

of the drug. When conducted in accordance with § 361.1, clinical investigations of radioactive drugs are not subject to the requirements for INDs stated in 21 CFR part 312.

To facilitate discussion at the public meeting and assist us in our review of this matter, we invited comments on several questions we set forth in the **Federal Register** notice concerning the application of § 361.1. Interested persons were invited to present information at the public meeting and were given until January 16, 2005, to submit comments on the notice.

We held the public meeting on November 16, 2004. Subsequent to the public meeting, we received requests from the American College of Nuclear Physicists, the Society of Nuclear Medicine, and others that we extend the comment period on the notice on § 361.1 so that persons can consider the issues raised in the notice and at the public meeting in light of the information in the draft guidance on exploratory INDs that we expected to issue in the near future. We published a notice of availability of that draft guidance in the **Federal Register** of April 14, 2005 (70 FR 19764).

In response to these requests, we have decided to reopen the comment period on the questions and issues stated in the October 5, 2004, notice and discussed at the November 16, 2004, public meeting. This will allow interested persons more time to review and comment on these issues in light of the information in the draft guidance on exploratory INDs.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Transcripts

You can examine a transcript of the November 16, 2004, public meeting on the Internet at <http://www.fda.gov/ohrms/dockets/default.htm> or at the Division of Dockets Management (see **ADDRESSES**), Monday through Friday between 9 a.m. and 4 p.m. You may also request a copy of the transcript from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville,

MD 20857, at a cost of 10 cents per page or on CD at a cost of \$14.25 each.

Dated: May 4, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD05-05-041]

RIN 1625-AA09

Drawbridge Operation Regulations; Atlantic Intracoastal Waterway (AICW), Elizabeth River, Southern Branch, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the regulations that govern the operation of the Dominion Boulevard (U.S. 17) Bridge across the Southern Branch of the Elizabeth River, at Atlantic Intracoastal Waterway (AICW) mile 8.8, at Chesapeake, Virginia. The proposal would change the morning rush hour closure period so that it starts at 7 a.m. and ends at 9 a.m., and also allow the bridge to open every hour from 9 a.m. to 4 p.m., Monday through Friday, except holidays. The proposed change is necessary to relieve vehicular traffic congestion and reduce traffic delays between weekday rush hours while still providing for the reasonable needs of navigation.

DATES: Comments and related material must reach the Coast Guard on or before June 24, 2005.

ADDRESSES: You may mail comments and related material to Commander (obr), Fifth Coast Guard District, Federal Building, 1st Floor, 431 Crawford Street, Portsmouth, VA 23704-5004. The Fifth Coast Guard District maintains the public docket for this rulemaking. 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 Commander (obr), Fifth Coast Guard District between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Waverly W. Gregory, Jr., Bridge Administrator, Fifth Coast Guard District, at (757) 398-6222.

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 CGD05-05-041, 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 a return receipt, please enclose a stamped, self-addressed postcard or envelope. We will consider all submittals received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to Commander (obr), Fifth Coast Guard District at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one public meeting at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

Current regulations require the Dominion Boulevard (US 17) Bridge across the Southern Branch of Elizabeth River, at AICW mile 8.8, to open on signal at any time for commercial vessels carrying liquefied flammable gas or other hazardous materials and for commercial vessels that provide a two-hour advance notice. In addition, from Memorial Day to Labor Day, from 8:30 a.m. to 4 p.m., Monday through Friday, except Federal holidays, the draw is opened only every hour on the half-hour. From 6:30 a.m. to 8:30 a.m. and from 4 p.m. to 6 p.m., Monday through Friday, except Federal holidays, the draw need not open for the passage of recreational vessels and commercial vessels carrying non-hazardous material that do not provide a 2-hour advance notice.

On December 17, 2004, we published a notice of temporary deviation from the regulations and request for comments entitled "Drawbridge Operation Regulations; Atlantic Intracoastal Waterway (AICW), Elizabeth River, Southern Branch, VA" in the **Federal Register** (69 FR 75472). The temporary deviation was an effort to test an alternate drawbridge operation schedule for 90 days and to solicit comments from the public. In accordance with the temporary deviation, from December 13,

2004, to March 13, 2005, from 8:30 a.m. to 4 p.m., Monday through Friday, except Federal holidays, the draw was opened only every hour on the half hour.

The Coast Guard received 52 e-mail messages and 4 on-paper responses commenting on the provisions of the temporary deviation. The majority of the comments, from motorists, favored scheduled versus unscheduled bridge openings, so they could better plan their movements. Many respondents indicated that even though the vehicular rush hour traffic starts at 6:30 a.m., the weekday rush hour traffic peaks between 7 a.m. and 9 a.m. In addition, they stated a preference that commercial vessels carrying non-hazardous materials be regulated. However, since tugs and tugs with tows have no place to tie up in the proximity of the bridge in order to wait for a bridge opening, the Coast Guard will continue to include them in the 2-hour advance notice requirement.

