

§ 1002.11

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

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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

the accidental radiation occurrence, the nature and magnitude of their exposure and/or injuries and, if requested by the Director, Center for Devices and Radiological Health, the names of the persons involved;

(6) The actions, if any, which may have been taken by the manufacturer, to control, correct, or eliminate the causes and to prevent reoccurrence; and

(7) Any other pertinent information with respect to the accidental radiation occurrence.

(c) If a manufacturer is required to report to the Director under paragraph (a) of this section and also is required to report under part 803 of this chapter, the manufacturer shall report in accordance with part 803. If a manufacturer is required to report to the Director under paragraph (a) of this section and is not required to report under part 803, the manufacturer shall report in accordance with paragraph (a) of this section. A manufacturer need not file a separate report under this section if an incident involving an accidental radiation occurrence is associated with a defect or noncompliance and is reported pursuant to §1003.10 of this chapter.

[38 FR 28625, Oct. 15, 1973, as amended at 49 FR 36351, Sept. 14, 1984; 53 FR 11254, Apr. 6, 1988; 60 FR 48386, Sept. 19, 1995; 72 FR 17400, Apr. 9, 2007; 75 FR 20916, Apr. 22, 2010]

Subpart D—Manufacturers' Records

§ 1002.30 Records to be maintained by manufacturers.

(a) Manufacturers of products listed under table 1 of §1002.1 shall establish and maintain the following records with respect to such products:

(1) Description of the quality control procedures with respect to electronic product radiation safety.

(2) Records of the results of tests for electronic product radiation safety, including the control of unnecessary, secondary or leakage electronic product radiation, the methods, devices, and procedures used in such tests, and the basis for selecting such methods, devices, and procedures.

(3) For those products displaying aging effects which may increase elec-

tronic product radiation emission, records of the results of tests for durability and stability of the product, and the basis for selecting these tests.

(4) Copies of all written communications between the manufacturer and dealers, distributors, and purchasers concerning radiation safety including complaints, investigations, instructions, or explanations affecting the use, repair, adjustment, maintenance, or testing of the listed product.

(5) Data on production and sales volume levels if available.

(b) In addition to the records required by paragraph (a) of this section, manufacturers of products listed in table 1 of §1002.1 shall establish and maintain the following records with respect to such products:

(1) A record of the manufacturer's distribution of products in a form which will enable the tracing of specific products or production lots to distributors or to dealers in those instances in which the manufacturer distributes directly to dealers.

(2) Records received from dealers or distributors pursuant to §1002.41.

[38 FR 28625, Oct. 15, 1973, as amended at 60 FR 48386, Sept. 19, 1995; 75 FR 16352, Apr. 1, 2010]

§ 1002.31 Preservation and inspection of records.

(a) Every manufacturer required to maintain records pursuant to this part, including records received pursuant to §1002.41, shall preserve such records for a period of 5 years from the date of the record.

(b) Upon reasonable notice by an officer or employee duly designated by the Department, manufacturers shall permit such officer or employee to inspect appropriate books, records, papers, and documents as are relevant to determining whether the manufacturer has acted or is acting in compliance with Federal standards.

(c) Upon request of the Director, Center for Devices and Radiological Health, a manufacturer of products listed in table 1 of §1002.1 shall submit to the Director, copies of the records