

Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (the PRA). The collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB Control No. 0910–0120. The collections of information in 21 CFR part 801 and 21 CFR 809.10, regarding labeling, have been approved under OMB Control No. 0910–0485. The collections of information in 21 CFR part 820 have been approved under OMB Control No. 0910–0073.

## VI. References

The following references have 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 XDx, Inc., dated August 15, 2008.
2. Order classifying XDx AlloMap Test, dated August 26, 2008.

## List of Subjects in 21 CFR Part 862

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 862 is amended as follows:

### PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 862 continues to read as follows:

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

■ 2. Section 862.1163 is added to subpart B to read as follows:

#### § 862.1163 Cardiac allograft gene expression profiling test system.

(a) *Identification.* A cardiac allograft gene expression profiling test system is a device that measures the ribonucleic acid (RNA) expression level of multiple genes and combines this information to yield a signature (pattern, classifier, index, score) to aid in the identification of a low probability of acute cellular rejection (ACR) in heart transplant recipients with stable allograft function.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Cardiac Allograft Gene Expression Profiling Test Systems." See § 862.1(d) for the availability of this guidance document.

Dated: October 9, 2009.

**Jeffrey Shuren,**

*Acting Director, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG–2009–0895]

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 temporary final rule is effective from 7 a.m. on October 21, 2009, until 5 p.m. on November 15, 2009. This temporary final rule is enforceable with actual notice by Coast Guard personnel beginning October 15, 2009.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket USCG–2009–0895 and are available online by going to <http://www.regulations.gov>, inserting USCG–2009–0895 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 final rule, call Lieutenant Junior Grade Laura van der Pol, Waterways Management Division Chief, U.S. Coast Guard Sector Northern New England, telephone 207–741–5421, e-mail [laura.k.vanderpol1@uscg.mil](mailto:laura.k.vanderpol1@uscg.mil). 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 Portsmouth Naval Facility will be beginning diving operations in this area within a short timeframe thus making publication of a NPRM and Final Rule impractical. Further, 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 as well as to minimize the risk to commercial vessels and recreational boaters who transit the area. 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.

### Background and Purpose

As part of ongoing ship construction projects at the Portsmouth Naval Shipyard, vessels are being launched, creating a period of particular sensitivity to the personnel and equipment involved. Specifically, divers will be working on the hull of a vessel for approximately four weeks beginning on October 15, 2009. Underwater work includes the removal and installation of heavy equipment. Unexpected and uncontrolled movement of the vessel while divers are in the water creates a significant risk of serious injury or death. Additionally, loading operations

onto ships that are severely constrained by their draft could also be adversely affected by unexpected and uncontrolled movement. Wake produced from vessels operating in the vicinity of the Portsmouth Naval Shipyard could cause unexpected and uncontrolled movement of the vessels in the shipyard. In order to minimize such unexpected and uncontrolled movement during the timeframe that divers will be operating and vessel loading conducted, 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 regulated navigation area encompasses all the navigable waters on the Piscataqua River in Portsmouth, NH near the Portsmouth Naval Shipyard between Henderson Point Light 10 (LLNR 8375; 43-04-29.319N, 070-44-10.189W) on Seavey Island and Badgers Island Buoy 14 (LLNR 8405; 43-04-51.951N, 070-45-21.518W).

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 may occur at any time, at day or night, during the effective period of the rule; however, the regulated navigation area will only be enforced during times when divers are conducting underwater operations and during vessel loading operations.

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 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. The Captain of the Port will issue a Broadcast Notice to Mariners notifying the public when enforcement of the regulated navigation area is suspended. 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.

#### Regulatory Planning and Review

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.

We expect the economic impact of this rule to be minimal because this regulated navigation area only requires vessels to reduce speed through a small section of the Piscataqua River therefore only causing a small delay to a vessel's transit. Further, the regulation is only enforced when a vessel's wake would cause undue risk to life and safety of personnel at the Portsmouth Naval Shipyard. The regulation period is for approximately one month.

#### Small Entities

Under the Regulatory Flexibility Act (RFA) (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 October 15, 2009 and November 15, 2009. This regulated navigation area will not have a significant economic impact on a substantial number of small entities 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) 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 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 that this action is one of the 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 will be 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, and 160.5; Public Law 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T01-0895 to read as follows:

#### § 165.T01-0895 Regulated Navigation Area; Piscataqua River, Portsmouth, NH.

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

(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 restrictions contained in paragraphs (b)(2)(i) through (b)(2)(iv) of this section 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 October 15, 2009 until November 15, 2009.

(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 effect 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: October 13, 2009.

**Joseph L. Nimmich,**

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

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