codified into the conditions and limitations of exemption described in § 878.4040(b)(1).

N95s are the only devices included within the scope of the MOU. As such, this exemption only applies to devices currently regulated by FDA under product code MSH. This exemption does not affect any other subset of surgical apparel classified under § 878.4040. In addition to being subject to the general limitations to the exemptions found in 21 CFR 878.9 and the conditions of exemption identified in this final order, these devices will also remain subject to current good manufacturing practices and other general controls under the FD&C Act. An exemption from the requirement of 510(k) does not mean that the device is exempt from any other statutory or regulatory requirements, unless such exemption is explicitly provided by order or regulation.

This exemption will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with Federal regulations. Specifically, regulated industry will no longer have to invest time and resources in 510(k)s, including preparation of documents and data for submission to FDA, payment of user fees associated with 510(k) submissions, and responding to questions and requests for additional information from FDA during 510(k) review for devices in this exempted device type, subject to the conditions and limitations of the exemption.

VI. Paperwork Reduction Act of 1995

This order refers to previously approved collections of information found in 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 21 CFR part 807, subpart, E have been approved under OMB control number 0910–0120.

VII. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA Guidance, ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' February 19, 1998, available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf.*

2. ''Memorandum of Understanding Between the Food and Drug Administration, Center for Devices and Radiological Health, and the Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory,'' available at *https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/.*

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.,* as amended) 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. In § 878.4040, paragraph (b)(1) is revised to read as follows:

§ 878.4040 Surgical apparel.

* * * * *

(b) *Classification.* (1) Class II (special controls) for surgical gowns and surgical masks. A surgical N95 respirator or N95 filtering facepiece respirator is not exempt if it is intended to prevent specific diseases or infections, or it is labeled or otherwise represented as filtering surgical smoke or plumes, filtering specific amounts of viruses or bacteria, reducing the amount of and/or killing viruses, bacteria, or fungi, or affecting allergenicity, or it contains coating technologies unrelated to filtration (*e.g.,* to reduce and or kill microorganisms). Surgical N95 respirators and N95 filtering facepiece respirators are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9, and the following conditions for exemption:

(i) The user contacting components of the device must be demonstrated to be biocompatible.

(ii) Analysis and nonclinical testing must:

(A) Characterize flammability and be demonstrated to be appropriate for the intended environment of use; and

(B) Demonstrate the ability of the device to resist penetration by fluids, such as blood and body fluids, at a velocity consistent with the intended use of the device.

(iii) NIOSH approved under its regulation.

* * * * *

Dated: May 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10563 Filed 5–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Parts 50 and 51

[Public Notice 10417]

RIN 1400–AD54

Passports

AGENCY: Department of State.

ACTION: Final rule; stay.

SUMMARY: The Department of State published a final rule in the **Federal Register** on May 11, 2018, amending the passport rules for the Department of State (the Department). The document stays the amendments in the May 11 rule until June 10, 2018.

DATES: Effective May 17, 2018, §§ 50.7(d), 50.11(b), 51.4(g)(1) and (8), 51.60(h) and (i), 51.62, 51.65, 51.66, and 51.70 through 51.74, are stayed until June 10, 2018.

FOR FURTHER INFORMATION CONTACT: Anita Mody, Office of Legal Affairs, Passport Services, (202) 485–6500, *PassportRules@state.gov.* Hearing- or speech-impaired persons may use the Telecommunications Devices for the Deaf (TDD) by contacting the Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The Department of State published a final rule on May 11, 2018 (83 FR 21872), which provided that the rule was effective on the date of publication. This document provides a stay of the amendments in that rule until 30 days after the date of the May 11, 2018, publication. The Regulatory Analysis published with that final rule is unchanged by this publication.

List of Subjects

22 CFR Part 50

Citizenship and naturalization.

22 CFR Part 51

Administrative practice and procedure, Drug traffic control,

Passports and visas, Reporting and recordkeeping requirements.

Accordingly, for the reasons set forth above, the changes to 22 CFR parts 50 and 51 are stayed as follows:

PART 50—NATIONALITY PROCEDURES

■ 1. The authority citation for part 50 continues to read as follows:

Authority: 22 U.S.C. 2651a; 8 U.S.C. 1104 and 1401 through 1504.

§ 50.7 [Amended]

■ 2. In § 50.7, effective May 17, 2018, until June 10, 2018, paragraph (d) is stayed.

§ 50.11 [Amended]

■ 3. In § 50.11, effective May 17, 2018, until June 10, 2018, paragraph (b) is stayed.

