

48. Section 888.3650 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 888.3650 Shoulder joint metal/polymer non-constrained cemented prosthesis.

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(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards

Organization's:

(i) ISO 10993 "Biological Evaluation of Medical Devices Part I: Evaluation and Testing,"

(ii) ISO 5832 "Implants for Surgery—Metallic Materials,"

(iii) ISO 5833 "Implants for Surgery—Acrylic Resin Cements,"

(iv) ISO 5834 "Implants for Surgery—Ultra High Molecular Weight Polyethylene,"

(v) ISO 9001 "Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing," and

(vi) ISO 6018 "General Requirements for Marketing, Packaging, and Labeling,"

(2) FDA's:

(i) "510(k) Sterility Review Guidance and Revision of 11/18/94 K90-1,"

(ii) "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,"

(iii) "Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Orthopedic Devices," and

(iv) "Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components,"

(3) American Society for Testing and Materials':

(i) F75-92 "Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Material,"

(ii) F799-96 "Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,"

(iii) F1108-97 "Ti6Al4V Alloy Castings for Surgical Implants,"

(iv) F648-96 "Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,"

(v) F1537-94 "Specification for Wrought Cobalt-Chromium-Molybdenum Alloy for Surgical Implants,"

(vi) F1044 "Test Method for Shear Testing of Porous Metal Coatings,"

(vii) F1147 "Test Method for Tension Testing of Porous Metal Coatings," and

(viii) F1378 "Specification for Shoulder Prosthesis."

49. Section 888.3660 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.

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(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards

Organization's:

(i) ISO 10993 "Biological Evaluation of Medical Devices Part I: Evaluation and Testing,"

(ii) ISO 5832 "Implants for Surgery—Metallic Materials,"

(iii) ISO 5833 "Implants for Surgery—Acrylic Resin Cements,"

(iv) ISO 5834 "Implants for Surgery—Ultra High Molecular Weight Polyethylene,"

(v) ISO 9001 "Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing," and

(vi) ISO 6018 "General Requirements for Marketing, Packaging, and Labeling,"

(2) FDA's:

(i) "510(k) Sterility Review Guidance and Revision of 11/18/94 K90-1,"

(ii) "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,"

(iii) "Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Orthopedic Devices," and

(iv) "Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components," and

(3) American Society for Testing and Materials':

(i) F75-92 "Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Material,"

(ii) F799-96 "Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,"

(iii) F1108-97 "Specification for Ti6Al4V Alloy Castings for Surgical Implants,"

(iv) F648-96 "Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,"

(v) F1537-94 "Specification for Wrought Cobalt-Chromium-Molybdenum Alloy for Surgical Implants,"

(vi) F1044 "Test Method for Shear Testing of Porous Metal Coatings,"

(vii) F1147 "Test Method for Tension Testing of Porous Metal Coatings," and

(viii) F1378 "Standard Specification for Shoulder Prosthesis."

Dated: March 1, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD08-99-007]

RIN 2115-AE47

Drawbridge Operation Regulation; Inner Harbor Navigation Canal, LA

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to temporarily change the regulation for the operation of the draw of the L & N Railroad/Old Gentilly Road bascule span drawbridge across the Inner Harbor Navigation Canal, mile 2.9 at New Orleans, Orleans Parish, Louisiana. This proposal would allow the draw of the L&N Railroad/Old Gentilly Road bascule span drawbridge to remain closed to navigation daily from 8 a.m. until noon and from 1 p.m. until 5 p.m. from May 17 through May 28, 1999, June 1 through July 2, 1999, July 6 through September 3, 1999 and from September 7 through September 22. This proposed temporary rule will allow for replacement of the damaged fender system, an extensive but necessary maintenance operation. Presently, the draw opens on signal at all times.

DATES: Comments must be received on or before April 29, 1999.

ADDRESSES: Unless otherwise indicated, documents referred to in this notice are 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 4 p.m., Monday through Friday, except Federal holidays. Comments should also be submitted to the same address. The Bridge Administration Branch of the Eighth Coast Guard District maintains the public docket for this proposed temporary rule.

FOR FURTHER INFORMATION CONTACT: Phil Johnson, Bridge Administration Branch, at the address given above. Telephone (504) 589-2965.

