

million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

XI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

XII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

FDA also tentatively concludes that the draft special controls guidance document does not contain new information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the draft guidance document entitled “Class II Special Controls Guidance: Topical Oxygen Chamber for Extremities”; the notice contains an analysis of the paperwork burden for the draft guidance.

XIII. Comments

Interested persons may submit to the Division of Dockets Management Branch (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.

XIV. References

The following references have been placed on display in the Division of

dockets management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

1. 515(i) Submission submitted by Gaymar Industries, Inc., Orchard Park, NY, dated August 4, 1997, received August 11, 1997.

2. 515(i) Submission submitted by Stephen's Medical Inc./Wound Cure, Inc., Northbrook, IL, dated August 11, 1997, received August 12, 1997.

3. General and Plastic Surgery Devices Panel, Transcript, November 17, 1998, pages 120–201.

4. Heng, M.C.Y., J. Harker, V.B. Bardakjian, and H. Ayvazian, “Enhanced Healing and Cost-Effectiveness of Low Pressure Oxygen Therapy in Healing Necrotic Wounds: A feasibility study of technology transfer,” *Ostomy Wound Management*, 46: 52–60, 2000.

5. Heng, M.C.Y., J. Harker, G. Csathy, C. Marshall, J. Brazier, S. Socorro, and E.P. Gomez, “Angiogenesis in Necrotic Ulcers Treated with Hyperbaric Oxygen,” *Ostomy Wound Management*, 46: 18–32, 2000.

6. Kalliainen, L.K., G.M. Gordillo, R. Schlanger, and C.K. Sen, “Topical oxygen as an adjunct to wound healing: a clinical case series,” *Pathophysiology* 9: 81–87, 2003.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 878 be amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:

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

2. Section 878.5650 is revised in Subpart F to read as follows:

§ 878.5650 Topical oxygen chamber for extremities.

(a) *Identification.* A topical oxygen chamber for extremities is a device that is intended to surround a patient's limb and apply humidified oxygen topically at a pressure slightly greater than atmospheric pressure to aid healing of chronic skin ulcers such as bedsores.

(b) *Classification.* Class II (special controls). The special control for the device is FDA's “Class II Special Controls Guidance: Topical Oxygen Chamber for Extremities.” See § 878.1(e) for the availability of this guidance document.

Dated: March 27, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–4962 Filed 4–5–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD05–06–017]

RIN 1625–AA09

Drawbridge Operation Regulations; Atlantic Intracoastal Waterway (Alternate Route), Dismal Swamp Canal, NC

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish regulations that govern the operation of the new Dismal Swamp Canal Bridge, at the Alternate Route of the Atlantic Intracoastal Waterway (AICW) mile 28.0, in South Mills, NC. The proposed regulations will maintain a level of operational capabilities that will continue to provide for the reasonable needs of the North Carolina Department of Parks and Recreation Visitor Center, at Dismal Swamp, and vessel navigation.

DATES: Comments and related material must reach the Coast Guard on or before June 5, 2006.

ADDRESSES: You may mail comments and related material to Commander (obr), Fifth Coast Guard District, Federal Building, 4th 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: Bill H. Brazier, Bridge Management Specialist, Fifth Coast Guard District, at (757) 398–6422.

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 CGD05–06–017, 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 at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The North Carolina Department of Parks and Recreation (NC Parks and Recreation) will own and operate this proposed new swing-type bridge at the Alternate Route of the AICW mile 28.0 across Dismal Swamp Canal. This proposed rule will allow the Dismal Swamp Canal Bridge to remain open to vessel traffic, closing only for pedestrian crossings and periodic maintenance. This proposed rule will also allow the Dismal Swamp Canal Bridge to be operated from a remote location at the Dismal Swamp Visitors Center.

NC Parks and Recreation has installed closed circuit cameras in the area of the bridge mounted on the fender systems on both sides. Infrared sensors have also been installed to cover the swing radius of the bridge. This equipment enhances the controller's ability to monitor vessel traffic from the remote location. The controller will also monitor marine channel 13.

