

promulgate the body system listings again. Therefore, we have determined that opportunity for prior comment is unnecessary, and we are issuing this regulation as a final rule.

In addition, for the reasons cited above, we find good cause for dispensing with the 30-day delay in the effective date of this final rule. 5 U.S.C. 553(d)(3). We are not making any substantive changes to the listings in these body systems. Without an extension of the expiration dates for these listings, we will not have the criteria we need to assess medical impairments in these two body systems at step three of the sequential evaluation processes. We therefore find it is in the public interest to make this final rule effective on the publication date.

Executive Order 12866, as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that this final rule does not meet the requirements for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB did not review it. We also determined that this final rule meets the plain language requirement of Executive Order 12866.

Regulatory Flexibility Act

We certify that this final rule does not have a significant economic impact on a substantial number of small entities because it affects only individuals. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

Paperwork Reduction Act

This final rule does not create any new or affect any existing collections and, therefore, it does not require OMB's approval under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-age, Survivors and Disability

Insurance, Reporting and recordkeeping requirements, Social Security.

Nancy Berryhill,

Deputy Commissioner for Operations, performing the duties and functions not reserved to the Commissioner of Social Security.

For the reasons set out in the preamble, we are amending appendix 1 to subpart P of part 404 of chapter III of title 20 of the Code of Federal Regulations as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950—)

Subpart P—[Amended]

- 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a)–(b) and (d)–(h), 216(i), 221(a) and (h)–(j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a)–(b) and (d)–(h), 416(i), 421(a) and (h)–(j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

- 2. Amend appendix 1 to subpart P of part 404 by revising items 3 and 11 of the introductory text before Part A to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

3. Special Senses and Speech (2.00 and 102.00): April 24, 2020.

* * * * *

11. Congenital Disorders That Affect Multiple Body Systems (10.00 and 110.00): April 3, 2020.

* * * * *

[FR Doc. 2018–06671 Filed 3–30–18; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 890, 900, 1020, and 1040

[Docket No. FDA–2018–N–0011]

Medical Devices; Technical Amendment

AGENCY: Food and Drug Administration; HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending certain medical device regulations. This action is editorial in nature to correct typographical errors

and to ensure accuracy and clarity in the Agency's regulations.

DATES: This rule is effective April 2, 2018.

FOR FURTHER INFORMATION CONTACT:

Karen Fikes, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5244, Silver Spring, MD 20993–0002, 301–796–9603.

SUPPLEMENTARY INFORMATION: FDA is amending our regulations in 21 CFR parts 890, 900, 1020, and 1040 to correct typographical errors and to update addresses, office titles, and wording to ensure accuracy and clarity in the Agency's medical device regulations.

FDA is making nonsubstantive changes to the following regulations:

1. FDA is revising § 890.5525(b)(2)(i)(A) by replacing “Testing using a drug approved for iontophoretic delivery, or a solution, if identified in the labeling, to demonstrate safe use of the device as intended” with “Testing using a drug approved for iontophoretic delivery, or a solution if identified in the labeling, to demonstrate safe use of the device as intended”.

2. FDA is revising § 900.3(b)(1) by replacing “Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiology Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, marked Attn: Mammography Standards Branch” with “Division of Mammography Quality Standards, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4445, Silver Spring, MD 20993, Attn: Program Management Branch”.

3. FDA is revising § 900.11(b)(2)(i) by replacing “42 U.S.C. 263b(c)(2)” with “42 U.S.C. 263b(c)(4)”.

4. FDA is revising § 1020.30(c) by replacing “Director of the Office of Communication, Education, and Radiation Programs of the Center for Devices and Radiological Health” with “Director, Center for Devices and Radiological Health”.

5. FDA is revising § 1040.10(a)(3)(i) by replacing “Food and Drug Administration, Center for Devices and Radiological Health, Director, Office of Compliance, 10903 New Hampshire Ave., Bldg. 66, Rm. 3521, Silver Spring, MD 20993–0002” with “Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002”.

6. FDA is revising § 1040.10(f)(6)(ii) by replacing “Director, Office of

Compliance (HFZ-300), Center for Devices and Radiological Health” with “Director, Center for Devices and Radiological Health”.

7. FDA is revising § 1040.10(g)(10) by replacing “Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health” with “Director, Center for Devices and Radiological Health”.

