his designated representative.

**DATES:** Comments and related material must be received by the Coast Guard on or before July 20, 2012.

**ADDRESSES:** You may submit comments identified by docket number USCG–2011–0906 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 Ensign Brett M. DiManno, Prevention, Sector Los Angeles—Long Beach, Coast Guard; telephone 310–521–3869, email [brett.m.dimanno@uscg.mil](mailto:brett.m.dimanno@uscg.mil). If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

#### SUPPLEMENTARY INFORMATION:

##### 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.

##### Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2011–0906), 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 (via <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 via [www.regulations.gov](http://www.regulations.gov), 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>, click on the “submit a comment” box, which will then become highlighted in blue. In the “Document Type” drop down menu select “Proposed Rule” and insert “USCG–2011–0906” in the “Keyword” box. Click “Search” then click on the balloon shape in the “Actions” column. 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.

#### *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>, click on the “read comments” box, which will then become highlighted in blue. In the “Keyword” box insert “USCG–2011–0906” and click “Search.” Click the “Open Docket Folder” in the “Actions” column. 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. We have an agreement with the Department of Transportation to use the Docket Management Facility.

#### *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).

#### *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**.

#### **Basis and Purpose**

In its effort to thwart terrorist activity, the Coast Guard has increased safety and security measures on U.S. ports and waterways. As part of the Diplomatic Security and Antiterrorism Act of 1986 (Pub. L. 99–399), Congress added section 7 of the Ports and Waterways Safety Act (PWSA), 33 U.S.C. 1226, to allow the Coast Guard to take actions, including the establishment of security and safety zones, to prevent or respond to acts of terrorism against individuals, vessels, or public or commercial structures. The Coast Guard also has authority to establish security zones pursuant to the Magnuson Act (50 U.S.C. 191 *et seq.*) and implementing regulations promulgated by the President in subparts 6.01 and 6.04 of part 6 of title 33 of the Code of Federal Regulations.

In this particular rulemaking, to address the aforementioned security concerns, and to take steps to prevent the catastrophic impact a terrorist attack against a cruise ship would have on the public interest, the Coast Guard proposes to establish security zones around and under cruise ships visiting Santa Barbara Harbor, Santa Barbara, California. This security zone helps the Coast Guard to prevent vessels or persons from engaging in terrorist actions against cruise ships. The Coast Guard has determined the establishment of security zones is prudent for cruise ships because they carry a multitude of passengers.

Based on experience with security zone enforcement operations, the Captain of the Port (COTP) Los Angeles—Long Beach has concluded that these security zones should encompass all navigable waters from the surface to the sea floor within a 100-yard radius of any cruise ship which is located within 3 nautical miles seaward of the Santa Barbara Harbor Breakwater Light (Light List Number 3750; 34–24–17.364 N, 119–41–16.260W). These security zones are necessary to provide for the safety of the cruise ship, vessels, and users of the waterway.

#### **Discussion of Proposed Rule**

The Coast Guard proposes to establish security zones around and under cruise ships which visit Santa Barbara Harbor, Santa Barbara, California. This proposed rule, for security concerns, prohibits entry of any vessel inside the security zone surrounding a cruise ship. These security zones would encompass all navigable waters from the surface to the sea floor within a 100-yard radius of any cruise ship located within 3 nautical miles of the Santa Barbara Harbor

Breakwater Light (Light List Number 3750; 34–24–17.364 N, 119–41–16.260W). These security zones are needed for national security reasons to protect cruise ships, the public, and transiting vessels, from potential subversive acts, accidents, or other events of a similar nature. Entry into the zone would be prohibited unless specifically authorized by the Captain of the Port or his designated representative. Vessels already moored or anchored when these security zones take effect are not required to get underway to avoid the zones unless specifically ordered to do so by the Captain of the Port or his designated representative.

The Captain of the Port will enforce these zones and may request the use of resources and personnel of other government agencies to assist in the patrol and enforcement of the regulation.

#### **Regulatory Analyses**

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

#### *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. We expect the economic impact of this rule to be so minimal that full Regulatory Evaluation is unnecessary. Although this regulation restricts access to a portion of navigable waters, the effect of this regulation is not significant because:

- i. The zones only encompass a small portion of the waterway;
- ii. Vessels are able to pass safely around the zones; and
- iii. Vessels may be allowed to enter these zones on a case-by-case basis with permission of the Captain of the Port (COTP) Los Angeles—Long Beach, or his designated representative.

The size of the zone is the minimum necessary to provide adequate protection for all cruise ships and other vessels operating in the vicinity of these vessels, adjoining areas, and the public. The entities most likely to be affected are fishing vessels and pleasure craft engaged in recreational activities and sightseeing.

### *Small Entities*

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. 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.

This rule will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit or anchor in Santa Barbara Harbor within a 100-yard radius of cruise ships covered by this rule.

This security zone regulation will not have a significant economic impact on a substantial number of small entities because vessel traffic can pass safely around the zones.

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.

### *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 so that they can better evaluate its effects on them and participate in the rulemaking. 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 1–888–REG–FAIR (1–888–734–3247). 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.

