

### III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because classification of these devices into class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

### IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in

the Executive Order and, consequently, a federalism summary impact statement is not required.

### V. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) is not required. FDA concludes that the special controls guidance document contains information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the guidance document entitled, “Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses”; the notice contains an analysis of the paperwork burden for the guidance.

### VI. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from CDC, dated January 26, 2006.

### List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

### PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

- 1. The authority citation for 21 CFR part 866 continues to read as follows:

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

- 2. Section 866.3332 is added to subpart D to read as follows:

#### **§ 866.3332 Reagents for detection of specific novel influenza A viruses.**

(a) *Identification.* Reagents for detection of specific novel influenza A viruses are devices that are intended for use in a nucleic acid amplification test to directly detect specific virus RNA in human respiratory specimens or viral cultures. Detection of specific virus RNA aids in the diagnosis of influenza caused by specific novel influenza A viruses in patients with clinical risk of infection with these viruses, and also

aids in the presumptive laboratory identification of specific novel influenza A viruses to provide epidemiological information on influenza. These reagents include primers, probes, and specific influenza A virus controls.

(b) *Classification.* Class II (special controls). The special controls are:

(1) FDA’s guidance document entitled “Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses.” See § 866.1(e) for information on obtaining this document.

(2) The distribution of these devices is limited to laboratories with experienced personnel who have training in standardized molecular testing procedures and expertise in viral diagnosis, and appropriate biosafety equipment and containment.

Dated: March 10, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[CGD13–06–011]

RIN 1625–AA00

#### **Safety Zone: Camp Rilea Offshore Small Arms Firing Range; Warrenton, OR**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone offshore of Camp Rilea, Warrenton, Oregon. Small arms training and fire will be conducted within this zone, and a safety zone is needed to ensure the safety of persons and vessels operating in this area during the specified periods. Entry into this safety zone is prohibited unless authorized by the Captain of the Port or his/her designated representative.

**DATES:** This rule is effective from 5 a.m. to 8 p.m. from March 10, 2006 through March 20, 2006. This rule is enforced during daylight hours from March 10, 2006 through March 20, 2006.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket CGD13–06–011 and are available for inspection or copying at Coast Guard Sector Portland, 6767 North Basin Avenue, Portland, OR

97217–3992 between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** LT Shadrack Scheirman, Chief Port Operations, USCG Sector Portland, 6767 N. Basin Ave., Portland, OR 97217, telephone number (503) 240–9311.

**SUPPLEMENTARY INFORMATION:**

**Regulatory Information**

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B) and 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for not publishing an NPRM and making this rule effective less than 30 days after publication in the **Federal Register**. Publishing an NPRM and delaying the effective date of this rule would be contrary to the public interest since immediate action is necessary to minimize potential danger to the public from small arms fire during the live fire training. Such training is necessary in order to ensure Coast Guard crews are qualified to carry Crew Served Weapons required to fulfill their Military and Homeland Security responsibilities.

In order to maintain an increased maritime security posture, the Coast Guard has increased training requirements for the carriage of weapons during homeland security operations. The crews required to carry out homeland security operations must be trained to perform their operational obligations.

Publishing an NPRM and delaying the effective date of this rule would be contrary to the public interest since immediate action is necessary to minimize potential danger to the public from small arms fire during the live fire training. Such training is necessary in order to ensure Coast Guard crews are qualified to carry Crew Served Weapons required to fulfill their Military and Homeland Security responsibilities.

**Background and Purpose**

Changes in Coast Guard policy and procedures require small boat crews to train on and fire crew served weapons from a vessel. In order to ensure the safety of persons and vessels operating in vicinity of this training from March 10, 2006 through March 20, 2006 a safety zone will be in effect during all small arms firing evolutions.

