[60 FR 48382, Sept. 19, 1995; 61 FR 13423, Mar. 27, 1996, as amended at 88 FR 3652, Jan. 20, 2023]

§ 1002.2 [Reserved]

§ 1002.3 Notification to user of performance and technical data.

The Director and Deputy Director of the Center for Devices and Radiological Health, as authorized under delegated authority, may require a manufacturer of a radiation emitting electronic product to provide to the ultimate purchaser, at the time of original purchase, such performance data and other technical data related to safety of the product as the Director or Deputy Director finds necessary.

[69 FR 17292, Apr. 2, 2004]

§ 1002.4 Confidentiality of information.

The Secretary or his representative shall not disclose any information reported to or otherwise obtained by him, pursuant to this part, which concerns or relates to a trade secret or other matter referred to in section 1905 of title 18 of the United States Code, except that such information may be disclosed to other officers or employees of the Department and of the other agencies concerned with carrying out the requirements of the Act. Nothing in this section shall authorize the withholding of information by the Secretary, or by any officers or employees under his control, from the duly authorized committees of the Congress.

§ 1002.7 Submission of data and reports.

All submissions such as reports, test data, product descriptions, and other information required by this part, or voluntarily submitted to the Director, Center for Devices and Radiological Health, shall be filed with the number of copies as prescribed by the Director, Center for Devices and Radiological Health, and shall be signed by the person making the submission. The submissions required by this part shall be addressed to the Food and Drug Administration, Center for Devices and Radiological Health, ATTN: Electronic Product Reports, Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, rm. G609, Silver Spring, MD 20993–0002.

(a) In addition to the requirements of this part, all material submitted to the Director, Center for Devices and Radiological Health, shall be submitted pursuant to the provisions of part 20—Public Information, of this chapter.

(b) Where guides or instructions have been issued by the Director for the submission of material required by this part, such as test data, product reports, abbreviated reports, supplemental reports, and annual reports, the material submitted shall conform to the applicable reporting guides or instructions. Where it is not feasible or where it would not be appropriate to conform to any portion of a prescribed reporting guide or instruction, an alternate format for providing the information requested by that portion of the guide or instruction may be used provided the submitter of such information submits adequate explanation and justification for use of an alternate format. If the Director, Center for Devices and Radiological Health, determines that such justification is inadequate and that it is feasible or appropriate to conform to the prescribed reporting guide or instruction, he may require resubmission of the information in conformance with the reporting guide or instruction.

(c) Where the submission of quality control and testing information is common to more than one model, or model family of the same product category, a ''common aspects report'' consolidating similar information may be provided, if applicable.

[42 FR 18062, Apr. 5, 1977, as amended at 53 FR 11254, Apr. 6, 1988; 60 FR 48385, Sept. 19, 1995; 72 FR 17400, Apr. 9, 2007; 75 FR 20916, Apr. 22, 2010]

Subpart B—Required Manufacturers' Reports for Listed Electronic Products

SOURCE: 60 FR 48386, Sept. 19, 1995, unless otherwise noted.

§ 1002.10 Product reports.

Every manufacturer of a product or component requiring a product report as set forth in table 1 of § 1002.1 shall submit a product report to the Food

and Drug Administration, Center for Devices and Radiological Health, ATTN: Electronic Product Reports, Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, rm. G609, Silver Spring, MD 20993–0002, prior to the introduction of such product into commerce. The report shall be distinctly marked ''Radiation Safety Product Report of (name of manufacturer)'' and shall:

(a) Identify which listed product is being reported.

(b) Identify each model of the listed product together with sufficient information concerning the manufacturer's code or other system of labeling to enable the Director to determine the place of manufacture.

(c) Include information on all components and accessories provided in, on, or with the listed product that may affect the quantity, quality, or direction of the radiation emissions.

(d) Describe the function, operational characteristics affecting radiation emissions, and intended and known uses of each model of the listed product.

(e) State the standard or design specifications, if any, for each model with respect to electronic product radiation safety. Reference may be made to a Federal standard, if applicable.

(f) For each model, describe the physical or electrical characteristics, such as shielding or electronic circuitry, incorporated into the product in order to meet the standards or specifications reported pursuant to paragraph (e) of this section.

(g) Describe the methods and procedures employed, if any, in testing and measuring each model with respect to electronic product radiation safety, including the control of unnecessary, secondary, or leakage electronic product radiation, the applicable quality control procedures used for each model, and the basis for selecting such testing and quality control procedures.

(h) For those products which may produce increased radiation with aging, describe the methods and procedures used, and frequency of testing of each model for durability and stability with respect to electronic product radiation safety. Include the basis for selecting such methods and procedures, or for determining that such testing and quality control procedures are not necessary.

(i) Provide sufficient results of the testing, measuring, and quality control procedures described in accordance with paragraphs (g) and (h) of this section to enable the Director to determine the effectiveness of those test methods and procedures.

(j) Report for each model all warning signs, labels, and instructions for installation, operation, and use that relate to electronic product radiation safety.

(k) Provide, upon request, such other information as the Director may reasonably require to enable him/her to determine whether the manufacturer has acted or is acting in compliance with the Act and any standards prescribed thereunder, and to enable the Director to carry out the purposes of the Act.

[60 FR 48386, Sept. 19, 1995, as amended at 72 FR 17400, Apr. 9, 2007; 75 FR 20916, Apr. 22, 2010]

§ 1002.11 Supplemental reports.

Prior to the introduction into commerce of a new or modified model within a model or chassis family of a product listed in table 1 of § 1002.1 for which a report under § 1002.10 is required, each manufacturer shall submit a report with respect to such new or modified model describing any changes in the information previously submitted in the product report. Reports will be required for changes that:

(a) Affect actual or potential radiation emission.

(b) Affect the manner of compliance with a standard or manner of testing for radiation safety.

§ 1002.12 Abbreviated reports.

Manufacturers of products requiring abbreviated reports as specified in table 1 of § 1002.1 shall submit, prior to the introduction of such product, a report distinctly marked ''Radiation Safety Abbreviated Report'' which shall include:

(a) Firm and model identification.

(b) A brief description of operational characteristics that affect radiation emissions, transmission, or leakage or that control exposure.