

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

#### **PART 878—GENERAL AND PLASTIC SURGERY DEVICES**

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

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

■ 2. Add § 878.5050 to subpart F to read as follows:

##### **§ 878.5050 Surgical smoke precipitator.**

(a) *Identification.* A surgical smoke precipitator is a prescription device intended for clearance of the visual field by precipitation of surgical smoke and other aerosolized particulate matter created during laparoscopic surgery.

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

(1) Adverse tissue reaction must be mitigated through the following:

(i) Chemical characterization and toxicological risk assessment of the treated surgical smoke.

(ii) Demonstration that the elements of the device that may contact the patient are biocompatible.

(2) Electrical safety and electromagnetic compatibility testing must demonstrate that the device performs as intended.

(3) Software verification, validation, and hazard analysis must be performed.

(4) Performance data must demonstrate the sterility of the patient contacting components of the device.

(5) Performance data must support the shelf life of the sterile components of the device by demonstrating continued functionality, sterility, and package integrity over the identified shelf life.

(6) Animal simulated-use testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Device must be demonstrated to be effectively inserted, positioned, and removed from the site of use.

(ii) Device must be demonstrated to precipitate surgical smoke particulates to clear the visual field for laparoscopic surgeries.

(iii) Device must be demonstrated to be non-damaging to the site of use and animal subject.

(7) Labeling must identify the following:

(i) Detailed instructions for use.

(ii) Electrical safety and electromagnetic compatibility information.

(iii) A shelf life.

Dated: January 24, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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#### **DEPARTMENT OF STATE**

##### **22 CFR Part 51**

**[Public Notice: 9867]**

**RIN 1400–AE01**

##### **Passports: Service Passports**

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** This rule finalizes the interim final rule from the Department of State that established a new service passport, which may be approved for certain non-personal services contractors who travel abroad in support of and pursuant to a contract with the U.S. government. The Department received no public comments in response to the rule.

**DATES:** Effective January 30, 2018.

**FOR FURTHER INFORMATION CONTACT:** Sitara Kedilaya, Attorney-Adviser, *PassportRules@state.gov*, (202) 485–6500.

**SUPPLEMENTARY INFORMATION:** On September 30, 2016, the Department published an interim final rule amending 22 CFR part 51, to create a “service passport” that would be used by non-personal services contractors to carry out critical security, maintenance and other functions on behalf of the U.S. government. As noted in the interim final rule, the Department estimates that this rulemaking will affect approximately 1,000 non-personal services contractors per year. Further information concerning the rationale for this rule can be found in the interim final rule.

The Department provided 60 days for the public to comment on this rule. This period expired on November 29, 2016. The Department received no public comments.

The Regulatory Findings included with the interim final rule are incorporated herein. This rule is not an E.O. 13771 regulatory action because it is not significant under E.O. 12866.

##### **List of Subjects in 22 CFR Part 51**

Administrative practice and procedure, Drug traffic control, Passports and visas, Reporting and recordkeeping requirements.

#### **PART 51—PASSPORTS**

■ Accordingly, the interim final rule amending 22 CFR part 51, which was published at 81 FR 67156 on September 30, 2016, is adopted as a final rule without change.

**Carl C. Risch,**

*Assistant Secretary, Consular Affairs.*

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#### **DEPARTMENT OF HOMELAND SECURITY**

##### **Coast Guard**

##### **33 CFR Part 117**

**[Docket No. USCG–2018–0025]**

##### **Drawbridge Operation Regulation; Willamette River, Portland, OR**

**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 Broadway Bridge across the Willamette River, mile 11.7, at Portland, OR. The deviation is necessary to make adjustments to new equipment. This deviation allows the bridge to operate the double bascule span one side at a time, single leaf.

**DATES:** This deviation is effective without actual notice from January 30, 2018, to 11:59 p.m. on February 23, 2018. For the purposes of enforcement, actual notice will be used from 1 a.m. on January 27, 2018, through January 30, 2018.

**ADDRESSES:** The docket for this deviation, USCG–2018–0025, is available at <http://www.regulations.gov>. Type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this deviation.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *Steven.M.Fischer@uscg.mil*.

**SUPPLEMENTARY INFORMATION:** Multnomah County, the bridge owner, requested the Broadway Bridge be authorized to open half the span in single leaf mode to make adjustments to newly installed equipment. The Broadway Bridge crosses the Willamette River at mile 11.7, and provides 90 feet of vertical clearance above Columbia