

**§ 211.103 Calculation of yield.**

Actual yields and percentages of theoretical yield shall be determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product. Such calculations shall either be performed by one person and independently verified by a second person, or, if the yield is calculated by automated equipment under § 211.68, be independently verified by one person.

13. Section 211.110 is amended by revising paragraph (a) introductory text and by adding paragraph (a)(6) to read as follows:

**§ 211.110 Sampling and testing of in-process materials and drug products.**

(a) To assure batch uniformity and integrity of drug products, written procedures shall be established and followed that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch. Such control procedures shall be established to monitor the output and to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. Such control procedures shall include, but are not limited to, the following, where appropriate:

\* \* \* \* \*

(6) Bioburden testing.

\* \* \* \* \*

14. Section 211.113 is amended by revising paragraph (b) to read as follows:

**§ 211.113 Control of microbiological contamination.**

\* \* \* \* \*

(b) Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and sterilization processes.

15. Section 211.160 is amended by revising paragraph (b)(1) to read as follows:

**§ 211.160 General requirements.**

\* \* \* \* \*

(b) \* \* \*

(1) Determination of conformity to applicable written specifications for the acceptance of each lot within each shipment of components, drug product containers, closures, and labeling used in the manufacture, processing, packing, or holding of drug products. The specifications shall include a description of the sampling and testing procedures used. Samples shall be

representative and adequately identified. Such procedures shall also require appropriate retesting of any component, drug product container, or closure that is subject to deterioration.

\* \* \* \* \*

16. Section 211.182 is revised to read as follows:

**§ 211.182 Equipment cleaning and use log.**

A written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use shall be included in individual equipment logs that show the date, time, product, and lot number of each batch processed. If equipment is dedicated to manufacture of one product, then individual equipment logs are not required, provided that lots or batches of such product follow in numerical order and are manufactured in numerical sequence. In cases where dedicated equipment is employed, the records of cleaning, maintenance, and use shall be part of the batch record. The persons performing and double-checking the cleaning and maintenance (or, if the cleaning and maintenance is performed using automated equipment under § 211.68, just the person verifying the cleaning and maintenance done by the automated equipment) shall date and sign or initial the log indicating that the work was performed. Entries in the log shall be in chronological order.

17. Section 211.188 is amended by revising paragraph (b)(11) to read as follows:

**§ 211.188 Batch production and control records.**

\* \* \* \* \*

(b) \* \* \*

(11) Identification of the persons performing and directly supervising or checking each significant step in the operation, or if a significant step in the operation is performed by automated equipment under § 211.68, the identification of the person checking the significant step performed by the automated equipment.

\* \* \* \* \*

Dated: November 26, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 117**

[Docket No. USCG-2007-0096]

RIN 1625-AA09

**Drawbridge Operation Regulations; Pinellas Bayway Structure "E" (SR 679) Bridge, Gulf Intracoastal Waterway, mile 113, St. Petersburg Beach, Pinellas County, FL**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to change the drawbridge regulation of the Pinellas Bayway Structure "E" (SR 679) Bridge, Gulf Intracoastal Waterway, mile 113, St. Petersburg Beach, Pinellas County, Florida. This rule is needed to provide vehicular traffic relief during heavy vehicular traffic periods flowing into a nearby county park while still meeting the reasonable needs of mariners.

**DATES:** Comments and related material must reach the Coast Guard on or before January 18, 2008.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number USCG-2007-0096 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) Online: <http://www.regulations.gov>.

(2) Mail: Docket Management Facility (M-30), U.S. Department of Transportation, West Building, Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001.

(3) Hand delivery: Room W12-140 on the Ground Floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(4) Fax: 202-493-2251.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this proposed rule, call Michael Lieberum, Seventh Coast Guard District, Bridge Branch, telephone number 305-415-6744. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

**SUPPLEMENTARY INFORMATION:**

### Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to <http://www.regulations.gov> and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's "Privacy Act" paragraph below.

### Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG-2007-0096), indicate the specific section of this document to which each comment applies, and give the reason for each comment. We recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, 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 them.

### Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov> at any time, click on "Search for Dockets," and enter the docket number for this rulemaking (USCG-2007-0096) in the Docket ID box, and click enter. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

### Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or

signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit <http://DocketsInfo.dot.gov>.

### Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to the Bridge Branch, Seventh 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 at a time and place announced by a later notice in the **Federal Register**.

### Background and Purpose

The Pinellas Bayway Structure "E" (SR 679) Bridge, Gulf Intracoastal Waterway, mile 113, St. Petersburg Beach, Pinellas County, Florida, currently opens on signal; except that, from 9 a.m. to 7 p.m. the draw need only open on the hour, 20 minutes after the hour, and 40 minutes after the hour. The bridge provides vehicular access into and out of a popular county park.

At the request of Florida State Representative Frishe's office, who is acting on behalf of local citizens, the Coast Guard is proposing this regulation that will require the Pinellas Bayway "E" Bridge to open on signal, except that from 7 a.m. to 9 p.m. the bridge will open on the hour and half-hour. Public vessels of the United States, tugs with tows and vessels in distress shall be allowed to pass on signal.

### Discussion of Proposed Rule

Under this proposed rule, the draw of the Pinellas Bayway Structure "E" Bridge would be required to open on signal, except that from 7 a.m. to 9 p.m. the bridge would only need to open on the hour and half-hour. The draw would be required to open, upon proper signal, for the passage of tugs with tows, public vessels of the United States and vessels in a situation where a delay would endanger life or property.

This proposed rule is expected to provide vehicular traffic relief during heavy traffic periods by allowing two openings an hour instead of the current three openings an 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.

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation is unnecessary, because the rule would allow for scheduled bridge openings of this drawbridge and all waterway restrictions or closure times would be published with adequate time for mariners to plan accordingly.

### 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, as the rule will allow for scheduled bridge openings.

This proposed rule would affect the following entities, some of which may be small entities: The owners or operators of vessels needing to transit the Gulf Intracoastal Waterway in the vicinity of the Pinellas Bayway Structure "E" Bridge, persons intending to drive over the bridge, and nearby business owners. The revision to the opening schedule would not have a significant impact on a substantial number of small entities. Vehicle traffic and small business owners in the area may benefit from the improved traffic flow that regularly scheduled openings will offer this area. Although bridge openings would be less frequent, vessel traffic would still be able to transit the Gulf Intracoastal Waterway on the hour and half-hour between 7 a.m. until 9 p.m.

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 the Seventh Coast Guard District Bridge Branch at the address under ADDRESSES. 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 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 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.ID which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321-4370f), and have made a preliminary determination that this action is not likely to have a significant effect on the human environment because it simply promulgates the operating regulations or procedures for drawbridges. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

**List of Subjects in 33 CFR Part 117**

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

2. Revise § 117.287(d)(4) to read as follows:

\* \* \* \* \*

**§ 117.287 Gulf Intracoastal Waterway.**

(d)(4) Pinellas Bayway Structure "E" (SR 679) bridge, mile 113.0 at St. Petersburg Beach. The draw shall open on signal, except that from 9 a.m. to 7 p.m. the draw need open only on the hour and 30 minutes past the hour.

\* \* \* \* \*

Dated: November 21, 2007.

**William Lee,**  
*CAPT, USCG, Acting D7 District Commander.*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

**[EPA-R07-OAR-2007-1055; FRL-8502-1]**

**Approval and Promulgation of Implementation Plans; State of Missouri; General Conformity**

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve a revision to the Missouri State Implementation Plan (SIP) to amend the