

## PART 1002 RECORDS AND REPORTS

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## Subpart A--General Provisions

### Sec. 1002.1 Applicability.

The provisions of this part are applicable as follows:

(a) All manufacturers of electronic products are subject to 1002.20.

(b) Manufacturers, dealers, and distributors of electronic products are subject to the provisions of part 1002 as set forth in table 1 of this section, unless excluded by paragraph (c) of this section, or unless an exemption has been granted under 1002.50 or 1002.51.

(c) The requirements of part 1002 as specified in table 1 of this section are not applicable to:

(1) Manufacturers of electronic products intended solely for export if such product is labeled or tagged to show that the product meets all the applicable requirements of the country to which such product is intended for export.

(2) Manufacturers of electronic products listed in table 1 of this section if such product is sold exclusively to other manufacturers for use as components of electronic products to be sold to purchasers, with the exception that the provisions are applicable to those manufacturers certifying components of diagnostic x-ray systems pursuant to provisions of 1020.30(c) of this chapter.

(3) Manufacturers of electronic products that are intended for use by the U.S. Government and whose function or design cannot be divulged by the manufacturer for reasons of national security, as evidenced by government security classification.

(4) Assemblers of diagnostic x-ray equipment subject to the provisions of 1020.30(d) of this chapter, provided the assembler has submitted the report required by 1020.30(d)(1) or (d)(2) of this chapter and

retains a copy of such report for a period of 5 years from its date.

Table 1--Record and Reporting Requirements By Product

Manufacturer							Dealer & Distributor
Products	Product reports 1002.10	Supplemental reports 1002.11	Abbreviated reports 1002.12	Annual reports 1002.13	Test records 1002.30(a) <sup>1</sup>	Distribution records 1002.30(b) <sup>2</sup>	Distribution records 1002.40 and 1002.41
DIAGNOSTIC X-RAY <sup>3</sup> (1020.30, 1020.31, 1020.32, 1020.33)							
Computed tomography	X	X		X	X	X	X
X-ray system <sup>4</sup>	X	X		X	X	X	X
Tube housing assembly	X	X		X	X	X	
X-ray control	X	X		X	X	X	X
X-ray high voltage generator	X	X		X	X	X	X
X-ray table or cradle			X		X	X	X
X-ray film changer			X		X	X	
Vertical cassette			X		X	X	X

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holders mounted in a fixed location and cassette holders with front panels							
Beam-limiting devices	X	X		X	X	X	X
Spot-film devices and image intensifiers manufactured after April 26, 1977	X	X		X	X	X	X
Cephalometric devices manufactured after February 25, 1978			X		X	X	
Image receptor support devices for mammographic X-ray systems manufactured after September			X		X	X	X

5, 1978							
CABINET X RAY (1020. 40)							
Baggage inspection	X	X		X	X	X	X
Other	X	X		X	X	X	
PRODUCTS INTENDED TO PRODUCE PARTICULAT E RADIATION OR X-RAYS OTHER THAN DIAGNOSTIC OR CABINET DIAGNOSTIC X-RAY							
Medical			X	X	X	X	
Analytical			X	X	X	X	
Industrial			X	X	X	X	
TELEVISION PRODUCTS (1020. 10)							
<25 kilovolt (kV) and <0.1 milliroent gen per hour (mR/hr IRLC <sup>5 6</sup>			X	X <sup>6</sup>			
[gteq]25k V and <0.1mR/hr IRLC <sup>5</sup>	X	X		X			

[gteqt]0.1 mR/hr IRLC 5	X	X		X	X	X	
MICROWAVE/ RF							
MW ovens (1030. 10)	X	X		X	X	X	
MW diathermy			X				
MW heating, drying, security systems			X				
RF sealers, electromag netic induction and heating equipment, dielectric heaters (2-500 megahertz)			X				
OPTICAL							
Photothera py products	X	X					
Laser products (1040. 10, 1040. 11)							
Class I lasers and products containing	X			X	X		

such lasers <sup>7</sup>							
Class I laser products containing class IIa, II, IIIa, lasers <sup>7</sup>	X			X	X	X	
Class IIa, II, IIIa lasers and products other than class I products containing such lasers <sup>7</sup>	X	X		X	X	X	X
Class IIb and IV lasers and products containing such lasers <sup>7</sup>	X	X		X	X	X	X
Sunlamp products (1040.20)							
Lamps only	X						
Sunlamp products	X	X		X	X	X	X
Mercury vapor lamps (1040.30)							
T lamps	X	X		X			
R lamps			X				

ACOUSTIC							
Ultrasonic therapy (1050.10)	X	X		X	X	X	X
Diagnostic ultrasound			X				
Medical ultrasound other than therapy or diagnostic	X	X					
Nonmedical ultrasound			X				

<sup>1</sup>However, authority to inspect all appropriate documents supporting the adequacy of a manufacturer's compliance testing program is retained.

<sup>2</sup>The requirement includes 1002.31 and 1002.42, if applicable.

<sup>3</sup>Report of Assembly (Form FDA 2579) is required for diagnostic x-ray components; see 21 CFR 1020.30(d)(1) through (d)(3).

<sup>4</sup>Systems records and reports are required if a manufacturer exercises the option and certifies the system as permitted in 21 CFR 1020.30(c).

<sup>5</sup>Determined using the isoexposure rate limit curve (IRLC) under phase III test conditions (1020.10(c)(3)(iii)).

