

device is intended for over-the-counter use.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), 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 consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review 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 this rule will relieve a burden and simplify the marketing of these devices, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. 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 order and, consequently, a federalism summary impact statement is not required.

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 862.1710 is amended by revising paragraph (b) to read as follows:

§ 862.1710 Total triiodothyronine test system.

* * * * *

(b) *Classification.* Class II. This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

Dated: October 12, 2000.

Linda S. Kahan,

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

[FR Doc. 00–26740 Filed 10–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Parts 110 and 165

[CGD05–00–048]

RIN 2115–AA98

Safety Zone and Anchorage Regulations; Delaware Bay and River

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Army Corps of Engineers will begin dredging parts of the Delaware River including the Marcus Hook Range Ship Channel. Because of the dredging operations, temporary additional requirements will be imposed in Marcus Hook Anchorage (Anchorage 7), the Deepwater Point Anchorage (Anchorage 6), and the

Mantua Creek Anchorage (Anchorage 9). The Coast Guard is also establishing a temporary moving safety zone around the dredge vessel *Essex* that will be working in the Marcus Hook Range Ship Channel adjacent to Anchorage 7.

DATES: This rule is effective from October 3, 2000 until November 30, 2000.

ADDRESSES: Documents indicated in this preamble as being available are part of docket CGD05–00–048 and are available for inspection or copying at Coast Guard Marine Safety Office/Group Philadelphia, One Washington Avenue, Philadelphia, Pennsylvania 19147 between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Lieutenant Junior Grade Wade Kirschner or Senior Chief Robert Ward, Coast Guard Marine Safety Office/Group Philadelphia, (215) 271–4889 or (215) 271–4888.

SUPPLEMENTARY INFORMATION:

Regulatory Information

A Notice of Proposed Rule Making (NPRM) was not published for this regulation. In keeping with 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. In keeping with the requirements of 5 U.S.C. 533(d)(3), the Coast Guard also finds good cause exists for making this regulation effective less than 30 days after publication in the **Federal Register**. U.S. Army Corps of Engineers, Philadelphia District, informed the Coast Guard on September 13, 2000 that dredging operations would commence on October 1, 2000. Publishing a NPRM and delaying its effective date would be contrary to the public interest, since immediate action is needed to protect mariners against potential hazards associated with the dredging operations in the Marcus Hook Range Ship Channel and to modify the anchorage regulations to facilitate vessel traffic.

Background and Purpose

The U.S. Army Corps of Engineers (ACOE) notified the Coast Guard that it needed to conduct dredging operations on the Delaware River, in the vicinity of the Marcus Hook Range Ship Channel. The dredging is needed to maintain the project depth of the channel. Similar dredging is conducted each year. This period of dredging begins October 1, 2000 and is anticipated to end on November 30, 2000.

To reduce the hazards associated with dredging the channel, vessel traffic that would normally transit through the Marcus Hook Range Ship Channel may

divert through a portion of anchorage 7 to maintain a 150 foot radius around dredging operations. This necessitates additional requirements/restrictions on the use of Anchorage 7. For the protection of mariners transiting in the vicinity of dredging operations, the Coast Guard is also establishing a safety zone around the dredging vessel *Essex*. The safety zone will ensure mariners remain a safe distance from the potentially dangerous dredging equipment.

Discussion of the Regulation

33 CFR 110.157(b)(2) allows vessels to anchor for up to 48 hours in the anchorages listed in § 110.157(a), which includes Anchorage 7. However, because of the limited anchorage space available in Anchorage 7 during dredging operations, the Coast Guard is adding a temporary paragraph in 33 CFR 110.157(b)(11) to provide additional requirements and restrictions on vessels utilizing Anchorage 6, 7 and 9.

Vessels desiring to use the Marcus Hook Anchorage (Anchorage 7) must seek permission from the Captain of the Port at least 24 hours in advance. Only one vessel will be allowed to anchor in Anchorage 7 at one time, and the Captain of the Port will grant permission on a "first come, first serve basis." A vessel desiring to use anchorage 7 will be directed to a location within the anchorage, and no vessel may remain in the anchorage beyond twelve hours.

