

## § 1010.5

## 21 CFR Ch. I (4-1-08 Edition)

in compliance with such regulations, a brief statement of the reason for the noncompliance.

(x) [Reserved]

(xi) If the electronic product is used in a clinical investigation involving human subjects, is subject to the requirements for institutional review set forth in part 56 of this chapter, and is subject to the requirements for informed consent set forth in part 50 of this chapter, the investigation shall be conducted in compliance with such requirements.

(2) The application for amendment or extension of a variance shall include the following information:

(i) The variance number and expiration date.

(ii) The amendment or extension requested and basis for the amendment or extension.

(iii) A description of the effect of the amendment or extension on protection from radiation produced by the product.

(iv) An explanation of how alternate or suitable means of protection will be provided.

(c) *Ruling on applications.* (1) The Director, Center for Devices and Radiological Health, may approve or deny, in whole or in part, a requested variance or any amendment or extension thereof, and the director shall inform the applicant in writing of this action on a requested variance or amendment or extension. The written notice will state the manner in which the variance differs from the standard, the effective date and the termination date of the variance, a summary of the requirements and conditions attached to the variance, any other information that may be relevant to the application or variance, and, if appropriate, the number of units or other similar limitations for which the variance is approved. Each variance will be assigned an identifying number.

(2) The Director, Center for Devices and Radiological Health, shall amend or withdraw a variance whenever the Director determines that this action is necessary to protect the public health or otherwise is justified by this subchapter. Such action will become effective on the date specified in the written notice of the action sent to the ap-

plicant, except that it will become effective immediately upon notification to the applicant when the Director determines that such action is necessary to prevent an imminent health hazard.

(3) All applications for variances and for amendments and extensions thereof and all correspondence (including written notices of approval) on these applications will be available for public disclosure in the office of the Division of Dockets Management, except for information regarded as confidential under section 360A(e) of the act.

(d) *Certification of equipment covered by variance.* The manufacturer of any product for which a variance is granted shall modify the tag, label, or other certification required by §1010.2 to state:

(1) That the product is in conformity with the applicable standard, except with respect to those characteristics covered by the variance;

(2) That the product is in conformity with the provisions of the variance; and

(3) The assigned number and effective date of the variance.

[39 FR 13879, Apr. 18, 1974, as amended at 44 FR 48191, Aug. 17, 1979; 50 FR 7518, Feb. 22, 1985; 50 FR 13565, Apr. 5, 1985; 53 FR 11254, Apr. 6, 1988; 53 FR 52683, Dec. 29, 1988; 59 FR 14365, Mar. 28, 1994; 65 FR 17137, Mar. 31, 2000]

### § 1010.5 Exemptions for products intended for United States Government use.

(a) *Criteria for exemption.* Upon application by a manufacturer (including assembler) or by a U.S. department or agency, the Director, Center for Devices and Radiological Health, Food and Drug Administration, may grant an exemption from any performance standard under subchapter J of this chapter for an electronic product, or class of products, otherwise subject to such standard when he determines that such electronic product or class is intended for use by departments or agencies of the United States and meets the criteria set forth in paragraph (a) (1) or (2) of this section.

(1) The procuring agency shall prescribe procurement specifications for the product or class of products governing emissions of electronic product radiation, and the product or class

shall be of a type used solely or predominantly by a department or agency of the United States.

(2) The product or class of products is intended for research, investigations, studies, demonstration, or training, or for reasons of national security.

(b) *Consultation between the procuring agency and the Food and Drug Administration.* The United States department or agency that intends to procure or manufacture a product or class of products subject to electronic product radiation safety standards contained in this subchapter should consult with the Center for Devices and Radiological Health, Food and Drug Administration, whenever it is anticipated that the specifications for the product or class must deviate from, or be in conflict with, such applicable standards. Such consultation should occur as early as possible during development of such specifications. The department or agency should include in the specifications all requirements of such standards that are not in conflict with, or are not inappropriate for, the special or unique uses for which the product is intended. The procuring agency should indicate to the Center for Devices and Radiological Health if it desires to be notified of the approval, amendment, or withdrawal of the exemption.

(c) *Application for exemption.* If you are submitting an application for exemption, or for amendment or extension thereof, you must submit an original and two copies to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. For an exemption under the criteria prescribed in paragraph (a)(1) of this section, the application shall include the information prescribed in paragraphs (c)(1) through (c)(13) of this section. For an exemption under the criteria prescribed in paragraph (a)(2) of this section, the application shall include the information prescribed in paragraphs (c)(3) through (c)(13) of this section. An application for exemption, or for amendment or extension thereof, and correspondence relating to such application shall be made available for public disclosure in the Division of Dockets Management, except for confidential or proprietary information

submitted in accordance with part 20 of this chapter. Information classified for reasons of national security shall not be included in the application. Except as indicated in this paragraph, the application for exemption shall include the following:

(1) The procurement specifications for the product or class of products that govern emissions of electronic product radiation.

(2) Evidence that the product or class of products is of a type used solely or predominantly by departments or agencies of the United States.

(3) Evidence that such product or class of products is intended for use by a department or agency of the United States.

(4) A description of the product or class of products and its intended use.

(5) An explanation of how compliance with the applicable standard would restrict or be inappropriate for this intended use.

(6) A description of the manner in which it is proposed that the product or class of products shall deviate from the requirements of the applicable standard.

(7) An explanation of the advantages to be derived from such deviation.

(8) An explanation of how means of radiation protection will be provided where the product or class of products deviates from the requirements of the applicable standard.

(9) The period of time it is desired that the exemption be in effect, and, if appropriate, the number of units to be manufactured under the exemption.

(10) The name, address, and telephone number of the manufacturer or his agent.

(11) The name, address, and telephone number of the appropriate office of the United States department or agency purchasing the product or class of products.

(12) Such other information required by regulation or by the Director, Center for Devices and Radiological Health, to evaluate and act on the application. Where such information includes nonclinical laboratory studies, the information shall include, with respect to each nonclinical study, either

a statement that each study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations. When such information includes clinical investigations involving human subjects, the information shall include, with respect to each clinical investigation, either a statement that each investigation was conducted in compliance with the requirements set forth in part 56 of this chapter, or a statement that the investigation is not subject to such requirements in accordance with § 56.104 or § 56.105 and a statement that each investigation was conducted in compliance with the requirements set forth in part 50 of this chapter.

(13) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(d) *Amendment or extension of an exemption.* An exemption is granted on the basis of the information contained in the original application. Therefore, if changes are needed in the radiation safety specifications for the product, or its use, or related radiation control procedures such that the information in the original application would no longer be correct with respect to radiation safety, the applicant shall submit in advance of such changes a request for an amendment to the exemption. He also shall submit a request for extension of the exemption, if needed, at least 60 days before the expiration date. The application for amendment or extension of an exemption shall include the following information:

- (1) The exemption number and expiration date.
- (2) The amendment or extension requested and basis for the amendment or extension.
- (3) If the radiation safety specifications for the product or class of products or the product's or class of prod-

ucts' use or related radiation control procedures differ from the description 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]