

3. Section 803.10 is amended by revising paragraph (b) and by removing paragraph (c)(5) to read as follows:

§ 803.10 General description of reports required from user facilities, importers, and manufacturers.

* * * * *

(b) *Device importers.* Importers must submit the following reports, which are described more fully in subpart D of this part.

(1) Importers must submit MDR reports of individual adverse events within 30 days after the importer becomes aware of an MDR reportable event as described in §§ 803.40 and 803.42.

(i) Importers must submit reports of device-related deaths or serious injuries to FDA and to the manufacturer.

(ii) Importers must submit reports of malfunctions to the manufacturer.

(2) [Reserved]

* * * * *

4. Section 803.17 is amended by revising paragraph (b)(3) to read as follows:

§ 803.17 Written MDR procedures.

* * * * *

(b) * * *

(3) Any information that was evaluated for the purpose of preparing the submission of annual reports; and

* * * * *

5. Section 803.19 is amended by revising paragraph (a)(2) to read as follows:

§ 803.19 Exemptions, variances, and alternative reporting requirements.

(a) * * *

(2) An individual who manufactures devices intended for use in humans solely for such person's use in research or teaching and not for sale, including any person who is subject to alternative reporting requirements under the investigational device exemption regulations, part 812 of this chapter, which require reporting of all adverse device effects.

* * * * *

6. Section 803.20 is amended by revising the introductory text of paragraph (a), and paragraphs (a)(2) and (c)(1) to read as follows:

§ 803.20 How to report.

(a) *Description of form.* There are two versions of the MEDWATCH form for individual reports of adverse events. FDA Form 3500 is available for use by health professionals and consumers for the submission of voluntary reports regarding FDA-regulated products. FDA Form 3500A is the mandatory reporting form to be used for submitting reports

by user facilities, importers, and manufacturers of FDA-regulated products. The form has some sections that must be completed by all reporters and other sections that must be completed only by the user facility, importer, or manufacturer.

* * * * *

(2) The back part of the form contains sections to be completed by user facilities, importers, and manufacturers. User facilities and importers must complete section F; device manufacturers must complete sections G and H. Manufacturers are not required to recopy information submitted to them on a Form 3500A unless the information is being copied onto an electronic medium. If the manufacturer corrects or supplies information missing from the other reporter's 3500A form, it should attach a copy of that form to the manufacturer's report form. If the information from the other reporter's 3500A form is complete and correct, the manufacturer can fill in the remaining information on the same form.

* * * * *

(c) *Information that reasonably suggests a reportable event occurred.* (1) Information that reasonably suggests that a device has or may have caused or contributed to an MDR reportable event (i.e., death, serious injury, and, for manufacturers and importers, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur) includes any information, such as professional, scientific or medical facts and observations or opinions, that would reasonably suggest that a device has caused or may have caused or contributed to a reportable event.

* * * * *

7. Section 803.50 is amended by revising paragraphs (b)(1)(i) and (b)(2) to read as follows:

§ 803.50 Individual adverse event reports; manufacturers.

* * * * *

(b) * * *

(1) * * *

(i) Any information that can be obtained by contacting a user facility, importer, or other initial reporter;

* * * * *

(2) Manufacturers are responsible for obtaining and providing FDA with information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. Manufacturers are also responsible for conducting an investigation of each event and evaluating the cause of the event. If a manufacturer cannot provide complete

information on an MDR report, it must provide a statement explaining why such information was incomplete and the steps taken to obtain the information. Any required information not available at the time of the report, which is obtained after the initial filing, must be provided by the manufacturer in a supplemental report under § 803.56.

8. Section 803.52 is amended by revising paragraphs (d)(1), (f)(11)(i), and (f)(11)(ii) to read as follows:

§ 803.52 Individual adverse event report data elements.