<sup>6</sup>Annual report is for production status information only.

<sup>7</sup>Determination of the applicable reporting category for a laser product shall be based on the worst-case hazard present within the laser product.

#### Sec. 1002.2 [Reserved]



**Sec. 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.

**Sec. 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.

**Sec. 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.

## Subpart B--Required Manufacturers' Reports for Listed Electronic Products

### Sec. 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.

#### **Sec. 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.

**Sec. 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.

**Sec. 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**

**Sec. 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.

## Subpart D--Manufacturers' Records

### Sec. 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 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.

#### **Sec. 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.

### **Subpart E--Dealer and Distributor Records**

#### **Sec. 1002.40 Records to be obtained by dealers and distributors.**

(a) Dealers and distributors of electronic products for which there are performance standards and for which the retail price is \$50 or more shall obtain such information as is necessary to identify and locate first purchasers if the product is subject to this section by virtue of table 1 of 1002.1.

(b) Such information shall include:

(1) The name and mailing address of the distributor, dealer, or purchaser to whom the product was transferred.

(2) Identification and brand name of the product.

(3) Model number and serial or other identification number of the product.

(4) Date of sale, award, or lease.

(c) The information obtained pursuant to this section shall be forwarded immediately to the appropriate manufacturer of the electronic product, or preserved as prescribed in 1002.41.

**Sec. 1002.41 Disposition of records obtained by dealers and distributors.**

(a) Information obtained by dealers and distributors pursuant to 1002.40 shall immediately be forwarded to the appropriate manufacturer unless:

(1) The dealer or distributor elects to hold and preserve such information and to immediately furnish it to the manufacturer when advised by the manufacturer or the Director, Center for Devices and Radiological Health, that such information is required for purposes of section 535 of the Act; and

(2) The dealer or distributor, upon making the election under paragraph (a) (1) of this section, promptly notifies the manufacturer of such election; such notification shall be in writing and shall identify the dealer or distributor and the electronic product or products for which the information is being accumulated and preserved.

(b) Every dealer or distributor who elects to hold and preserve information required pursuant to 1002.40 shall preserve the information for a period of 5 years from the date of the sale, award, or lease of the product, or until the dealer or distributor discontinues dealing in, or distributing the product, whichever is sooner. If the dealer or distributor discontinues dealing in, or distributing the product, such information as obtained pursuant to 1002.40 shall be furnished at that time, or before, to the manufacturer of the product.

**Sec. 1002.42 Confidentiality of records furnished by dealers and distributors.**

All information furnished to manufacturers by dealers and distributors pursuant to this part shall be treated by such manufacturers as confidential information which may be used only as necessary to notify persons pursuant to section 535 of the Act.

## Subpart F--Exemptions From Records and Reports Requirements

### Sec. 1002.50 Special exemptions.

(a) Manufacturers of electronic products may submit to the Director a request, together with accompanying justification, for exemption from any requirements listed in table 1 of 1002.1. The request must specify each requirement from which an exemption is requested. In addition to other information that is required, the justification must contain documented evidence showing that the product or product type for which the exemption is requested does not pose a public health risk and meets at least one of the following criteria:

(1) The products cannot emit electronic product radiation in sufficient intensity or of such quality, under any conditions of operation, maintenance, service, or product failure, to be hazardous;

(2) The products are produced in small quantities;

(3) The products are used by trained individuals and are to be used by the same manufacturing corporation or for research, investigation, or training.

(4) The products are custom designed and used by trained individuals knowledgeable of the hazards; or

(5) The products are produced in such a way that the requirements are inappropriate or unnecessary.

(b) The Director may, subject to any conditions that the Director deems necessary to protect the public health, exempt manufacturers from all or part of the record and reporting requirements of this part on the basis of information submitted in accordance with paragraph (a) of this section or such other information which the Director may possess if the Director determines that such exemption

is in keeping with the purposes of the Act.

(c) The Director will provide written notification of the reason for any denial. If the exemption is granted, the Director will provide written notification of:

(1) The electronic product or products for which the exemption has been granted;

(2) The requirements from which the product is exempted; and

(3) Such conditions as are deemed necessary to protect the public health and safety. Copies of exemptions shall be available upon request from the Food and Drug Administration, Center for Devices and Radiological Health, Division of Mammography Quality and Radiation Programs, 10903 New Hampshire Ave., Bldg. 66, rm. 4521, Silver Spring, MD 20993-0002.

(d) The Director may, on the Director's own motion, exempt certain classes of products from the reporting requirements listed in table 1 of 1002.1, provided that the Director finds that such exemption is in keeping with the purposes of the act.

(e) Manufacturers of products for which there is no applicable performance standard under parts 1020 through 1050 of this chapter and for which an investigational device exemption has been approved under 812.30 of this chapter or for which a premarket approval application has been approved in accordance with 814.44(d) of this chapter are exempt from submitting all reports listed in table 1 of 1002.1.

**Sec. 1002.51 Exemptions for manufacturers of products intended for the U.S. Government.**

Upon application therefor by the manufacturer, the Director, Center for Devices and Radiological Health, may exempt from the provisions of this part a manufacturer of any electronic product intended for use by departments or agencies of the United States provided such

department or agency has prescribed procurement specifications governing emissions of electronic product radiation and provided further that such product is of a type used solely or predominantly by departments or agencies of the United States.



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