PART 51—PASSPORTS

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

Authority: 8 U.S.C. 1504; 18 U.S.C. 1621, 2423; 22 U.S.C. 211a, 212, 212a, 212b, 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 P.L. 103–317, 108 Stat. 1760]; E.O. 11295, FR 10603; Pub. L. 114–119, 130 Stat. 15; Sec. 1 of P.L. 109–210, 120 Stat. 319; Sec. 2 of P.L. 109–167, 119 Stat. 3578; Sec. 5 of P.L. 109–472, 120 Stat. 3554; P.L. 108–447, Div. B, Title IV 118 Stat. 2896; P.L. 108–458, 118 Stat. 3638, 3823.

§ 51.4 [Amended]

■ 5. In § 51.4, effective May 17, 2018, until June 10, 2018, paragraphs (g)(1) and (8) are stayed.

§ 51.60 [Amended]

■ 6. In § 51.60, effective May 17, 2018, until June 10, 2018, paragraphs (h) and (i) are stayed.

§ 51.62 [Amended]

■ 7. Effective May 17, 2018, until June 10, 2018, § 51.62 is stayed.

§ 51.65 [Amended]

■ 8. Effective May 17, 2018, until June 10, 2018, § 51.65 is stayed.

§ 51.66 [Amended]

■ 9. Effective May 17, 2018, until June 10, 2018, § 51.66 is stayed.

§ 51.70 [Amended]

■ 10. Effective May 17, 2018, until June 10, 2018, § 51.70 is stayed.

§ 51.71 [Amended]

■ 11. Effective May 17, 2018, until June 10, 2018, § 51.71 is stayed.

§ 51.72 [Amended]

■ 12. Effective May 17, 2018, until June 10, 2018, § 51.72 is stayed.

§ 51.73 [Amended]

■ 13. Effective May 17, 2018, until June 10, 2018, § 51.73 is stayed.

§ 51.74 [Amended]

■ 14. Effective May 18, 2018, until June 10, 2018, § 51.74 is stayed.

Janet M. Freer,

Director, Office of Directives Management, Department of State.

[FR Doc. 2018–10653 Filed 5–16–18; 8:45 am]

BILLING CODE 4710–24–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 925

[SATS No. MO–042–FOR; Docket ID: OSM–2014–0002; S1D1S SS08011000 SX064A000 189S180110; S2D2S SS08011000 SX064A000 18XS501520]

Missouri Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval and required amendments.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are approving, in part, an amendment to the Missouri regulatory program (Missouri program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Missouri proposed revisions to its coal Ownership and Control Rules. Missouri intends to revise its program to be no less effective than the Federal regulations and to improve operational efficiency.

DATES: The effective date is June 18, 2018.

FOR FURTHER INFORMATION CONTACT: Len Meier, Division Chief, Alton Field Division, Office of Surface Mining Reclamation and Enforcement, 501 Belle Street, Suite 216, Alton, IL 62002. Telephone: (618) 463–6460. Email: *lmeier@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Missouri Program
II. Submission of the Amendment
III. OSMRE's Findings
IV. Summary and Disposition of Comments
V. OSMRE's Decision
VI. Procedural Determinations

I. Background on the Missouri Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Missouri program on November 21, 1980. You can find background information on the Missouri program, including the Secretary's findings, the disposition of comments, and conditions of approval, in the November 21, 1980, **Federal Register** (45 FR 77027). You can also find later subsequent actions concerning the Missouri program and program amendments at 30 CFR 925.10, 925.12, 925.15, and 925.16.

II. Submission of the Amendment

By letter dated February 18, 2014 (Administrative Record No. MO–679), Missouri sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). Missouri submitted the amendment in response to a September 30, 2009, letter (Administrative Record No. MO–670A) that OSMRE had sent to Missouri in accordance with 30 CFR 732.17(c) and to improve operational efficiency. Missouri proposed revisions to Title 10 of its Code of State Regulations (CSR) under Division 40 Land Reclamation Commission. The specific sections of 10 CSR 40 changed by Missouri's amendment are discussed in Part III OSMRE's Findings. Missouri revised its program to be no less effective than the Federal regulations, to change terms, add clarifying language, make grammatical changes, and correct reference errors.

We announced receipt of the proposed amendment in the May 20, 2014, **Federal Register** (79 FR 28852). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. We did not hold a public hearing or meeting because neither was requested. The public comment period ended on June 19, 2014. We did not receive any public comments.

III. OSMRE's Findings

The following are the findings we made concerning Missouri's amendment