



4164-01-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 [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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;

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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.

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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.

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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.

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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.

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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.

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Dated: March 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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