SUPPLEMENTARY INFORMATION:

Requests for Comments

The Coast Guard encourages interested parties to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify this rulemaking (CGD 08-99-007) and the specific section of this document to

which each comment applies, and give the reason for each comment. Please submit two copies of all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgement of receipt of comments should enclose stamped, self-addressed postcards or envelopes.

The Coast Guard will consider all comments received during the comment period. It may change this proposed rule in view of the comments.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Eighth Coast Guard District, Bridge Administration Branch at the address under **ADDRESSES**. The request should include the reasons why a hearing would be beneficial. If it is determined that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register**. The comment period will be limited to 45 days because the rule needs to be effective by May 15, 1999.

The L&N Railroad/Old Gentilly Road bascule span drawbridge across the inner Harbor Navigation Canal, mile 2.9, in New Orleans, Louisiana has a vertical clearance of one foot above mean high water in the closed-to-navigation position and unlimited in the open-to-navigation position. Navigation on the waterway consists of tugs with tows, small ships, fishing vessels, sailing vessels and other recreational craft. The Board of Commissioners of the Port of New Orleans requested a proposed temporary rule for the operation of the drawbridge to accommodate maintenance work, involving removing portions of the existing damaged fender system, driving new pilings and replacing the timbers. This work is essential for continued safe transit of vessels through the bridge. This proposal would allow the draw of the L&N Railroad/Old Gentilly Road bascule span drawbridge to operate as follows: From May 17 through May 28, 1999, June 1 through July 2, 1999, July 6 through September 3, 1999 and from September 7 through September 22, 1999 the draw need not open for the passage of vessels from 8 a.m. until noon and from 1 p.m. until 5 p.m.

In the event of an approaching tropical storm or hurricane, the draw will return to normal operation within 12 hours notice from the Coast Guard. Presently, the draw opens on signal at any time.

Regulatory Evaluation

This proposed temporary rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential cost and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and Budget 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 proposed temporary rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This is because the number of vessels affected by the closure is minimal. Commercial vessels, sailboats and most of the other recreational craft which normally transit the bridge will be able to do so between the hours of 5 p.m. and 8 a.m. and during the one-hour, mid-day opening between noon and 1 p.m.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Coast Guard must consider whether this proposed temporary rule will have a significant economic impact on a substantial number of small entities. "Small entities" may 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. Commercial vessels and fishing vessels which normally transit the causeway bridge will still be able to do so between the hours of 5 p.m. and 8 a.m. and during the one hour mid-day opening between noon and 1 p.m. Thus, the Coast Guard expects there to be no significant impact on these vessels. The Coast Guard is not aware of any other waterway users who would suffer economic hardship from being unable to transit the waterway during these closure periods. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposed temporary rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This proposed temporary rule contains no collection-of-information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

Federalism

The Coast Guard has analyzed this proposal under the principles and

criteria contained in Executive Order 12612, and it has been determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this proposed temporary rule and concluded that this action is categorically excluded from further environmental documentation under current Coast Guard (CE # 32(e), in accordance with Section 2.B.2 and Figure 2-1 of the National Environmental Protection Act Implementing Procedures, COMDTINST M16475.1C. A "Categorical Exclusion Determination" is available in the docket for inspection or copying where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons set out in the preamble, the Coast Guard proposes to amend Part 117 of Title 33 Code of Federal Regulations 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; and 33 CFR 1.05-1(g); section 117.255 also issued under the authority of Pub. L. 102-587, 106 Stat. 5039.

2. Effective from May 17, 1999 through September 22, 1999 § 117.458 is amended by adding a new paragraph (c) to read as follows:

§ 117.458 Inner Harbor Navigation Canal, New Orleans.

* * * * *

(c) The draw of the L&N Railroad/Old Gentilly Road bridge, mile 2.9, shall operate as follows: From May 17 through May 28, 1999, June 1 through July 2, 1999, July 6 through September 3, 1999 and from September 7 through September 22, 1999 the draw need not open for the passage of vessels from 8 a.m. until noon and from 1 p.m. until 5 p.m. At all other times the bridge opens on signal. In the event of an approaching tropical storm or hurricane, the bridge will be returned to normal operation within 12 hours of notification by the Coast Guard.

Dated: March 1, 1999.

Paul J. Pluta,
Rear Admiral, U.S. Coast Guard Commander,
Eighth Coast Guard District.

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