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.

(c) A list of applications or uses.

(d) Radiation emission, transmission, or leakage levels.

(e) If necessary, additional information as may be requested to determine compliance with the Act and this part.

§ 1002.13 Annual reports.

(a) Every manufacturer of products requiring an annual report as specified in table 1 of § 1002.1 shall submit an annual report summarizing the contents of the records required to be maintained by § 1002.30(a) and providing the volume of products produced, sold, or installed.

(b) Reports are due annually by September 1. Such reports shall cover the 12-month period ending on June 30 preceding the due date of the report.

(c) New models of a model family that do not involve changes in radiation emission or requirements of a performance standard do not require supplemental reports prior to introduction into commerce. These model numbers should be reported in quarterly updates to the annual report.

Subpart C—Manufacturers' Reports on Accidental Radiation Occurrences

§ 1002.20 Reporting of accidental radiation occurrences.

(a) Manufacturers of electronic products shall, where reasonable grounds for suspecting that such an incident has occurred, immediately report to the Director, Center for Devices and Radiological Health, all accidental radiation occurrences reported to or otherwise known to the manufacturer and arising from the manufacturing, testing, or use of any product introduced or intended to be introduced into commerce by such manufacturer. Reasonable grounds include, but are not necessarily limited to, professional, scientific, or medical facts or opinions documented or otherwise, that conclude or lead to the conclusion that such an incident has occurred.

(b) Such reports shall be addressed to Food and Drug Administration, Center for Devices and Radiological Health, ATTN: Accidental Radiation Occurrence Reports, Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, rm. G609, Silver Spring, MD 20993–0002, and the reports and their envelopes shall be distinctly marked ''Report on 1002.20'' and shall contain all of the following information where known to the manufacturer:

(1) The nature of the accidental radiation occurrence;

(2) The location at which the accidental radiation occurrence occurred;

(3) The manufacturer, type, and model number of the electronic product or products involved;

(4) The circumstances surrounding the accidental radiation occurrence, including causes;

(5) The number of persons involved, adversely affected, or exposed during