

§ 1002.20

21 CFR Ch. I (4-1-01 Edition)

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 the Director, Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, MD 20857, 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]

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