Subpart C—Exportation of Electronic Products

1010.20 Electronic products intended for export.

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

SOURCE: 38 FR 28631, Oct. 15, 1973, unless otherwise noted.

Subpart A—General Provisions

§ 1010.1 Scope.

The standards listed in this subchapter are prescribed pursuant to section 534 of Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968) (21 U.S.C. 360kk) and are applicable to electronic products as specified herein, to control electronic product radiation from such products. Standards so prescribed are subject to amendment or revocation and additional standards may be prescribed as are determined necessary for the protection of the public health and safety.

[73 FR 34861, June 19, 2008]

§ 1010.2 Certification.

(a) Every manufacturer of an electronic product for which an applicable standard is in effect under this subchapter shall furnish to the dealer or distributor, at the time of delivery of such product, the certification that such product conforms to all applicable standards under this subchapter.

(b) The certification shall be in the form of a label or tag permanently affixed to or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use, unless the applicable standard prescribes some other manner of certification. All such labels or tags shall be in the English language.

(c) Such certification shall be based upon a test, in accordance with the standard, of the individual article to which it is attached or upon a testing program which is in accordance with good manufacturing practices. The Director, Center for Devices and Radiological Health may disapprove such a testing program on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic products comply with the standards prescribed under this subchapter.

(d) In the case of products for which it is not feasible to certify in accordance with paragraph (b) of this section, upon application by the manufacturer, the Director, Center for Devices and Radiological Health may approve an alternate means by which such certification may be provided.

(e) Laser products under §1040.10 of this chapter that incorporate a certified laser system (laser product) will be considered to have met the certification requirements in this section if all of the following conditions are met:

(1) The incorporated laser system is not a laser product intended for use as a component or replacement as described in §1040.10(a)(1) and (2) of this chapter;

(2) The manufacturer of the incorporated laser system has certified such laser system under this section and meets the reporting requirements under part 1002 of this chapter;

(3) The product incorporating the certified laser system is not independently subject to additional reporting or performance standards requirements;

(4) The incorporated laser system is not modified as defined in §1040.10(i) of this chapter, and all performance features that apply to the incorporated laser system under §1040.10(f) are available on the product incorporating the certified laser system;

(5) All labeling requirements that apply to the incorporated laser system under §§1010.2, 1010.3, 1040.10(g), and 1040.11(a)(3) of this chapter are visible on the outside of the product incorporating the certified laser system, with the exception that the certification or identification labels need not be visible on the outside of products incorporating a certified Class I laser;

(6) The incorporated laser system is installed in accordance with the instructions provided by the manufacturer of the incorporated laser system, including instructions for placing additional externally facing labels found in paragraph (e)(5) of this section, and

meeting the other conditions in paragraphs (e)(1) through (8) of this section;

(7) The manufacturer of the product that incorporates the laser system provides the end user with information required under §1040.10(h)(1) of this chapter as provided to them by the manufacturer of the incorporated laser system; and

(8) The labeling requirements under part 1010 and §1040.10(g) of this chapter for the incorporated laser system would be met in any service configuration of the product incorporating the laser system or when the incorporated laser system is removed from the product into which it had been incorporated, and reproductions of such labels are found in the user information.

[38 FR 28631, Oct. 15, 1973, as amended at 40 FR 32257, July 31, 1975; 42 FR 18063, Apr. 5, 1977; 53 FR 11254, Apr. 6, 1988; 88 FR 3653, Jan. 20, 2023]

§ 1010.3 Identification.

(a) Every manufacturer of an electronic product to which a standard under this subchapter is applicable shall set forth the information specified in paragraphs (a)(1) and (2) of this section. This information shall be provided in the form of a tag or label permanently affixed or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use or in such other manner as may be prescribed in the applicable standard. Except for foreign equivalent abbreviations as authorized in paragraph (a)(1) of this section all such labels or tags shall be in the English language.

(1) The full name and address of the manufacturer of the product; abbreviations such as ''Co.,'' ''Inc.,'' or their foreign equivalents and the first and middle initials of individuals may be used. Where products are sold under a name other than that of the manufacturer of the product, the full name and address of the individual or company under whose name the product was sold may be set forth, provided such individual or company has previously suppled the Director, Center for Devices and Radiological Health with sufficient information to identify the manufacturer of the product.

(2) The place and month and year of manufacture:

(i) The place of manufacture may be expressed in code provided the manufacturer has previously supplied the Director, Center for Devices and Radiological Health with the key to such code.

(ii) The month and year of manufacture shall be provided clearly and legibly, without abbreviation, and with the year shown as a four-digit number as follows in this paragraph. Alternatively, a manufacturer may utilize a manufacturing symbol and date format that conforms with an applicable FDA recognized consensus standard.

MANUFACTURED: (INSERT MONTH AND YEAR OF MANUFACTURE.)

(b) In the case of products for which it is not feasible to affix identification labeling in accordance with paragraph (a) of this section, upon application by the manufacturer, the Director, Center for Devices and Radiological Health may approve an alternate means by which such identification may be provided.

(c) Every manufacturer of an electronic product to which a standard under this subchapter is applicable shall provide to the Director, Center for Devices and Radiological Health a list identifying each brand name which is applied to the product together with the full name and address of the individual or company for whom each product so branded is manufactured.

[40 FR 32257, July 31, 1975, as amended at 42 FR 18063, Apr. 5, 1977; 53 FR 11254, Apr. 6, 1988; 88 FR 3653, Jan. 20, 2023]

§ 1010.4 Variances.

(a) *Criteria for variances.* (1) Upon application by a manufacturer (including an assembler), the Director, Center for Devices and Radiological Health, Food and Drug Administration, may grant a variance from one or more provisions of any performance standard under subchapter J of this chapter for an electronic product subject to such standard when the Director determines that granting such a variance is in keeping with the purposes of Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the