

9. Manta: Vital Info on Small Businesses, <http://www.manta.com>, accessed June 11, 2010.
10. Blozan, Carl F. and Steven A. Tucker, "Pre-market Notifications: The First 24,000," Medical Device & Diagnostic Industry: 59–69, January 1986.
11. U.S. Department of Commerce, Bureau of Economic Analysis, 2010, National Income and Product Accounts Table 1.1.9., <http://www.bea.gov/national/nipaweb/SelectTable.asp>, accessed March 25, 2011.
12. Geiger, Dale R. FY 2003 and 2004 Unit Costs for the Process of Medical Device Review, <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109216.pdf>, accessed September 2005.

List of Subjects in 21 CFR Part 882

Medical devices, Neurological 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 882 be amended as follows:

PART 882—NEUROLOGICAL DEVICES

1. The authority citation for 21 CFR part 882 continues to read as follows:

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

2. Section 882.5800 is amended by revising paragraph (c) to read as follows:

§ 882.5800 Cranial electrotherapy stimulator.

* * * * *

(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 [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL RULE IN THE **FEDERAL REGISTER**], for any cranial electrotherapy stimulator device that was in commercial distribution before May 28, 1976, or that has, on or before [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL RULE IN THE **FEDERAL REGISTER**], been found to be substantially equivalent to any cranial electrotherapy stimulator device that was in commercial distribution before May 28, 1976. Any other cranial electrotherapy stimulator device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: August 2, 2011.

Nancy K. Stade,

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

[FR Doc. 2011–19957 Filed 8–5–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–0254]

RIN 1625–AA11

Regulated Navigation Area, Zidell Waterfront Property, Willamette River, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes the establishment of a Regulated Navigation Area (RNA) at the Zidell Waterfront Property located on the Willamette River in Portland, Oregon. This RNA is necessary to preserve the integrity of an engineered sediment cap as part of an Oregon Department of Environmental Quality (DEQ) required remedial action. This proposed RNA will do so by prohibiting activities that could disturb or damage the engineered sediment cap. **DATES:** Comments and related material must be received by the Coast Guard on or before November 7, 2011.

ADDRESSES: You may submit comments identified by docket number USCG–2011–0254 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 e-mail MST1 Jaime Sayers,

Waterways Management Division, Marine Safety Unit Portland, Coast Guard; telephone 503–240–9319, e-mail Jaime.a.Sayers@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–2011–0254), 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 <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 e-mail 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–2011–0254” 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-2011-0254" 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 on or before September 7, 2011 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

The Zidell Waterfront Property is placing an engineered sediment cap over contaminated sediments adjacent to the west bank of the Willamette River between approximate river miles 13.5 and 14.2 as part of an Oregon Department of Environmental Quality (DEQ) required remedial action. Geographically this location starts at approximately the West bank of the Marquam Bridge and continues southerly, along the west bank of the Willamette River to the North end of Ross Island.

The engineered sediment cap is designed to be compatible with normal port operations, but could be damaged by other maritime activities including anchoring, dragging, dredging, grounding of large vessels, deployment

of barge spuds, etc. Such damage could disrupt the function or impact the effectiveness of the cap to contain the underlying contaminated sediment and shoreline soil in these areas. As such, this RNA is necessary to help ensure the cap is protected and will do so by prohibiting certain maritime activities that could disturb or damage it.

The engineered sediment cap will also reduce the depth of the water close to the west bank of the Willamette River and, as a result, may limit some vessels from using that area of the river.

Discussion of Proposed Rule

The proposed rule would create an RNA covering all waters adjacent to the Zidell Waterfront Property on the Willamette River extending from the west bank of the river out 200 to 400 feet into the river depending on the exact location between approximate river mile 14.2 near the Ross Island Bridge and approximate river mile 13.5 near the Marquam Bridge.

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. The Coast Guard has made this determination based on the fact that the RNA is limited in size and will not limit vessels from transiting or using the waters covered, except for activities that may damage the engineered sediment cap.

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 proposed rule would affect the following entities, some of which might be small entities: The owners or operators of vessels operating in the area covered by the RNA. The RNA would not have a significant economic impact on a substantial number of small entities, however, because the RNA is limited in size and will not limit vessels from transiting or using the waters covered, except for activities that may damage the engineered sediment cap.

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 MST1 Jaime Sayers, Waterways Management Division, Marine Safety Unit Portland, Coast Guard; telephone 503–240–9319, e-mail Jaime.A.Sayers@uscg.mil. 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 M16475.1D, 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 creation of a regulated navigation area. 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. 1226, 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, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.1337 to read as follows:

§ 165.1337 Regulated Navigation Area, Zidell Waterfront Property, Willamette River, OR.

(a) *Regulated Navigation Area.* The following area is a regulated navigation area: All waters within the area bounded by the following points: 45°29'55.12" N/122°40'2.19" W; thence continuing to 45°29'55.14" N/122°39'59.36" W; thence continuing to 45°29'56.30" N/122°39'59.09" W; thence continuing to 45°29'57.51" N/122°39'59.64" W; thence continuing to 45°29'58.72" N/122°39'59.64" W; thence continuing to 45°30'0.52" N/122°39'59.94" W; thence continuing to 45°30'1.95" N/122°40'0.46" W; thence continuing to 45°30'3.44" N/122°40'0.78" W; thence continuing to 45°30'4.87" N/122°40'0.95" W; thence continuing to 45°30'7.33" N/122°40'1.80" W; thence continuing to 45°30'8.11" N/122°40'2.69" W; thence continuing to 45°30'8.83" N/122°40'3.81" W; thence continuing to 45°30'13.06" N/122°40'5.39" W; thence continuing to 45°30'15.30" N/122°40'6.93" W; thence continuing to 45°30'17.78" N/122°40'8.16" W; thence continuing to 45°30'20.53" N/122°40'9.07" W; thence continuing to 45°30'20.90" N/122°40'11.52" W; thence continuing to 45°30'24.04" N/122°40'12.53" W; thence continuing to 45°30'23.79" N/122°40'14.87" W; thence continuing along the shoreline to 45°29'55.12" N/122°40'2.19" W.

Geographically the regulated navigation area covers all waters adjacent to the Zidell Waterfront Property on the Willamette River extending from the west bank of the river out 200 to 400 feet into the river depending on the exact location between approximate river mile 14.2 near the Ross Island Bridge and approximate river mile 13.5 near the Marquam Bridge.

(b) *Regulations.* All vessels are prohibited from anchoring, dragging, dredging, or trawling in the regulated navigation area established by this section. See 33 CFR part 165 subpart B for additional information and requirements.

Dated: July 6, 2011.

G.T. Blore,

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

[FR Doc. 2011–19986 Filed 8–5–11; 8:45 am]

BILLING CODE 9110–04–P