

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

■ 4. The authority citation for 21 CFR part 884 continues to read as follows:

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

■ 5. Section 884.5330 is amended by revising paragraph (c) to read as follows:

§ 884.5330 Female condom.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before November 21, 2011, for any female condom that was in commercial distribution before May 28, 1976, or that has, on or before November 21, 2011, been found to be substantially equivalent to any female condom that was in commercial distribution before May 28, 1976. Any other female condom shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: August 10, 2011.

Nancy K. Stade,

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

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

[Docket No. USCG-2011-0708]

RIN 1625-AA11

Regulated Navigation Area; Portsmouth Naval Shipyard, Portsmouth, NH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a regulated navigation area on the Piscataqua River near Portsmouth, NH. This temporary final rule places speed restrictions on all vessels transiting the navigable waters on the Piscataqua River, Portsmouth, NH near the Portsmouth Naval Shipyard between Henderson Point Light on Seavey Island and Badgers Island Buoy 14. This rule is necessary to provide for the safety of life on the navigable waters during ongoing ship construction.

DATES: This rule is effective from August 16, 2011 until 5 p.m. on

September 5, 2011. This rule will be enforced with actual notice from 7 a.m. on August 5, 2011 until 5 p.m. on September 5, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2011-0708 and are available online by going to <http://www.regulations.gov>, inserting USCG-2011-0708 in the "Keyword" box, and then clicking "Search." They are also available for inspection or copying at the 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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail Lieutenant Junior Grade Terence Leahy, Waterways Management Division at Coast Guard Sector Northern New England, telephone 207-767-0398, e-mail Terence.O.Leahy@uscg.mil or Lieutenant Junior Grade Isaac Slavitt, Waterways Management Division at Coast Guard First District, telephone 617-223-8385. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:**Regulatory Information**

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Coast Guard was not notified of the need for this rule until 13 July 2011, and the Portsmouth Naval Facility will begin diving operations in this area within a short timeframe making publication of a NPRM and Final Rule impractical. This regulated navigation area is necessary to provide for the safety of the divers and others working in the area as wake from passing vessels could cause the ship to move erratically and unexpectedly, injuring the divers and their support crews. Not providing for the safety of the divers and others in the area is

contrary to the public interest of creating a safe work environment.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** as immediate action is necessary to provide for the safety of divers and workers on the vessel. In addition to the reasons stated within this preamble, a delay in the effective date of this rule is contrary to the public's interest in ensuring the ship construction project continues as scheduled.

Basis and Purpose

Under the Ports and Waterways Safety Act, the Coast Guard has the authority to establish RNAs in defined water areas that are determined to have hazardous conditions and in which vessel traffic can be regulated in the interest of safety. See 33 U.S.C. 1231 and Department of Homeland Security Delegation No. 0170.1.

As part of ongoing ship construction projects at the Portsmouth Naval Shipyard, divers will be working on the hull of a vessel for approximately four weeks beginning on August 5, 2011. Unexpected and uncontrolled movement of the vessel due to wake while divers are in the water creates a significant risk of serious injury or death. In order to ensure the safety of vessel workers such as divers during the period of ship construction work, the Coast Guard is creating a regulated navigation area to limit the speed, and thus wake, of all vessels operating in the vicinity of the shipyard.

Discussion of Rule

This action places speed restrictions on all vessels transiting the navigable waters on the Piscataqua River, Portsmouth, NH near the Portsmouth Naval Shipyard between Henderson Point Light on Seavey Island and Badgers Island Buoy 14 when necessary for the safety of navigation during periods of ship construction work. All vessels operating in this area shall proceed with caution; operate at no more than 5 knots and in a manner so as to produce no wake. Diving operations and other vessel construction may occur at any time, day or night.

The Captain of the Port Sector Northern New England will cause notice of enforcement or suspension of enforcement of this regulated navigation area to be made by all appropriate means in order to affect the widest distribution among the affected segments of the public. Such means of notification will include, but is not limited to, Broadcast Notice to Mariners

and Local Notice to Mariners. In addition, Captain of the Port Sector Northern New England maintains a telephone line that is staffed 24 hours a day, seven days a week. The public can obtain information concerning enforcement of the regulated navigation area by contacting Sector Northern New England Command Center at (207) 767-0303.

Regulatory Analyses

We developed this 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.

Executive Order 12866 and Executive Order 13563

This 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, 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.

