

V. Paperwork Reduction Act of 1995

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.

VI. Reference

The following reference has 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 Digital Angel Corp., dated August 4, 2004.

List of Subjects in 21 CFR Part 880

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 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 1. The authority citation for 21 CFR part 880 continues to read as follows:

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

■ 2. Section 880.1 is amended by adding new paragraph (e) to read as follows:

§ 880.1 Scope.

* * * * *

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

■ 3. Section 880.6300 is added to subpart G to read as follows:

§ 880.6300 Implantable radiofrequency transponder system for patient identification and health information.

(a) *Identification.* An implantable radiofrequency transponder system for patient identification and health information is a device intended to enable access to secure patient identification and corresponding health information. This system may include a passive implanted transponder, inserter, and scanner. The implanted transponder is used only to store a unique electronic identification code that is read by the scanner. The identification code is used to access patient identity and corresponding health information stored in a database.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient

Identification and Health Information." See § 880.1(e) for the availability of this guidance document. This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

Dated: November 30, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04-27077 Filed 12-9-04; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 117**

[CGD01-04-106]

RIN 1625-AA09

Drawbridge Operation Regulations: Connecticut River, CT

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary final rule governing the operation of the Route 82 Bridge, at mile 16.8, across the Connecticut River at East Haddam, Connecticut. This temporary final rule allows the bridge to operate on a fixed opening schedule and also authorizes several bridge closures from December 1, 2004, through March 31, 2006. The purpose of this temporary final rule is to facilitate the rehabilitation construction at the Route 82 Bridge.

DATES: This temporary final rule is effective from December 1, 2004, through March 31, 2006.

ADDRESSES: Material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket (CGD01-04-106) and are available for inspection or copying at the First Coast Guard District, Bridge Branch Office, 408 Atlantic Avenue, Boston, Massachusetts, 02110, 6:30 a.m. to 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ms. Judy Leung-Yee, Project Officer, First Coast Guard District, (212) 668-7195.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On October 19, 2004, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulations; Connecticut River,

Connecticut, in the **Federal Register** (69 FR 61455). We received no comments in response to the notice of proposed rulemaking. No public hearing was requested and none was held.

Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

The bridge rehabilitation construction has already been delayed over a year due to funding issues and as a result of those delays the rehabilitation repairs at the bridge need to be performed as soon as possible.

Any delay encountered in this regulation's effective date would be unnecessary and contrary to the public interest because the rehabilitation construction is necessary in order to assure continued safe reliable operation of the bridge.

Background and Purpose

The Route 82 Bridge has a vertical clearance of 22 feet at mean high water, and 25 feet at mean low water in the closed position. The existing drawbridge operating regulations listed at 33 CFR 117.205(c), require the bridge to open on signal at all times; except that, from May 15 to October 31, 9 a.m. to 9 p.m., the bridge is required to open for recreational vessels on the hour and half hour only. The bridge is required to open on signal at all times for commercial vessels.

The Route 82 Bridge was scheduled for major repairs in the summer of 2001, and again in 2002, but due to a project funding shortfall the work was delayed. Subsequent to that, the bridge has continued to deteriorate. Funding has now been made available and the necessary repairs need to be performed with all due speed to assure safe reliable continued operation of the bridge.

The bridge owner, Connecticut Department of Transportation, requested a temporary rule to allow the bridge to open at specific times. Commercial vessels may obtain bridge openings at any time provided they provide a two-hour advance notice to the bridge tender.

The bridge owner has also requested additional bridge closures that will restrict both recreational and commercial vessel traffic. The requested dates include: One seven day bridge closure from March 21, 2005 through March 28, 2005; three 8 hour closures on October 18, 19, and 20, 2005; and one 24 hour closure on December 14, 2005.

The exact dates and times for the above closures possibly may change due to unforeseen issues. Should the above

dates and times change, the Coast Guard will revise this temporary rule and publish the exact times and dates in the Local Notice to Mariners at least thirty-days in advance of the anticipated occurrence of each closure to assist mariners in their planning.

Under this final rule, in effect from December 1, 2004 through March 31, 2006, the Route 82 Bridge will operate as follows:

From November 1 through July 6, the draw will open on signal at 5:30 a.m., 1:30 p.m., and 8 p.m., daily.

From July 7 through October 31, the draw will open on signal Monday through Friday at 5:30 a.m., 1:30 p.m., and 8 p.m. On Friday the draw will open on signal at 5:30 a.m., 1:30 p.m., 8 p.m., and 11:30 p.m. On Saturday and Sunday the draw will open at 5:30 a.m., 8:30 a.m., 1:30 p.m., 4 p.m., 8 p.m., and 11:30 p.m.

At all times, other than during the closed periods identified above, the draw will open on signal for Commercial vessels provided at least a two-hour advance notice is given.