8. FDA is revising § 1040.20(d)(3)(iii) by replacing “Director, Office of Communication, Education, and Radiation Programs 10903 New Hampshire Ave., Bldg. 66, Rm. 4312, Silver Spring, MD 20993-0002, Center for Devices and Radiological Health” with “Director, Center for Devices and Radiological Health”.

9. FDA is revising § 1040.20(d)(3)(iv) by replacing “manufacturer” with “manufacturer,” and replacing “Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health” with “Director, Center for Devices and Radiological Health”.

List of Subjects

21 CFR Part 890

Medical devices, Physical medicine devices.

21 CFR Part 900

Electronic products, Health facilities, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

21 CFR Part 1020

Electronic products, Medical devices, Radiation protection, Reporting and recordkeeping requirements, Television, X-rays.

21 CFR Part 1040

Electronic funds transfers, Incorporation by reference, Labeling, Lasers, Medical devices, Radiation protection, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 890, 900, 1020, and 1040 are amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

■ 1. The authority citation for part 890 continues to read as follows:

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

■ 2. Revise § 890.5525(b)(2)(i)(A) to read as follows:

§ 890.5525 Iontophoresis device.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(A) Testing using a drug approved for iontophoretic delivery, or a solution if identified in the labeling, to demonstrate safe use of the device as intended;

* * * * *

PART 900—MAMMOGRAPHY

■ 3. The authority citation for part 900 continues to read as follows:

Authority: 21 U.S.C. 360i, 360nn, 374(e), 42 U.S.C. 263b.

■ 4. Revise § 900.3(b)(1) to read as follows:

§ 900.3 Application for approval as an accreditation body.

* * * * *

(b) * * *

(1) An applicant seeking initial FDA approval as an accreditation body shall inform the Division of Mammography Quality Standards, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4445, Silver Spring, MD 20993, Attn: Program Management Branch, of its desire to be approved as an accreditation body and of its requested scope of authority.

* * * * *

■ 5. Revise § 900.11(b)(2)(i) to read as follows:

§ 900.11 Requirements for certification.

* * * * *

(b) * * *

(2) * * *

(i) A new facility beginning operation after October 1, 1994, is eligible to apply for a provisional certificate. The provisional certificate will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process. To apply for and receive a provisional certificate, a facility must meet the requirements of 42 U.S.C. 263b(c)(4) and submit the necessary information to an approved accreditation body or other entity designated by FDA.

* * * * *

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

■ 6. The authority citation for part 1020 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360e-360j, 360hh-360ss, 371, 381.

■ 7. Revise § 1020.30(c) to read as follows:

§ 1020.30 Diagnostic x-ray systems and their major components.

* * * * *

(c) *Manufacturers' responsibility.* Manufacturers of products subject to §§ 1020.30 through 1020.33 shall certify that each of their products meets all applicable requirements when installed into a diagnostic x-ray system according to instructions. This certification shall be made under the format specified in § 1010.2 of this chapter. Manufacturers may certify a combination of two or more components if they obtain prior authorization in writing from the Director, Center for Devices and Radiological Health. Manufacturers shall not be held responsible for noncompliance of their products if that noncompliance is due solely to the improper installation or assembly of that product by another person; however, manufacturers are responsible for providing assembly instructions adequate to assure compliance of their components with the applicable provisions of §§ 1020.30 through 1020.33.

* * * * *

PART 1040—PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

■ 8. The authority citation for part 1040 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e-360j, 360hh-360ss, 371, 381.

■ 9. In § 1040.10 revise paragraphs (a)(3)(i), (f)(6)(ii), and (g)(10) to read as follows:

§ 1040.10 Laser products.

(a) * * *

(3) * * *

(i) Registers, and provides a listing by type of such laser products manufactured that includes the product name, model number, and laser medium or emitted wavelength(s), and the name and address of the manufacturer. The manufacturer must submit the registration and listing to the Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993-0002.

* * * * *

(f) * * *

(6) * * *

(ii) If the configuration, design, or function of the laser product would make unnecessary compliance with the requirement in paragraph (f)(6)(i) of this section, the Director, Center for Devices and Radiological Health, may, upon written application by the manufacturer, approve alternate means to accomplish

the radiation protection provided by the beam attenuator.