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 transit the portion of the Piscataqua River affected by this rule between August 5, 2011 and September 5, 2011.

This regulation may have some impact on the public, but the potential impact will be minimized for the following reasons: This rule allows vessels to continue to transit through the regulated area, but only at a reduced speed. The reduced speed area is relatively small (approximately 1 nautical mile long) and will only be enforced when necessary to protect the safety of personnel at the Portsmouth Naval Shipyard. Further, the Coast Guard will advise mariners as to the

enforcement of the regulated navigation area through broadcast and local notice to mariners thus allowing mariners to plan their transits accordingly.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we offer to assist small entities in understanding the rule so that they can 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). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

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 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 concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction. This rule involves the establishing of a regulated navigation area and therefore falls within the categorical exclusion noted above. An environmental analysis checklist and a 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, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6, 160.5; Public Law 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T01-0708 to read as follows:

§ 165.T01-0708 Regulated Navigation Area; Portsmouth Naval Base, Portsmouth, NH.

(a) *Location.* The following area is a regulated navigation area: All navigable waters on the Piscataqua River, Portsmouth, NH and Kittery, ME near the Portsmouth Naval Shipyard between 43°04'29.319" N, 070°44'10.189" W (Henderson Point Light 10, LLNR 8375) on Seavey Island and 43°04'51.951" N, 070°45'21.518" W (Badgers Island Buoy 14, LLNR 8405).

(b) *Regulations:* (1) The general regulations contained in 33 CFR 165.10, 165.11 and 165.13 apply.

(2) In accordance with the general regulations, the following restrictions apply to all vessels operating within the regulated area noted above.

(i) No vessel may operate in this regulated area at a speed in excess of five knots.

(ii) All vessels must proceed through the area with caution and operate in such a manner as to produce no wake.

(iii) Vessels operating within the regulated navigation area must comply with all directions given to them by the Captain of the Port Sector Northern New England or his on-scene representative. The "on-scene representative" of the Captain of the Port is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port to act on his behalf. The on-scene representative may be on a Coast Guard vessel, State Marine Patrol vessel or other designated craft, or may be on shore and will communicate with vessels via VHF-FM radio or loudhailer. Members of the Coast Guard Auxiliary or Naval Harbor Security Patrol may be present to inform vessel operators of this regulation.

(iv) For purposes of navigational safety, the Captain of the Port or on-scene representative may authorize a deviation from this regulation.

(c) *Enforcement.* (1) This regulated navigation area is enforceable 24 hours a day from August 5, 2011 until September 5, 2011.

(2) Notice of suspension of enforcement: The Captain of the Port Sector Northern New England may temporarily suspend enforcement of the regulated navigation area. If enforcement of the zone is temporarily suspended, the Captain of the Port Sector Northern New England will cause a notice of the suspension of enforcement of this regulated navigation area to be made by all appropriate means to affect the widest publicity among the affected segments of the public. Such means of notification may also include but are not limited to, Broadcast Notice to Mariners or Local Notice to Mariners. Such notification will include the date and time that enforcement is suspended as well as the date and time that enforcement will resume.

(3) Violations of this regulated navigation area should be reported to the Captain of the Port Sector Northern New England, at (207) 767-0303 or on VHF-Channel 16. Persons in violation of this regulated navigation area may be subject to civil and/or criminal penalties.

Dated: August 5, 2011.

Daniel A. Neptun,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2009-0559]

RIN 1625-AA00

Safety Zones; Eleventh Coast Guard District Annual Fireworks Events

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending multiple permanent safety zones to ensure public safety during annual firework displays at various locations in the Eleventh Coast Guard District. These amendments will standardize the safety zone language, update listed events, delete events that are no longer occurring, add new unlisted annual fireworks events to the regulations, and standardize the format for all tables in these four sections. When these safety zones are activated, and thus subject to enforcement, this rule would limit the movement of vessels within the established firework display area.

DATES: This rule is effective September 15, 2011.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2009-0559 and are available online by going to <http://www.regulations.gov>, inserting USCG-2009-0559 in the "Keyword" box, and then clicking "Search." This material is also available for inspection or copying at the 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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Lieutenant Lucas Mancini, Eleventh Coast Guard District Prevention Division, Waterways Management Branch, Coast Guard; telephone 510-437-3801, e-mail Lucas.W.Mancini@uscg.mil. If you have questions on viewing or submitting material to the docket, call Renee V.