Discussion of Comments and Changes

We received no comments in response to the notice of proposed rulemaking. No changes have been made to this temporary final rule as a result.

Regulatory Evaluation

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. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS).

This conclusion is based on the fact vessel traffic will still be able to transit through the Route 82 Bridge under a fixed time schedule that is expected to meet the reasonable needs of navigation.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we 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 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 conclusion is based on the fact that vessel traffic will still be able to transit through the Route 82 Bridge under a fixed time schedule that is expected to meet the reasonable needs of navigation.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

No small entities requested Coast Guard assistance and none was given.

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).

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

Indian Tribal Governments

This final rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have 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 proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this final 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 (32)(e), of the Instruction, from further environmental documentation. It has been determined that this final rule does not significantly impact the environment.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

■ For the reasons set out in the preamble, the Coast Guard amends 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. From December 1, 2004 through March 31, 2006, § 117.205 is temporarily amended by suspending paragraph (c) and adding a new paragraph (d) to read as follows:

§ 117.205 Connecticut River.

* * * * *

(d) The draw of the Route 82 Bridge, mile 16.8, at East Haddam shall operate as follows:

(1) From November 1 through July 6 the draw shall open on signal at 5:30 a.m., 1:30 p.m., and 8 p.m., daily.

(2) From July 7 through October 31, Monday through Thursday, the draw shall open on signal at 5:30 a.m., 1:30 p.m., and 8 p.m. On Friday the draw shall open on signal at 5:30 a.m., 1:30 p.m., 8 p.m., and 11:30 p.m. On Saturday and Sunday the draw shall

open on signal at 5:30 a.m., 8:30 a.m., 1:30 p.m., 4 p.m., 8 p.m., and 11:30 p.m.

(3) The draw need not open for the passage of vessel traffic on the following dates: March 21, 2005 through March 28, 2005; October 18, 19 and 20, 2005; and December 14, 2005.

(4) At all times, other than the dates identified in paragraph (d)(3) of this section, the draw shall open on signal for commercial vessels provided at least a two-hour advance notice is given.

Dated: November 29, 2004.

David P. Pekoske,

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

[FR Doc. 04–27101 Filed 12–9–04; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD08–04–018]

RIN 1625–AA09

Drawbridge Operation Regulation; St. Croix River, Wisconsin, MN

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is changing the regulation governing the Prescott Highway Bridge, across the St. Croix River at Mile 0.3, at Prescott, Wisconsin. Under the rule, the drawbridge need not open for river traffic and may remain in the closed-to-navigation position from November 1, 2005, to April 1, 2006.

This rule allows the bridge owners to make necessary repairs to the bridge.

DATES: This rule is effective November 1, 2005, to April 1, 2006.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of the docket [CGD08–04–018] and are available for inspection or copying at room 2.107f in the Robert A. Young Federal Building at Eighth Coast Guard District, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Roger K. Wiebusch, Bridge Administrator, (314) 539–3900, extension 2378.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On September 21, 2004, we published a notice of proposed rulemaking

(NPRM) entitled Drawbridge Operation Regulation; St. Croix River, Wisconsin and Minnesota in the **Federal Register** (69 FR 56379). We received no comment letters on the proposed rule. No public hearing was requested, and none was held.

Background and Purpose

On May 3, 2004, the Wisconsin Department of Transportation requested a temporary change to the operation of the Prescott Highway Bridge across the St. Croix River, Mile 0.3, at Prescott, Wisconsin, to allow the drawbridge to remain in the closed-to-navigation position for a 5-month period while the electrical and hydraulic systems are overhauled. Navigation on the waterway consists of both commercial (excursion boat) and recreational watercraft, which may be minimally impacted by the closure period. Currently, the draw opens on signal for passage of river traffic from April 1 to October 31, 8 a.m. to midnight, except that from midnight to 8 a.m. the draw shall open on signal if notification is made prior to 11 p.m. From November 1 to March 31, the draw shall open on signal if at least 24 hours notice is given. The Wisconsin Department of Transportation requested the drawbridge be permitted to remain closed to navigation from November 1, 2005, to April 1, 2006.

Discussion of Comments and Changes

The Coast Guard received no comment letters. No changes will be made to this final rule.

Regulatory Evaluation

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. It is not “significant” under the regulatory policies and procedures of the Department of Homeland Security (DHS).

The Coast Guard expects this temporary change to operation of the Prescott Highway Bridge to have minimal economic impact on commercial traffic operating on the St. Croix River such that a full regulatory evaluation under the regulatory policies and procedures of DHS is unnecessary. This temporary change will cause minimal interruption of the drawbridge’s regular operation, since the change is only in effect during the winter months while the river is frozen.