* * * * *

(d) * * *

(1) Name, address, and phone number of the reporter who initially provided information to the user facility, manufacturer, or importer;

* * * * *

(f) * * *

(11) * * *

(i) Any information missing on the user facility report or importer report, including missing event codes, or information corrected on such forms after manufacturer verification;

(ii) For each event code provided by the user facility under § 803.32(e)(10) or the importer under § 803.42(e)(10), a statement of whether the type of event represented by the code is addressed in the device labeling; and

* * * * *

§ 803.58 [Amended]

9. Section 803.58 *Foreign manufacturers* is amended by removing paragraph (b)(3) and by redesignating paragraphs (b)(4), (b)(5), and (b)(6) as paragraphs (b)(3), (b)(4), and (b)(5), respectively.

Dated: April 18, 2001.

Linda S. Kahan,

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

[FR Doc. 01-11449 Filed 5-7-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD01-01-054]

RIN 2115-AE47

Drawbridge Operation Regulations: Harlem River, Newtown Creek, NY

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary final rule

governing the operation of the Third Avenue Bridge, mile 1.9, across the Harlem River between Manhattan and the Bronx; the Madison Avenue Bridge, mile 2.3, across the Harlem River between Manhattan and the Bronx; and the Pulaski Bridge, mile 0.6, across Newtown Creek between Brooklyn and Queens. This temporary final rule authorizes the bridge owner to close the above bridges on May 6, 2001, at different times of short duration to facilitate the running of the Five Borough Bike Tour. Vessels that can pass under the bridges without a bridge opening may do so at any time.

DATES: This temporary final rule is effective only on Sunday, May 6, 2001.

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 docket (CGD01-01-054) 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: Mr. Joseph Arca, Project Officer, First Coast Guard District, (212) 668-7165.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard has determined that good cause exists under the Administrative Procedure Act (5 U.S.C. 553) to forego notice and comment for this rulemaking because notice and comment are unnecessary. The Coast Guard believes notice and comment are unnecessary because the requested closures are of such short duration on a Sunday when there have been few requests to open these bridges. The Harlem River and Newtown Creek is used mostly by commercial vessels and those vessels normally pass under the draws without openings. The commercial vessels that do require openings are work barges that do not operate on Sundays. The Coast Guard, for the reasons just stated, has also determined that good cause exists for this rule to be effective less than 30 days after it is published in the **Federal Register**.

Background

Third Avenue Bridge

The Third Avenue Bridge, mile 1.9, across the Harlem River between Manhattan and the Bronx, has a vertical clearance of 25 feet at mean high water and 30 feet at mean low water in the closed position. The existing operating regulations listed at § 117.789(c) require

the draw to open on signal from 10 a.m. to 5 p.m., if at least a four-hour notice is given. From 5 p.m. to 10 a.m., the draw need not be opened for vessel traffic.

Madison Avenue Bridge

The Madison Avenue Bridge, mile 2.3, across the Harlem River between Manhattan and the Bronx, has a vertical clearance of 25 feet at mean high water and 29 feet at mean low water in the closed position. The existing operating regulations listed at § 117.789(c) require the draw to open on signal from 10 a.m. to 5 p.m., if at least a four-hour notice is given. From 5 p.m. to 10 a.m., the draw need not be opened for vessel traffic.

Pulaski Bridge

The Pulaski Bridge, mile 0.6, across the Newtown Creek between Brooklyn and Queens, has a vertical clearance of 39 feet at mean high water and 43 feet at mean low water in the closed position. The existing operating regulations listed at 117.801(g) require the draw to open on signal, if at least a two-hour advance notice is given. The Coast Guard published a temporary final rule on March 23, 2001, entitled Drawbridge operation regulations, New York, (66 FR 16128) which allows the Pulaski Bridge, to need open only one bascule span for the passage of vessel traffic, from April 23, 2001 through August 31, 2001.

The New York City Department of Transportation (NYCDOT) requested a change to the operating regulations for the Third Avenue Bridge, the Madison Avenue Bridge, and the Pulaski Bridge on May 6, 2001, to allow the bridges to remain in the closed position to facilitate the running of the Five Borough Bike Tour.