The proposed rule will require the draw to remain in the open-to-navigation position and only close to allow pedestrians (visitors to the park) to cross the bridge, and for periodic maintenance, and then the bridge will immediately reopen to navigation once the pedestrians have crossed the bridge. This will provide for an even flow of vessel traffic along the Dismal Swamp.

Discussion of Proposed Rule

The Coast Guard proposes to adopt new regulations to govern the operation of the Dismal Swamp Canal Bridge, at mile 28.0, in South Mills, NC. The Coast Guard proposes to insert this new specific regulation at 33 CFR § 117.820. The rule will allow the draw of the bridge to be remotely-operated by Park Service Rangers at the Dismal Swamp Visitors Center.

The draw will remain in the open position for navigation and shall only be

closed for the crossing of pedestrians and periodic maintenance authorized in accordance with 33 CFR Subpart A.

Before the Dismal Swamp Visitor Center Bridge closes for any reason, the remote operator will monitor waterway traffic in the area. The bridge will only be closed if the operator's visual inspection shows that the channel is clear and there are no vessels transiting in the area.

While the Dismal Swamp Visitor Center Bridge is moving from the full open to the full closed position, the operator will maintain constant surveillance of the navigation channel to ensure that no conflict with maritime traffic exists.

In the event of failure or obstruction of monitoring equipment, the operator will stop and return the bridge to the full open position to vessels.

Before closing the draw, the channel traffic lights will change from flashing green to flashing red and the horn will sound five short blasts. Five short blasts of the horn will continue until the bridge is seated and locked down to vessels, the channel traffic lights will continue to flash red.

When pedestrian traffic has cleared, the horn will automatically sound one prolonged blast followed by one short blast to indicate that the draw of the Dismal Swamp Canal Bridge is about to return to its full open position to vessels. During the open swing movement, the channel traffic lights will flash red until the bridge is in the full open position. In the full open position to vessels, the bridge channel lights will flash green.

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. Although the Dismal Swamp Canal Bridge will be untended and operated from a remote location, mariners can continue their transits

because the bridge will remain open to mariners, only to be closed for pedestrian crossings or periodic maintenance.

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 for the following reason. The rule allows the Dismal Swamp Canal Bridge to operate remotely and requires the bridge to remain in the open position to vessels the majority of the time, only closing for pedestrian crossings or periodic maintenance.

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. 04–121), 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); § 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. Add new § 117.820 immediately following the undesignated center heading North Carolina to read as follows:

§ 117.820 Atlantic Intracoastal Waterway (Alternate Route), Dismal Swamp Canal.

The draw of the Dismal Swamp Canal Bridge, mile 28.0 at South Mills, NC, shall operate as follows:

(a) The draw shall remain in the open position for navigation. The draw shall only be closed for pedestrian crossings or periodic maintenance authorized in accordance with Subpart A of this part.

(b) The bridge shall be remotely operated by the Park Service Rangers at the Dismal Swamp Visitors Center.

The remote operator shall monitor vessel traffic with closed circuit cameras and infrared sensors covering the swing radius. Operational information will be provided 24 hours a day on marine channel 13.

(c) The bridge shall not be operated from the remote location in the following events: Failure or obstruction of the infrared sensors, closed-circuit cameras or marine-radio communications, or when remote operator's visibility is impaired.

(d) Before the bridge closes for any reason, the remote operator will monitor waterway traffic in the area. The bridge shall only be closed if the off-site remote operator's visual inspection shows that the channel is clear and there are no vessels transiting in the area. While the bridge is moving, the operator shall maintain constant surveillance of the navigation channel.

(e) Before closing the draw, the channel traffic lights will change from flashing green to flashing red, the horn will sound five short blasts. Five short blasts of the horn will continue until the bridge is seated and locked down to vessels, the channel traffic lights will continue to flash red.