* * * * *

(g) * * *

(10) *Label specifications.* Labels required by this section and § 1040.11 shall be permanently affixed to, or inscribed on, the laser product, legible, and clearly visible during operation, maintenance, or service, as appropriate. If the size, configuration, design, or function of the laser product would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, the Director, Center for Devices and Radiological Health, on the Director's own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s) or alternate wording for such label(s) as applicable.

* * * * *

■ 10. In § 1040.20 revise paragraphs (d)(3)(iii) and (iv) to read as follows:

§ 1040.20 Sunlamp products and ultraviolet lamps intended for use in sunlamp products.

* * * * *

(d) * * *

(3) * * *

(iii) If the size, configuration, design, or function of the sunlamp product or ultraviolet lamp would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, or would render the required label unnecessary, the Director, Center for Devices and Radiological Health, on the center's own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s), alternate wording for such label(s), or deletion, as applicable.

(iv) In lieu of permanently affixing or inscribing tags or labels on the ultraviolet lamp as required by §§ 1010.2(b) and 1010.3(a), the manufacturer of the ultraviolet lamp may permanently affix or inscribe such required tags or labels on the lamp packaging uniquely associated with the lamp, if the name of the manufacturer and month and year of manufacture are permanently affixed or inscribed on the exterior surface of the ultraviolet lamp so as to be legible and readily accessible to view. The name of the manufacturer and month and year of manufacture affixed or inscribed on the exterior surface of the lamp may be expressed in code or symbols, if the manufacturer has previously supplied the Director, Center for Devices and Radiological Health,

with the key to such code or symbols and the location of the coded information or symbols on the ultraviolet lamp. The label or tag affixed or inscribed on the lamp packaging may provide either the month and year of manufacture without abbreviation, or information to allow the date to be readily decoded.

* * * * *

Dated: March 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-06308 Filed 3-30-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2018-0110]

Drawbridge Operation Regulation; Hackensack River, Jersey City, New Jersey

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 PATH Bridge across the Hackensack River, mile 3.0, at Jersey City, New Jersey. This temporary deviation is necessary to allow the bridge to remain in the closed-to-navigation position to facilitate the replacement of rails and timbers across the length of the span of the bridge.

DATES: This deviation is effective from 12:01 a.m. on March 31, 2018, to 12:01 a.m. on September 26, 2018.

ADDRESSES: The docket for this deviation, USCG-2018-0110 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 Judy Leung-Yee, Project Officer, First Coast Guard District, telephone 212-514-4330, email Judy.K.Leung-ye@uscg.mil.

SUPPLEMENTARY INFORMATION: The Port Authority Trans-Hudson Corporation, the owner of the bridge, requested a temporary deviation from the normal operating schedule to facilitate the replacement of rails and timbers across the length of the span of the bridge. The PATH Bridge across the Hackensack

River, mile 3.0, has a vertical clearance in the closed position of 40 feet at mean high water and 45 feet at mean low water. The existing bridge operating regulations are listed at 33 CFR 117.723(b).

Under this temporary deviation, the PATH Bridge shall remain in the closed position between 12:01 a.m. Saturday and 12:01 a.m. Monday as follows: March 31–April 2, 2018; April 7–9, 14–16, 21–23, and 28–30, 2018; May 5–7, 12–14, and 19–21, 2018; June 2–4, 9–11, 16–18, 23–25, and 30–July 2, 2018; July 7–9, 14–16, 21–23, and 28–30, 2018; August 4–6, 11–13, 18–20, and 25–27, 2018; September 8–10, 15–17, 22–24, 2018.

The waterway is transited by commercial and recreational traffic. The Coast Guard notified known companies of the commercial vessels that transit the area, including the Sandy Hook Pilots and the local Tug/Tow Committee; there were no objections to this temporary deviation. Vessels able to pass under the bridge in the closed position may do so at any time. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass.

The Coast Guard will inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operations can arrange their transits to minimize any impact caused by the 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: March 27, 2018.

Christopher J. Bisignano,

Supervisory Bridge Management Specialist, First Coast Guard District.

[FR Doc. 2018-06540 Filed 3-30-18; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2018-0253]

Drawbridge Operation Regulation; Lake Washington Ship Canal, Seattle, WA

AGENCY: Coast Guard, DHS.