The Third Avenue Bridge, mile 1.9, across the Harlem River between Manhattan and the Bronx and the Madison Avenue Bridge, mile 2.3, across the Harlem River between Manhattan and the Bronx, shall remain in the closed position from 8 a.m. to 12 p.m. on May 6, 2001. The Pulaski Bridge, mile 0.6, across the Newtown Creek between Brooklyn and Queens, shall remain in the closed position from 9:30 a.m. to 1:30 p.m. on May 6, 2001. Vessels that can pass under the bridges without bridge openings may do so at all times.

Regulatory Evaluation

This 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 not reviewed it 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). This conclusion is based on the fact that the requested closures are of short duration and on Sunday morning when there have been few requests to open these bridges.

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. "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 the requested closures are of short duration and on Sunday when there have been few requests to open these bridges.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 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. 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

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 unfunded mandate 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

The Coast Guard considered the environmental impact of this rule and concluded that under figure 2–1, paragraph (32)(e) of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation because promulgation of changes to drawbridge regulations have been found to not have a significant effect on the environment. A written "Categorical Exclusion Determination" is not required for the temporary final rule.

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.

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; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. In § 117.789, from 8 a.m. through 12 p.m. on May 6, 2001, paragraph (c) is temporarily suspended and a new paragraph (g) is added to read as follows:

§ 117.789 Harlem River

* * * * *

(g) The draws of the Third Avenue Bridge, mile 1.9, and the Madison Avenue Bridge, mile 2.3, across the Harlem River between Manhattan and the Bronx, need not open for vessel traffic on May 6, 2001, from 8 a.m. to 12 p.m.

3. In section 117.801, from 9:30 a.m. through 1:30 p.m. on May 6, 2001, paragraph (g) and (h) are suspended and a new paragraph (i) is added to read as follows:

§ 117.801 Newtown Creek, Dutch Kills, English Kills, and their tributaries.

* * * * *

(i) The draw of the Pulaski Bridge, mile 0.6, across the Newtown Creek between Brooklyn and Queens, need not open for vessel traffic, on May 6, 2001, from 9:30 a.m. to 1:30 p.m.

Dated: April 19, 2001.

G.N. Naccara,

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

[FR Doc. 01–11493 Filed 5–7–01; 8:45 am]

BILLING CODE 4910–15–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR PART 117

[CGD08–01–007]

RIN 2115–AE47

Drawbridge Operating Regulation; Ouachita River, LA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the regulation governing the operation of the Kansas

City Southern Railroad swing span bridge across the Ouachita River, mile 167.1, at Monroe, Ouachita Parish, Louisiana. This rule allows for the passage of vessels from June 4, 2001, through November 15, 2001 during the morning hours with proper advance notice. This rule is issued to facilitate the repairs to the turn span of the bridge. Normally, the draw opens on signal at all times.

DATES: This rule is effective from June 4, 2001, through November 15, 2001.

ADDRESSES: Comments and materials received from the public, as well as documents indicated in this preamble as being available in the docket, will be available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, Hale Boggs Federal Building, Room 1313, 501 Magazine Street, New Orleans, Louisiana 70130–3396 between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. David Frank, Bridge Administration Branch, Commander (ob), Eighth Coast Guard District, telephone number 504–589–2965.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On March 30, 2001, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operating Regulation; Ouachita River, Louisiana, in the **Federal Register** (66 FR 17376). We received one letter commenting on the proposed rule. No public hearing was requested, and none was held.

Background and Purpose

The Kansas City Southern Railroad has submitted plans to repair the turn span of the swing span bridge across the Ouachita River, mile 167.1, at Monroe. To facilitate the continued movement of trains across the bridge during the repairs, the railroad plans to remove the swing span and temporarily replace it with a removable span bridge with 70 feet of horizontal clearance. The railroad has requested limited openings during the repair period of May 7, 2001 through November 30, 2001. Frequent need to remove and replace the span will severely limit the railroad's ability to complete the repairs in a timely manner.

Discussions were held between the railroad, its contractor, waterway users, and facility operators to determine the best method of allowing vessels to transit the waterway during the repair period. The discussions centered on the mariner's ability to transit the bridge site on any day if proper notification was given. The railroad only wanted to