

the currently FDA-recognized editions of ANSI/AAMI/ISO 10993–1, “Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process,” ANSI/AAMI/ISO 10993–5, “Biological Evaluation of Medical Devices—Part 5: Tests for In Vitro Cytotoxicity,” and ANSI/AAMI/ISO 10993–10, “Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Skin Sensitization”) must validate that the skin-contacting components of the device are biocompatible;

(7) Appropriate analysis and non-clinical testing (such as that outlined in the currently FDA-recognized editions of IEC 62304, “Medical Device Software—Software Life Cycle Processes”) must validate the software life cycle and that all processes, activities, and tasks are implemented and documented;

(8) Appropriate analysis and non-clinical testing must validate that the device components are found to be non-flammable;

(9) Appropriate analysis and non-clinical testing must validate that the battery in the device (if applicable) performs as intended over the anticipated service life of the device; and

(10) Adequate patient labeling is provided to the user to document proper use and maintenance of the device to ensure safe use of the device by the patient in the intended use environment.

Dated: November 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29633 Filed 11–19–15; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Parts 22 and 51

[Public Notice: 9350]

RIN 1400–AD76

Elimination of Visa Page Insert Service for U.S. Passport Book Holders

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: On April 29, 2015, the Department of State published a notice of proposed rulemaking (NPRM) that proposed eliminating the visa page insert service for regular fee passport book holders beginning January 1, 2016. The Department is finalizing the proposed rule without change.

DATES: This rule is effective January 1, 2016.

FOR FURTHER INFORMATION CONTACT: Michael Holly, Passport Services, Bureau of Consular Affairs; 202–485–6373; PassportRules@state.gov.

SUPPLEMENTARY INFORMATION:

Background

On April 29, 2015, the Department of State published a NPRM that proposed eliminating the visa page insert service for regular fee passport book holders beginning January 1, 2016. See 80 FR 23754. As explained in the NPRM, the effective date of this rule coincides with when the Department expects to begin issuing an updated version of the Next Generation Passport book. The primary reason for eliminating visa page inserts is to protect the integrity of the Next Generation Passport books. Further discussion of the reasons for the rule is in the NPRM.

Public Comments

The Department received only one public comment in response to the notice of proposed rulemaking. The following analysis addresses the comment.

The commenter expressed concern that eliminating visa page inserts would be a considerable inconvenience. The commenter wrote that due to the extent of his travels, eliminating visa page inserts would require him to renew his passport every three or four years, even if he is issued the larger 52-page passport book. The commenter also wrote that running out of visa pages in his passport would cause some of his multi-year visas to expire, requiring him to renew his visas early or possibly carry his expired U.S. passport until the visas in it expire.

The Department recognizes that eliminating visa page inserts may pose an inconvenience to a very small number of U.S. passport holders whose travel requires the issuance of multiple visas. The Department has a policy in place to permit the issuance of a second regular fee passport to individuals who require their first passport books for travel while their visa applications are pending with foreign governments. (See 7 FAM 1310 Appendix R c(2) <http://www.state.gov/documents/organization/94669.pdf>).

The commenter questioned if visa page inserts present a genuine security concern. As described in the NPRM, an interagency working group studied the issue and determined that the elimination of visa page inserts added value to the security features of visa page inserts that far outweighed the inconvenience caused by the elimination of this service, for which there is very limited demand.

Finally, the problems the commenter describes are very rare among U.S. passport holders. The average U.S. passport holder uses six or fewer visa pages. Ninety-seven percent of all U.S. passport holders will have used 17 pages or less by the time they renew their passports. Less than one percent of U.S. passport holders will have used more than 32 pages when they renew their passports. On average, people who apply for visa page inserts for a U.S. passport do so seven years after the passport was issued and 17 percent of these individuals had the smaller passport book to begin with. Accordingly, while the Department certainly understands the commenter's concerns, it still expects the overall impact of this rule on U.S. passport holders to be minimal, and to be outweighed by the security concerns discussed in the NPRM.

Regulatory Findings

The Regulatory Findings included in the NPRM are incorporated herein. See 80 FR at 23755.

List of Subjects in 22 CFR Parts 22 and 51

Consular services, Fees, Passports and visas.

For the reasons stated in the preamble, the Department of State amends 22 CFR parts 22 and 51 as follows:

PART 22—SCHEDULE OF FEES FOR CONSULAR SERVICES—DEPARTMENT OF STATE AND FOREIGN SERVICE

■ 1. The authority citation for part 22 continues to read as follows:

Authority: 8 U.S.C 1101 note, 1153 note, 1183a note, 1351, 1351 note, 1714, 1714 note; 10 U.S.C. 2602(c); 11 U.S.C. 1157 note; 22 U.S.C. 214, 214 note, 1475e, 2504(a), 4201, 4206, 4215, 4219, 6551; 31 U.S.C. 9701; Executive Order 10718, 22 FR 4632; Executive Order 11295, 31 FR 10603.