During the spring and fall months, the flow of recreational vessels is constant due to vessel owners referred to as "snowbirds". Owners of these recreational vessels are either transiting north to south towards a warmer climate in the fall or south to north towards a cooler climate in the spring and this can result in excessive bridge openings. From Memorial Day to Labor Day, the current regulations restrict openings for vessels between the rush hour periods to every hour on the half hour.

In an effort to ease vehicle traffic congestion as a result of vessel openings of the drawbridge, the proposal will change the morning rush hour period so that it starts at 7 a.m. and ends at 9 a.m., Monday to Friday, except Federal holidays. Therefore, the first drawbridge opening for vessels after the morning rush hour will occur at 9 a.m. and the last opening before the evening rush hour will be at 4 p.m.

Also, the Coast Guard proposes that the hourly opening occur on the hour, between the rush hour closure periods from 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. The Coast Guard examined the operation of the Great Bridge (S168) Bridge across the Albemarle and Chesapeake at AICW mile 12.0 and the Great Bridge Locks (the Locks) located just south of the Dominion Boulevard Bridge. The Great Bridge (S168) Bridge provides vessel openings on the hour between 6 a.m. to 7 p.m., seven days a week, year round. The Locks, owned and operated by the U.S. Army Corps of Engineers, opens for vessels on demand from 7 a.m. to 6 p.m. Mariners suggested that if the Dominion

Boulevard Bridge must open only once each hour, on the hour is better.

Based on the above information, we have proposed to change the regulations that govern the Dominion Boulevard Bridge to open year round, every hour between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays, to coincide with the operation of the Great Bridge (S168) Bridge and the Locks. The proposal will enable transient craft to reduce delays in navigating the AICW, while also helping to ease vehicular traffic congestion.

Discussion of Proposed Rule

The Coast Guard proposes to amend 33 CFR § 117.997(g), by revising paragraphs (g)(2), (g)(3), and (g)(4).

Paragraph (g)(2) would modify the morning closure period, during rush hour, to 7 a.m. to 9 a.m., Monday to Friday, except Federal holidays. Paragraph (g)(3) would delete the phrase "From Memorial Day to Labor Day" and modify the paragraph to read "Year round from 9 a.m. to 4 p.m., Monday to Friday, except Federal holidays, the draw need be opened every hour". Paragraph (g)(4) would replace the wording from "on the half hour" to "on the hour."

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 section 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 (DHS).

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary. We reached this conclusion based on the fact that the proposed changes have only a minimal impact on maritime traffic transiting the bridge. Mariners can plan their transits in accordance with the scheduled bridge openings, to minimize delays.

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 not have a significant economic impact on a substantial number of small entities because the proposed rule only adds minimal restrictions to the movement of navigation, and mariners who plan their transits in accordance with the schedule bridge openings minimizes delays.

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 Waverly W. Gregory, Jr., Bridge Administrator, Fifth Coast Guard District, (757) 398–6222. 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 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 will 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 affect 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 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 proposed rule is categorically excluded, under figure 2–1, paragraph (32)(e) of the Instruction, from further environmental documentation because it has been determined that the promulgation of operating regulations for drawbridges are categorically excluded.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; Department of Homeland Security Delegation No. 0170.1; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. In §117.997, paragraphs (g)(2) introductory text, (g)(3) and (g)(4) are revised to read as follows:

§ 117.997 Atlantic Intracoastal Waterway, South Branch of the Elizabeth River to the Albermarle and Chesapeake Canal.

* * * * *

(g) * * *

(1) * * *

(2) From 7 a.m. to 9 a.m. and from 4 p.m. to 6 p.m., Monday through Friday, except Federal holidays:

(i) * * *

(ii) * * *

(3) From 9 a.m. to 4 p.m., Monday to Friday, except Federal holidays, the draw need be opened every hour on the hour.

(4) If any vessel is approaching the bridge and cannot reach the draw exactly on the hour, the drawtender may delay the opening up to ten minutes past the hour for the passage of the approaching vessel and any other vessels that are waiting to pass.

* * * * *

Dated: May 2, 2005.

Lawrence J. Bowling,

Captain, United States Coast Guard, Acting Commander, Fifth Coast Guard District.

[FR Doc. 05–9303 Filed 5–9–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[I.D. 040605D]

Atlantic Highly Migratory Species; Commercial Shark Management Measures

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Receipt of a petition for rulemaking; request for comments.

SUMMARY: NMFS announces the receipt of, and requests public comment on, a petition from the North Carolina Department of Environment and Natural Resources, Division of Marine Fisheries (Petitioner) to initiate rulemaking to amend the extent of the current time/area closure for Atlantic sharks off the Mid-Atlantic region.

DATES: Written comments must be received no later than 5 p.m., eastern standard time, on July 11, 2005.

ADDRESSES: Written comments on the petition should be sent to Jackie Wilson, Highly Migratory Species Management Division:

• E-mail: SF1.040605D@noaa.gov.

• Mail: 1315 East-West Highway, Silver Spring, MD 20910. Please mark the outside of the envelope "Comments on Petition for Rulemaking for Sharks."

• Fax: 301–713–1917.