(f) When pedestrian traffic has cleared, the horn will automatically sound one prolonged blast followed by one short blast to indicate the draw is opening to vessel traffic. During the

opening swing movement, the channel traffic lights will flash red until the bridge returns to the fully open position. In the full open position to vessels, the bridge channel lights will flash green.

Dated: March 23, 2006.

L.L. Hereth,

*Rear Admiral, United States Coast Guard,
Commander, Fifth Coast Guard District.*

[FR Doc. E6-4899 Filed 4-5-06; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01-06-024]

RIN 1625-AA09

Drawbridge Operation Regulations; Chelsea River, Chelsea, MA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to temporarily change the drawbridge operation regulations governing the operation of the P.J. McArdle Bridge, across the Chelsea River at mile 0.3, between East Boston and Chelsea, Massachusetts. This proposed rule would allow the bridge to remain closed from 9 a.m. to 5 p.m. on June 17, 2006, to facilitate the Third Annual Chelsea River Revel Festival and the running of the Chelsea River Revel 5K Road Race. Vessels that can pass under the bridge without a bridge opening may do so at all times.

DATES: Comments and related material must reach the Coast Guard on or before May 8, 2006.

ADDRESSES: You may mail comments and related material to Commander (dpb), First Coast Guard District Bridge Branch, 408 Atlantic Avenue, Boston, Massachusetts, 02110, or deliver them to the same address between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (617) 223-8364. The First Coast Guard District, Bridge Branch, 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 the First Coast Guard District, Bridge Branch, 7 a.m. to 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. John McDonald, Project Officer, First Coast Guard District, (617) 223-8364.

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 (CGD01-06-024), 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 to know if they reached us, 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.

Public Meeting

We do not now plan to hold a public meeting; however, you may submit a request for a meeting by writing to the First Coast Guard District, Bridge Branch, 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 P.J. McArdle Bridge across the Chelsea River at mile 0.3, has a vertical clearance of 21 feet at mean high water and 30 feet at mean low water in the closed position. The existing drawbridge operation regulations listed at 33 CFR 117.593 require the bridge to open on signal at all times.

On March 6, 2006, the Chelsea Creek Action Group (CCAG) requested a temporary change to the regulation that governs the operation of the P.J. McArdle Bridge. The temporary regulation would allow the bridge to remain closed to vessel traffic from 9 a.m. to 5 p.m. on Saturday, June 17, 2006, in the interest of public safety during the Third Annual Chelsea River Revel Festival and 5K Road Race.

Vessels that can pass under the bridge without a bridge opening may do so at all times.

Discussion of Proposed Rule

This proposed change would suspend § 117.593 and temporarily add a new § 117.T594.

The P.J. McArdle Bridge would remain in the closed position from 9

a.m. to 5 p.m. in the interest of public safety during the Third Annual Chelsea River Revel Festival and the running of the Chelsea River Revel 5K Road Race.

The 5K Road Race does not actually cross over the bridge; however, the Chelsea River passes through the middle of the festival which takes place on both sides of the Chelsea River in East Boston and Chelsea.

A large volume of pedestrian traffic is anticipated to cross over the bridge during the festival.

It would not be in the best interest of public safety and the coordination of this public event to have the bridge open during the time period this event is in progress.

The Chelsea River is predominantly transited by commercial tugs, barges, oil tankers. The Coast Guard coordinates this closure annually with the oil facilities and the one recreational marina which are upstream from the bridge.

This temporary rule is expected to meet the present and anticipated needs of navigation.

Under this proposed temporary rule, all drawbridges across the Chelsea River would open on signal; except that the P.J. McArdle Bridge, at mile 0.3, would need not open for the passage of vessel traffic from 9 a.m. to 5 p.m. on June 17, 2006.

The opening signal for each drawbridge would remain two prolonged blasts followed by two short blasts and one prolonged blast. The acknowledging signal would remain three prolonged blasts when the draw can be opened immediately and two prolonged blasts when the draw cannot be opened or is open and must be closed.

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 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.

This conclusion is based on the fact that the bridge will only be closed for 8 hours in the interest of public safety during the running of the 5K Road Race