**Discussion of Rule**

This safety zone will be in effect to ensure the safety of persons and vessels in the vicinity of the live fire training. Entry into this safety zone is prohibited unless authorized by the Captain of the Port or his/her designated

representative. A Coast Guard vessel will be on scene to ensure that the public is aware that the firing exercises are in progress and that the firing area is clear of traffic before firing commences. All persons and vessels shall comply with the instructions of the Captain of the Port or his/her designated on-scene U.S. Coast Guard representative. On-scene Coast Guard patrol personnel include commissioned, warrant, and petty officers of the Coast Guard on board Coast Guard, Coast Guard Auxiliary, and local, state, and federal law enforcement vessels.

**Regulatory Evaluation**

This 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 (DHS). This rule only affects a small area for a limited duration. The proposed regulations have been tailored in scope to impose the least impact on maritime interests, yet provide the level of safety necessary for such an event.

**Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this 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 rule will 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 anchor, fish or transit through the zone during daylight hours from March 10, 2006 through March 20, 2006. The Coast Guard expects a minimal economic impact on a substantial number of small entities because the zone is in effect during daylight hours only for 10 days, there is little commercial activity in this area during the month of March, and vessels will be able to freely transit the areas outside of the safety zone.

**Assistance for Small Entities**

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

**Collection of Information**

This rule calls 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 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 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

**Taking of Private Property**

This rule will not effect 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 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 rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

### Indian Tribal Governments

This 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.

### Energy Effects

We have analyzed this 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 rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

### Environment

We have analyzed this rule under Commandant Instruction M16475.ID, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. Categorical Exclusion is provided for temporary safety zones of less than one week in duration. A final "Environmental Analysis Check List" and a final "Categorical Exclusion Determination" are available in the docket where indicated under ADDRESSES.

### 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 amends 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. 1226, 1231; 46 U.S.C. Chapter 701; 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. A temporary § 165.T13–004 is added to read as follows:

#### § 165.T13–004 Safety Zone; Camp Rilea Offshore Small Arms Firing Range, Warrenton, Oregon

(a) *Location.* The following area is established as a safety zone: the waters bounded by the following coordinates: 46°10'00" N, 124°11'15" W following an imaginary line east to 46°09'00" N 124°02'48" W then south to 46°06'30" N 124°01'30" W following the west to 46°03'00" N 124°11'15" W then back to the point of origin.

(b) *Regulations.* (1) In accordance with the general regulations in Section 165.23 of this part, no person or vessel may enter or remain in this zone unless authorized by the Captain of the Port or his designated representatives.

(2) A Coast Guard vessel will be on-scene to ensure that the public is aware that the firing exercises are in progress and that the firing area is clear of traffic before firing commences.

(c) *Enforcement period.* This rule will be enforced during daylight hours from March 10, 2006 through March 20, 2006.

(d) The Captain of the Port will broadcast status updates for this safety zone by Marine Safety Radio Broadcast on VHF Marine Band Radio Channel 22 (157.1 MHz) and through the means required under 5 U.S.C. 553.

Dated: March 10, 2006.

**Patrick G. Garrity,**

*Captain, U.S. Coast Guard, Captain of the Port, Portland, OR.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[COTP St. Petersburg 06–034]

RIN 1625–AA00

#### Safety Zone for St Petersburg; Tampa Bay, FL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone on the waters within Tampa Bay, Florida in the vicinity of the St Petersburg Municipal Yacht Basin. The safety zone is needed to ensure the safety of all mariners during the St Petersburg Grand Prix. This rule is necessary to provide for the safety of life on the navigable waters of the United States.

**DATES:** This rule is effective from 9 a.m. on March 30, 2006, through 8 p.m. on April 2, 2006.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket [COTP St. Petersburg 06–034] and are available for inspection or copying at Coast Guard Sector St Petersburg, Prevention Department, 155 Columbia Drive, Tampa, Florida 33606–3598 between 7:30 a.m. and 3:30 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** BM1 Charles Voss at Coast Guard Sector St. Petersburg, Prevention Department, (813) 228–2191, Ext. 8307.

### SUPPLEMENTARY INFORMATION:

#### Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. The