### *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).

### *Federalism*

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct

effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

### *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.

### *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.

### *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.

### *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.

### *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.

### *Energy Effects*

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That

Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a “significant energy action” under that order because it is not a “significant regulatory action” under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

### *Technical Standards*

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

### *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. A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under **ADDRESSES**. This proposed rule involves the establishment of security zones. 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, 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(g), 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. Add § 165.1157 to read as follows:

### **§ 165.1157 Security Zone; Cruise Ships, Santa Barbara, California.**

(a) *Location.* The following areas are security zones: All navigable waters, from the surface to the sea floor within a 100-yard radius of any cruise ship located within 3 nautical miles of the Santa Barbara Harbor Breakwater Light (Light List Number 3750; 34–24–17.364 N, 119–41–16.260W).

(b) *Definition.* “*Cruise ship*” as used in this section means any vessel, except for a ferry, over 100 feet in length, authorized to carry more than 12 passengers for hire; making voyages lasting more than 24 hours, any part of which is on the high seas; and for which passengers are embarked or disembarked in the U.S. or its territories.

(c) *Regulations.* (1) Under general security zone regulations in subpart D, entry into or remaining in the zones described in paragraph (a) of this section is prohibited unless authorized by the Coast Guard Captain of the Port (COTP) Los Angeles—Long Beach (LA–LB), or a designated representative of COTP LA–LB.

(2) Persons desiring to transit the area of the security zone may contact the COTP LA–LB at telephone number 1–310–521–3801 or on VHF–FM channel 16 (156.800 MHz) to seek permission to transit the area. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port, or his designated representative.

Dated: May 11, 2012.

**R.R. Laferriere,**

*Captain, U.S. Coast Guard, Captain of the Port Los Angeles Long Beach.*

[FR Doc. 2012–14973 Filed 6–19–12; 8:45 am]

**BILLING CODE 9110–04–P**

## **DEPARTMENT OF EDUCATION**

### **34 CFR Chapter II**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **45 CFR Subtitle A, Subchapter A**

**[Docket ID ED–2012–OESE–0012; CFDA Number 84.412A]**

**RIN 1810–AB15**

### **Proposed Requirements—Race to the Top—Early Learning Challenge; Phase 2**

**AGENCY:** Department of Education and Department of Health and Human Services.

**ACTION:** Proposed requirements.

**SUMMARY:** The Secretary of Education and the Secretary of Health and Human Services (hereafter “the Secretaries”) propose requirements for Phase 2 of the Race to the Top—Early Learning Challenge (RTT–ELC) program. In this phase (Phase 2 of the RTT–ELC program), we would make awards to certain States that applied for, but did not receive, funding under Phase 1 of the RTT–ELC competition held in fiscal year (FY) 2011 (FY 2011 RTT–ELC competition). Specifically, we would consider eligible the five highest-scoring applicants that did not receive funding in the FY 2011 RTT–ELC competition, each of which received approximately 75 percent or more of the available points under the competition. We take this action to fund down the slate of the FY 2011 RTT–ELC competition and to establish the information and assurances that the eligible applicants would need to provide in order to receive funding under Phase 2 of the RTT–ELC program.

**DATES:** We must receive your comments on or before July 20, 2012.

**ADDRESSES:** Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments by fax or by email. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID and the term “Race to the Top–Early Learning Challenge Phase 2 Awards” at the top of your comments.

• *Federal eRulemaking Portal:* Go to [www.regulations.gov](http://www.regulations.gov) to submit your comments electronically. Information on using [Regulations.gov](http://Regulations.gov), including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under “How to Use This Site.”

• *Postal Mail, Commercial Delivery, or Hand Delivery.* If you mail or deliver your comments about these proposed requirements, address them to the Office of Elementary and Secondary Education (Attention: Race to the Top–Early Learning Challenge Phase 2 Comments), U.S. Department of Education, 400 Maryland Avenue SW., Washington, DC 20202–6200.

*Privacy Note:* The Department of Education’s policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov). Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

### **FOR FURTHER INFORMATION CONTACT:**

Deborah Spitz, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E230, Washington, DC 20202–6200. Telephone: (202) 260–3793 or by email:

[RTT.Early.Learning.Challenge@ed.gov](mailto:RTT.Early.Learning.Challenge@ed.gov).

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

### **SUPPLEMENTARY INFORMATION:**

#### **Executive Summary**

*Purpose of This Regulatory Action:* The Departments of Education and Health and Human Services (Departments) plan to implement Phase 2 of the RTT–ELC program by funding down the slate from the FY 2011 RTT–ELC competition. Specifically, the Departments plan to make awards available to the next five highest-scoring applicants that did not receive funding under the FY 2011 RTT–ELC competition. Because the amount of available funds in FY 2012 is limited, this action proposes specific requirements that the five eligible applicants must meet in order to receive up to 50 percent of the funds they requested in their FY 2011 RTT–ELC applications.

*Summary of the Major Provisions of This Regulatory Action:* In this notice, we propose to establish a limited number of application requirements, assurances, and budget requirements that the five eligible applicants must meet in order to receive funds under Phase 2 of the RTT–ELC program.

The *Application Requirements*, which can be found in section III of the *Proposed Requirements* section of this notice, include a requirement that each eligible applicant must: (1) Describe how it would implement the activities proposed in Core Area B (selection