The Coast Guard expects that vessels normally permitted to anchor in Anchorage 7 will use Anchorage 6 off Deepwater Point or Anchorage 9 near the entrance to Mantua Creek, because they are the closest anchorages to Anchorages 6 and 9, the Coast Guard is requiring any vessel 700 feet or greater in length to obtain advance permission from the Captain of the Port before anchoring. The Coast Guard is also concerned that the holding ground in Anchorages 6 and 9 is not as good as in Anchorage 7. As larger vessels do not typically use these anchorages, any vessel 700 to 750 feet in length is required to have one tug standing alongside while at anchor, and any vessel of over 750 feet in length must have two tugs standing alongside. The tug(s) must have sufficient horsepower to prevent the vessel they're attending from swinging into the channel.

The Coast Guard is also establishing a safety zone within a 150-yard radius of the dredging operations being conducted in the Marcus Hook Range Ship Channel in the vicinity of Anchorage 7 by the dredge vessel *Essex*.

The safety zone will protect mariners transiting the area from the potential hazards associated with dredging operations. Vessels transiting the Marcus Hook Range Ship Channel will have to divert from the main ship channel through Anchorage 7, and must operate at the minimum safe speed necessary to maintain steerage. No vessel may enter the safety zone unless it receives permission from the Captain of the Port.

Regulatory Evaluation

This temporary final rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866 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 exempted it from review under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Although this regulation requires certain vessels to have one or two tugs alongside while at anchor, the requirement only applies to vessels 700 feet or greater in length, that choose to anchor in Anchorages 6 and 9. Alternate anchorages, such as Anchorage A (Breakwater) and Anchorage 1 (Big Stone) in Delaware Bay, are also reasonably close and generally available. Vessels anchoring in Anchorage A and 1 are not required to have tugs alongside, except when specifically directed to do so by the Captain of the Port because of a specific hazardous condition. Furthermore, few vessels 700 feet or greater are expected to enter the port during the effective period. The majority of vessels expected are less than 700 feet and thus will not be required to have tugs alongside.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considered whether this temporary final rule will have a significant economic impact on a substantial number of small entities. "Small Entities" include 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. This regulation's greatest impact is on vessels greater than 700 feet in length which choose to anchor in Anchorages 6 and 9 and will have virtually no

impact on any small entities. Therefore, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this temporary final rule will not have a significant economic impact on a substantial number of small entities.

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

We have analyzed this rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that Order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those costs. This rule will not impose an unfunded mandate.

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 concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

We considered the environmental impact of this rule and concluded that, under figure 2–1, paragraphs (34)(f) and (g), of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation.

List of Subjects

33 CFR Part 110

Anchorage grounds.

33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

Regulation

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 110 and 33 CFR part 165 as follows:

PART 110—[AMENDED]

1. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C. 471, 1221 through 1236, 2030, 2035, and 2071; 49 CFR 1.46 and 33 CFR 1.05–1(g). Section 110.1a and each section listed in 110.1a is also issued under 33 U.S.C. 1223 and 1231.

2. A new temporary § 110.157(b)(11) is added to read as follows:

§ 110.157 Delaware Bay and River.

* * * * *

(b) * * *

(11) *Additional requirements and restrictions for the anchorages defined in paragraphs (a)(7), (a)(8), and (a)(10) of this section.*

(i) Prior to anchoring in Anchorage 7 off Marcus Hook, as described in paragraph (a)(8) of this section, a vessel must first obtain permission from the Captain of the Port, Philadelphia, at least 24 hours in advance of arrival. Permission to anchor will be granted on a “first-come, first-serve” basis. The Captain of the Port will allow only one vessel at a time to be at anchor in Anchorage 7, and no vessel may remain within Anchorage 7 for more than 12 hours.

(ii) For Anchorage 6 as described in paragraph (a)(7) of this section, and Anchorage 9 as described in paragraph (a)(10) of this section.

