

TABLE 1—BALLOON AORTIC VALVULOPLASTY CATHETER RISKS AND MITIGATION MEASURES—Continued

Identified risks	Mitigation measures
Inability for balloon deflation .....	Non-clinical performance evaluation. In Vivo evaluation.
Increased balloon inflation and deflation times .....	Non-clinical performance evaluation. In Vivo evaluation. Labeling.
Inability to steer towards valve of interest .....	Non-clinical performance evaluation. In Vivo evaluation.

FDA believes that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness.

Balloon aortic valvuloplasty catheters are not safe for use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109, *Prescription devices*).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification (510(k)), prior to marketing the device, which contains information about the balloon aortic valvuloplasty catheter they intend to market.

**II. Analysis of Environmental Impact**

We have determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**III. Paperwork Reduction Act of 1995**

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket

notification submissions, have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

**List of Subjects in 21 CFR Part 870**

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 870 is amended as follows:

**PART 870—CARDIOVASCULAR DEVICES**

- 1. The authority citation for part 870 continues to read as follows:

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

- 2. Add § 870.1255 to subpart B to read as follows:

**§ 870.1255 Balloon aortic valvuloplasty catheter.**

(a) *Identification.* A balloon aortic valvuloplasty catheter is a catheter with a balloon at the distal end of the shaft, which is intended to treat stenosis in the aortic valve when the balloon is expanded.

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

- (1) The device must be demonstrated to be biocompatible.
- (2) Sterility and shelf life testing must demonstrate the sterility of patient-contacting components and the shelf life of these components.
- (3) Non-clinical performance evaluation must demonstrate that the device performs as intended under anticipated conditions of use, including device delivery, inflation, deflation, and removal.

(4) In vivo evaluation of the device must demonstrate device performance, including the ability of the device to treat aortic stenosis.

(5) Labeling must include a detailed summary of the device-related and procedure-related complications pertinent to the use of the device.

Dated: July 21, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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**BILLING CODE 4164–01–P**

**DEPARTMENT OF STATE**

**22 CFR Part 147**

[Public Notice: 10027]

**RIN 1400–AE42**

**Electronic and Information Technology**

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** This rule provides a correction to a hyperlink included in the Section 508 implementing rule for the Department of State (the Department). The hyperlink takes the reader to a form that can be used by an employee or a member of the public to report accessibility issues to the Department, regarding its electronic and information technology.

**DATES:** This rule is effective on August 28, 2017.

**FOR FURTHER INFORMATION CONTACT:** Alice Kottmyer, Attorney-Adviser, 202–647–2318, [kottmyeram@state.gov](mailto:kottmyeram@state.gov).

**SUPPLEMENTARY INFORMATION:** Section 508 requires that when Federal departments and agencies develop, procure, maintain, or use electronic and information technology, they shall ensure that the electronic and information technology is accessible to individuals with disabilities. The Department’s implementing regulations, in 22 CFR part 147, were published in 2016. Due to a re-configuration of Web site assets within the Department, the hyperlink included in § 147.7(c) for the DS–4282 (Discrimination Complaint Form), is no longer valid. This rulemaking corrects the link.

The Department is preparing a more comprehensive update to Part 147, which will align its rule with the final rule published by the Access Board (see 82 FR 5790); and to parts 142 and 144

(implementing Section 504 of the Rehabilitation Act), to update terminology consistent with modern practice. For those interested in tracking, the RIN for the Department's "508 refresh" is 1400-AE35; for Section 504, it is 1400-AE03.

### Regulatory Analyses

The Department of State is publishing this rulemaking as a final rule, pursuant to 5 U.S.C. 553(b). This rulemaking is a rule of agency organization, procedure, or practice. The effective date of the rule is 30 days after publication, as provided in the Administrative Procedure Act.

The Department further finds that this is not a major rule; is not subject to the Unfunded Mandates Reform Act of 1995; will not have tribal implications as defined by Executive Order 13175; and will not have an impact on a substantial number of small entities under the Regulatory Flexibility Act. This rule is not an economically significant rule under Executive Order 12866, and the Department certifies that the benefits of this rulemaking outweigh any costs, which are minimal for the public. The Office of Information and Regulatory Affairs has designated this rule as "non-significant", as defined by Executive Order 12866. As this rule is not a significant regulatory action, this rule is exempt from the requirements of Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs." See OMB Memorandum M-17-21, "Guidance Implementing Executive Order 13771" of April 5, 2017.

