

§ 1002.30

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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]

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 electronic 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 paragraph (c) of §1002.61 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]

§ 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 required to be maintained by paragraph (b) of §1002.30.

[38 FR 28625, Oct. 15, 1973, as amended at 53 FR 11254, Apr. 6, 1988; 60 FR 48386, Sept. 19, 1995]