(A) Any vessel 700 feet or greater in length requesting anchorage shall obtain permission from the Captain of the Port, Philadelphia, Pennsylvania, at least 24 hours in advance.

(B) Any vessel from 700 to 750 feet in length shall have one tug alongside at all times while the vessel is at anchor.

(C) Any vessel greater than 750 feet in length shall have two tugs alongside at all times while the vessel is at anchor.

(D) The master, owner or operator of a vessel at anchor shall ensure that any tug required by this section is of sufficient horsepower to assist with necessary maneuvers to keep the vessel clear of the navigation channel.

(iii) *Effective Dates.* This paragraph (b)(11) is effective from October 3, 2000 until November 30, 2000.

PART 165—[AMENDED]

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46. Section 165.100 is also issued under authority of Sec. 311, Pub. L. 105–383.

4. Add temporary § 165.T05–048 to read as follows:

§ 165.T05–048 Safety Zone; Delaware Bay and River.

(a) *Location.* The following area is a safety zone: All waters within the arc of a circle with a 150 yard radius having at its center dredging vessel *Essex* operating in or near the Marcus Hook Range Ship Channel in the vicinity of Anchorage 7.

(b) *Regulations.* (1) All persons are required to comply with the general regulations governing safety zones in § 165.23 of this part.

(2) No person or vessel may enter or navigate within this safety zone unless authorized to do so by the Captain of the Port. Any person or vessel authorized to enter the safety zone must operate in strict conformance with any directions given by the Captain of the Port and leave the safety zone immediately if the Captain of the Port so orders.

(3) Vessels may navigate in and through Anchorage 7 (Marcus Hook Anchorage) to the minimum extent necessary to stay clear of the safety zone. Vessels navigating in Anchorage 7 for this purpose shall do so at minimum speed to maintain steerage, unless otherwise directed by the Captain of the Port.

(4) The Coast Guard vessels enforcing this section can be contacted on VHF Marine Band Radio, channels 13 and 16. The Captain of the Port can be contacted at telephone number (215) 271–4940.

(5) The Captain of the Port will notify the public of any changes in the status of this safety zone by Marine Safety Radio Broadcast on VHF-FM marine band radio, channel 22 (157.1 MHz).

(c) *Definitions.* *Captain of the Port* means the Commanding Officer of the Coast Guard Marine Safety Office/Group Philadelphia or any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port to act on his behalf.

(d) *Effective dates:* This section is effective from October 3, 2000 to November 30, 2000.

Dated: October 3, 2000.

T.C. Parr,

Captain, U.S. Coast Guard, Commander, Fifth U.S. Coast Guard District, Acting.

[FR Doc. 00–26768 Filed 10–17–00; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 154

[USCG–1999–5149]

RIN 2115–AF79

Response Plans for Marine Transportation-Related Facilities Handling Non-Petroleum Oils; Clarification

AGENCY: Coast Guard, DOT.

ACTION: Clarification to final rule.

SUMMARY: This document clarifies a preamble discussion to a final rule published in the **Federal Register** of June 30, 2000. The rule amended Coast Guard regulations requiring response plans for marine transportation-related (MTR) facilities that handle, store, or transport animal fats or vegetable oils. Specifically, this document clarifies the explanation for higher volume ports.

DATES: This document becomes effective on October 18, 2000.

FOR FURTHER INFORMATION CONTACT: For questions on this clarification or the final rule, call Lieutenant Claudia Gelzer, Project Manager, Coast Guard, telephone 202–267–1983. For questions on viewing or submitting material to the docket, call Dorothy Beard, Chief, Dockets, Department of Transportation, telephone 202–366–9329.

SUPPLEMENTARY INFORMATION:

Clarification of Preamble to Final Rule

On June 30, 2000, we published in the **Federal Register** the final rule titled “Response Plans for Marine Transportation-Related Facilities Handling Non-Petroleum Oils” (USCG–1999–5149)[65 FR 40820]. In the preamble to that rule, on page 40822, we stated that higher volume port areas were designated based on the availability of response equipment on hand in those ports. After that publication, the Coast Guard received comments from the affected public requesting clarification of our high volume ports discussion.