

effective date has been established for the requirement of premarket approval. (See § 872.3).

Dated: May 4, 2004.

**Linda S. Kahan,**

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

[FR Doc. 04-14767 Filed 6-29-04; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 110

[CGD01-03-107]

RIN 1625-AA01

#### Anchorage Regulations: Yonkers, NY

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to establish two Special Anchorage areas along the Hudson River adjacent to the City of Yonkers. This proposed action is necessary to facilitate safe navigation in that area and provide safe and secure anchorages for vessels not more than 20 meters in length. This action is intended to increase the safety of life and property on the Hudson River, improve the safety of anchored vessels in both anchorages, and provide for the overall safe and efficient flow of recreational vessel traffic and commerce.

**DATES:** Comments and related material must reach the Coast Guard on or before August 30, 2004.

**ADDRESSES:** You may mail comments and related material to Commander (oan) CGD01-03-107, First Coast Guard District, 408 Atlantic Ave., Boston, Massachusetts 02110, or deliver them to room 628 at the same address between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at room 628, First Coast Guard District Boston, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Mr. John J. Mauro, Commander (oan), First Coast Guard District, 408 Atlantic Ave., Boston, MA 02110, Telephone (617) 223-8355; E-mail [jmauro@d1.uscg.mil](mailto:jmauro@d1.uscg.mil).

**SUPPLEMENTARY INFORMATION:**

### Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking CGD01-03-107, indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of comments received.

### Public Meeting

We do not plan to hold a public meeting, but you may submit a request for a meeting by writing to Commander (oan) CGD01-03-107, First Coast Guard District, 408 Atlantic Ave., Boston, Massachusetts 02110 or delivering your request to room 628 at the same address above between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. In your request please explain why a public meeting would be beneficial. If we determine that a public meeting would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

### Background and Purpose

As part of a waterfront revitalization and redevelopment effort, the City of Yonkers is proactively encouraging waterfront use by the general public. This proposed rule is in response to a request made by the City of Yonkers to help ensure the safe navigation of increased vessel traffic expected to arrive along the city waterfront due to this revitalization effort.

The Coast Guard is designating the areas as special anchorage areas in accordance with 33 U.S.C. 471. In accordance with that statute, vessels will not be required to sound signals or exhibit anchor lights or shapes which are otherwise required by rule 30 and 35 of the Inland Navigation Rules, codified at 33 U.S.C. 2030 and 2035. The two proposed special anchorage areas will be located on the west side of the Hudson River in the vicinity of Main Street and the JFK Marina, well removed from the channel and located where general navigation will not endanger or be endangered by unlighted vessels. Providing anchorage well

removed from the channel and general navigation would greatly increase navigational safety.

While developing the proposed rule, in accordance with Title 33 of the Code of Federal Regulations, Part 109.05(b) the U.S. Coast Guard has consulted with the U.S. Army Corps of Engineers, New York District, located at 26 Federal Plaza, New York, NY 10278. The U.S. Army Corps of Engineers has determined that the proposed Special Anchorage Areas would not have an adverse affect on any federally maintained navigation channels in the area, structures the U.S. Army Corps of Engineers has permitted, or any pending permit applications submitted to the U.S. Army Corps of Engineers in this area.

### Discussion of Proposed Rule

The proposed rule would create two new special anchorage areas. The first, located on the Hudson River at Main Street, Yonkers, New York, would be that portion of the Hudson River starting on shore at point 40°56'15.4" N, 073°54'11.1" W; thence northwest to point 40°56'18.0" N, 073°54'21.0" W; thence south to point 40°55'58.8" N, 073°54'24.8" W; thence southeast to shore at point 40°55'58.0" N, 073°54'21.0" W.

The second, located on the Hudson River at JFK Marina, Yonkers, New York, would be that portion of the Hudson River starting on shore at point 40°57'28.5" N, 073°53'46.0" W; thence west to point 40°57'30.5" N, 073°53'56.8" W; thence southwest to point 40°57'07.5" N, 073°54'06.2" W; thence east to shore at point 40°57'08.0" N, 073°53'58.5" W. All proposed coordinates are North American Datum 1983 (NAD 83).

The special anchorage areas would be limited to vessels no greater than 20 meters in length. Vessels not more than 20 meters in length are not required to sound signals as required by rule 35 of the Inland Navigation Rules (33 U.S.C. 2035) or exhibit anchor lights or shapes required by rule 30 of the Inland Navigation Rules (33 U.S.C. 2030) when at anchor in a special anchorage area. Additionally, mariners utilizing the anchorage areas are encouraged to contact local and state authorities, such as the local harbor master, to ensure compliance with additional applicable state and local laws. Such laws may involve, for example, compliance with direction from the local harbor master when placing or using moorings within the anchorage.

## Regulatory Evaluation

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 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.

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of Department of Homeland Security is unnecessary. This finding is based on the fact that this proposal conforms to the changing needs of the City of Yonkers and the changing needs of recreational vessels along the Hudson River. This proposed rule is in the interest of safe navigation and property protection.

## Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we 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 recreational or commercial vessels intending to transit in a portion of the Hudson River encumbered by the special anchorage areas. These anchorage areas, however, would not have a significant economic impact on these entities for the following reasons. The proposed special anchorage areas extend past the 30-foot depth contour by approximately 200 feet on the east side of the Hudson River. This leaves approximately 2,200 feet of safe water before reaching the 30-foot depth contour on the west side. This is more than enough room for the types of vessels currently operating on the river, which include both small and large commercial vessels. Thus these special anchorage areas will not impede safe and efficient vessel transit on the Hudson River.

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 Mr. John J Mauro at the address listed in *ADDRESSES* above.

## 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 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 effect a taking of private property or otherwise have taking implications under E.O. 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 may 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. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs 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 Commandant Instruction M16475.1D, 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)(f), of the Instruction, from further environment documentation. A draft “Environmental Analysis Check List” and a draft “Categorical Exclusion Determination” are available in the docket where indicated under **ADDRESSES**. Comments on this section will be considered before we make the final decision on whether the rule should be categorically excluded from further environmental review.

#### List of Subjects in 33 CFR Part 110

Anchorage grounds.

#### Regulations

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR Part 110 as follows:

#### PART 110—ANCHORAGE REGULATIONS

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; 33 CFR 1.05–1(g); and Department of Homeland Security Delegation No. 0170.1.

2. In § 110.60 add new paragraphs (o–4) and (o–5) to read as follows:

#### § 110.60 Port of New York and vicinity.

\* \* \* \* \*

(o) \* \* \*

(o–4) *Hudson River, at Main Street, Yonkers.* That portion of the Hudson River starting on shore at point 40°56′15.4″ N, 073°54′11.1″ W; thence northwest to point 40°56′18.0″ N, 073°54′21.0″ W; thence south to point 40°55′58.8″ N, 073°54′24.8″ W; thence southeast to shore at point 40°55′58.0″ N, 073°54′21.0″ W.

**Note:** This area is limited to vessels no greater than 20 meters in length and is primarily for use by recreational craft on a seasonal or transient basis. These regulations do not prohibit the placement of moorings within the anchorage area, but requests for the placement of moorings should be

directed to the local government to ensure compliance with local and state laws. All moorings shall be so placed that no vessel, when anchored, will at any time extend beyond the limits of the area. Fixed mooring piles or stakes are prohibited. Mariners are encouraged to contact the local harbormaster for any additional ordinances and to ensure compliance with additional applicable state and local laws.

(o–5) *Hudson River, at JFK Marina, Yonkers.* That portion of the Hudson River starting on shore at point 40°57′28.5″ N, 073°53′46.0″ W; thence west to point 40°57′30.5″ N, 073°53′56.8″ W; thence southwest to point 40°57′07.5″ N, 073°54′06.2″ W; thence east to shore at point 40°57′08.0″ N, 073°53′58.5″ W.

**Note:** This area is limited to vessels no greater than 20 meters in length and is primarily for use by recreational craft on a seasonal or transient basis. These regulations do not prohibit the placement of moorings within the anchorage area, but requests for the placement of moorings should be directed to the local government to ensure compliance with local and state laws. All moorings shall be so placed that no vessel, when anchored, will at any time extend beyond the limits of the area. Fixed mooring piles or stakes are prohibited. Mariners are encouraged to contact the local harbormaster for any additional ordinances and to ensure compliance with additional applicable state and local laws.

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Dated: June 15, 2004.

**Vivien S. Crea,**

*RADM, U.S. Coast Guard, Commander, First Coast Guard District.*

[FR Doc. 04–14869 Filed 6–29–04; 8:45 am]

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Parts 52 and 81

[R07–OAR–2004–MO–0003; FRL–7779–8]

#### Approval and Promulgation of Implementation Plans; State of Missouri; Designation of Areas for Air Quality Planning Purposes; Arcadia and Liberty Townships

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to approve a State Implementation Plan (SIP) revision submitted by the state of Missouri and Missouri’s request to redesignate the lead nonattainment area in Iron County, Missouri, bounded by Arcadia and Liberty townships to attainment of the National Ambient Air

Quality Standard (NAAQS). EPA proposes to approve the maintenance plan for this area including a settlement agreement which was submitted with the redesignation request.

**DATES:** Comments on this proposed action must be received in writing by July 30, 2004.

**ADDRESSES:** Comments may be mailed to James Hirtz, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101. Comments may also be submitted electronically or through hand delivery/courier; please follow the detailed instructions in the **ADDRESSES** section of the direct final rule which is located in the rules section of this **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** James Hirtz at (913) 551–7472 or by e-mail at [hirtz.james@epa.gov](mailto:hirtz.james@epa.gov).

**SUPPLEMENTARY INFORMATION:** In the final rules section of the **Federal Register**, EPA is approving the state’s SIP revision and redesignation request as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no relevant adverse comments to this action. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated in relation to this action. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed action. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on part of this rule and if that part can be severed from the remainder of the rule, EPA may adopt as final those parts of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the rules section of this **Federal Register**.

Dated: June 21, 2004.

**James B. Gulliford,**

*Regional Administrator, Region 7.*

[FR Doc. 04–14702 Filed 6–29–04; 8:45 am]

**BILLING CODE 6560–50–P**