

provided in the original application, a description of such changes.

(e) *Ruling on an application.* (1) The Director, Center for Devices and Radiological Health, may grant an exemption including in the written notice of exemption such conditions or terms as may be necessary to protect the public health and safety and shall notify the applicant in writing of his action. The conditions or terms of the exemption may include specifications concerning the manufacture, use, control, and disposal of the excess or surplus exempted product of class of products as provided in the Code of Federal Regulations, title 41, subtitle C. Each exemption will be assigned an identifying number.

(2) The Director, Center for Devices and Radiological Health, shall amend or withdraw an exemption whenever he determines that such action is necessary to protect the public health or otherwise is justified by provisions of the act or this subchapter. Such action shall become effective on the date specified in the written notice of the action sent to the applicant, except that it shall become effective immediately when the Director determines that it is necessary to prevent an imminent health hazard.

(f) *Identification of equipment covered by exemption.* The manufacturer of any product for which an exemption is granted shall provide the following identification 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 exemption:

CAUTION

This electronic product has been exempted from Food and Drug Administration radiation safety performance standards prescribed in the Code of Federal Regulations, title 21, chapter I, subchapter J, pursuant to Exemption No. _____, granted on _____

[42 FR 44229, Sept. 2, 1977; 42 FR 61257, Dec. 2, 1977, as amended at 44 FR 17657, Mar. 23, 1979; 46 FR 8460, 8958, Jan. 27, 1981; 50 FR 7518, Feb. 22, 1985; 50 FR 13564, Apr. 5, 1985; 53 FR 11254, Apr. 6, 1988; 59 FR 14365, Mar. 28, 1994; 65 FR 17138, Mar. 31, 2000]

Subpart B—Alternate Test Procedures

§ 1010.13 Special test procedures.

The Director, Center for Devices and Radiological Health, may, on the basis of a written application by a manufacturer, authorize test programs other than those set forth in the standards under this subchapter for an electronic product if he determines that such products are not susceptible to satisfactory testing by the procedures set forth in the standard and that the alternative test procedures assure compliance with the standard.

[40 FR 32257, July 31, 1975, as amended at 53 FR 11254, Apr. 6, 1988]

Subpart C—Exportation of Electronic Products

§ 1010.20 Electronic products intended for export.

The performance standards prescribed in this subchapter shall not apply to any electronic product which is intended solely for export if:

(a) Such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export, and

(b) Such product meets all the applicable requirements of the country to which such product is intended for export.

[40 FR 32257, July 31, 1975]

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

Sec.

- 1020.10 Television receivers.
- 1020.20 Cold-cathode gas discharge tubes.
- 1020.30 Diagnostic x-ray systems and their major components.
- 1020.31 Radiographic equipment.
- 1020.32 Fluoroscopic equipment.
- 1020.33 Computed tomography (CT) equipment.
- 1020.40 Cabinet x-ray systems.

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

SOURCE: 38 FR 28632, Oct. 15, 1973, unless otherwise noted.