§ 22.1 [Amended]

■ 2. The table in § 22.1 is amended by removing and reserving item 2c.

PART 51—PASSPORTS

■ 3. The authority citation for part 51 continues to read as follows:

Authority: 8 U.S.C. 1504; 18 U.S.C. 1621; 22 U.S.C. 211a, 212, 213, 213n (Pub. L. 106–113 Div. B, Sec. 1000(a)(7) [Div. A, Title II, Sec. 236], 113 Stat. 1536, 1501A–430); 214, 214a, 217a, 218, 2651a, 2671(d)(3), 2705, 2714, 2721, & 3926; 26 U.S.C. 6039E; 31 U.S.C. 9701; 42 U.S.C. 652(k) [Div. B, Title V of Pub. L. 103–317, 108 Stat. 1760]; E.O. 11295, Aug. 6, 1966, FR 10603, 3 CFR, 1966–

1970 Comp., p. 570; Sec. 1 of Pub. L. 109–210, 120 Stat. 319; Sec. 2 of Pub. L. 109–167, 119 Stat. 3578; Sec. 5 of Pub. L. 109–472, 120 Stat. 3554; Pub. L. 108–447, Div. B, Title IV, Dec. 8, 2004, 118 Stat. 2809; Pub. L. 108–458, 118 Stat. 3638, 3823 (Dec. 17, 2004).

■ 4. In § 51.20, paragraph (a) is revised to read as follows:

§ 51.20 General.

(a) An application for a passport, a replacement passport, or other passport related service must be completed using the forms the Department prescribes.

* * * * *

■ 5. In § 51.56, paragraph (a) is revised to read as follows:

§ 51.56 Expedited passport processing.

(a) Within the United States, an applicant for passport service (including issuance or replacement of a passport) may request expedited processing. The Department may decline the request.

* * * * *

Dated: November 12, 2015.

David T. Donahue,

Acting Assistant Secretary for Consular Affairs.

[FR Doc. 2015–29618 Filed 11–19–15; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2015–1023]

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, Albemarle and Chesapeake Canal, Chesapeake (Great Bridge), VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulations.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the S168 Bridge (Battlefield Boulevard) across the Atlantic Intracoastal Waterway, Albemarle and Chesapeake Canal, mile 12.0, at Chesapeake (Great Bridge), VA. This deviation allows the bridge to remain in the closed-to-navigation position to facilitate the annual Chesapeake Christmas Parade.

DATES: This deviation is effective from 4 p.m. on December 5, 2015 until 10 p.m. on December 5, 2015.

ADDRESSES: The docket for this deviation, [USCG–2015–1023], 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. Hal R. Pitts, Bridge Administration Branch Fifth District, Coast Guard; telephone (757) 398–6222, email Hal.R.Pitts@uscg.mil.

SUPPLEMENTARY INFORMATION: The City of Chesapeake, VA, who owns and operates the S168 Bridge, has requested a temporary deviation from the current operating regulations to facilitate the annual Chesapeake Christmas Parade. The bridge is a double bascule draw bridge and has a vertical clearance in the closed position of 8 feet above mean high water.

The current operating schedule is set out in 33 CFR 117.997(g). Under this temporary deviation, the bridge will remain in the closed-to-navigation position from 4 p.m. to 6 p.m. and from 8 p.m. to 10 p.m. on December 5, 2015. The Atlantic Intracoastal Waterway, Albemarle and Chesapeake Canal is used by a variety of vessels including U.S. government vessels, small commercial vessels, recreational vessels and tug and barge traffic. The Coast Guard has carefully coordinated the restrictions with commercial and recreational waterway users.

Vessels able to pass through the bridge in the closed position may do so at anytime. The bridge will be able to open for emergencies and the Atlantic Ocean is the alternate route for vessels unable to pass through the bridge in the closed position. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notice to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impacts caused by this temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: November 16, 2015.

Hal R. Pitts,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2015–29677 Filed 11–19–15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2015–0388; FRL–9936–98]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances; Withdrawal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Partial withdrawal of direct final rule.

SUMMARY: EPA is withdrawing significant new use rules (SNURs) promulgated under the Toxic Substances Control Act (TSCA) for three chemical substances, which were the subject of premanufacture notices (PMNs). EPA published these SNURs using direct final rulemaking procedures, which requires EPA to take certain actions if a notice of intent to submit an adverse comment is received. EPA received notices of intent to submit adverse comments regarding the SNURs identified in this document. Therefore, the Agency is withdrawing the direct final rule SNURs identified in this document, as required under the direct final rulemaking procedures.

DATES: This document is effective December 1, 2015.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2015–0388, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Kenneth Moss, Chemical Control Division (7405M) Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: moss.kenneth@epa.gov.

For general information contact: The TSCA–Hotline, ABVI–Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–