The Department of State has reviewed this rule in light of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden. This rule will not have substantial direct effect on the states, on the relationships between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement.

The information collection referred to in this rulemaking has been approved by OMB. (OMB Control No. 1405-0220).

### List of Subjects in 22 CFR Part 147

Civil rights, Communications equipment, Computer technology, Government employees, Individuals with disabilities, Reporting and recordkeeping requirements, Telecommunications.

For the reasons set forth in the preamble, 22 CFR part 147 is amended as follows:

### PART 147—ELECTRONIC AND INFORMATION TECHNOLOGY

■ 1. The authority citation for part 147 continues to read as follows:

**Authority:** 22 U.S.C. 2651a; 29 U.S.C. 794, 794d; 36 CFR part 1194.

#### § 147.7 [Amended]

■ 2. Amend § 147.7 in paragraph (c) by removing "<https://eforms.state.gov/searchform.aspx>" and adding in its place "<https://eforms.state.gov/Forms/ds4282.PDF>".

**Janet Freer,**

*Director, Office of Directives Management, Department of State.*

[FR Doc. 2017-15823 Filed 7-26-17; 8:45 am]

**BILLING CODE 4710-05-P**

### DEPARTMENT OF HOMELAND SECURITY

#### Coast Guard

#### 33 CFR Part 100

[Docket No. USCG-2017-0593]

#### Special Local Regulations; Three Rivers Rowing Association/Head of the Ohio Regatta, Allegheny River Mile 0.0 to 4.0

**AGENCY:** Coast Guard, DHS

**ACTION:** Notice of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce a special local regulation during the Three Rivers Rowing Association/Head of the Ohio Regatta on the Allegheny River miles 0.0 to 4.0, for all navigable waters of the river. This regulation is needed to protect vessels transiting the area and event spectators from the hazards associated with the Three Rivers Rowing Association/Head of the Ohio Regatta. During the enforcement period, entry into, transiting, or anchoring in the regulated area is prohibited to all vessels not registered with the sponsor as participants or official patrol vessels, unless specifically authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative.

**DATES:** The regulations in 33 CFR 100.801, Table 1 Sector Ohio Valley, No. 36 will be enforced from 6 a.m. until 3:30 p.m., each day from October 7, 2017, through October 8, 2017.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notice of

enforcement, call or email MST1 Jennifer Haggins, Marine Safety Unit Pittsburgh, U.S. Coast Guard; telephone 412-221-0807, email [Jennifer.L.Haggins@uscg.mil](mailto:Jennifer.L.Haggins@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce special local regulations for the annual Three Rivers Rowing Association/Head of the Ohio Regatta in 33 CFR 100.801, Table 1 Sector Ohio Valley, No. 36 from 6 a.m. until 3:30 p.m. each day from October 7, 2017 through October 8, 2017. Entry into the regulated area is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative. Persons or vessels desiring to enter into or pass through the area must request permission from the COTP or a designated representative. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

This notice of enforcement is issued under authority of 33 CFR 100.801 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via Local Notice to Mariners and updates via Marine Information Broadcasts.

Dated: July 20, 2017.

**L. McClain, Jr.,**

*Commander, U.S. Coast Guard, Captain of the Port Marine Safety Unit Pittsburgh.*

[FR Doc. 2017-15829 Filed 7-26-17; 8:45 am]

**BILLING CODE 9110-04-P**

### DEPARTMENT OF HOMELAND SECURITY

#### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG-2017-0697]

#### Drawbridge Operation Regulation; Columbia River, Portland, OR and Vancouver, WA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of deviation from drawbridge regulation.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedule that governs the Interstate 5 (I-5) Bridges across the Columbia River, mile 106.5, between Portland, Oregon, and Vancouver, Washington. The deviation is necessary to facilitate the presence of participants in the Hands Across the Bridge Project. This deviation allows the bridges to remain in the closed-to-navigation position during the event.