

Food and Drug Administration, HHS

§ 1002.1

Subpart B—Required Manufacturers' Reports for Listed Electronic Products

- 1002.10 Product reports.
- 1002.11 Supplemental reports.
- 1002.12 Abbreviated reports.
- 1002.13 Annual reports.

Subpart C—Manufacturers' Reports on Accidental Radiation Occurrences

- 1002.20 Reporting of accidental radiation occurrences.

Subpart D—Manufacturers' Records

- 1002.30 Records to be maintained by manufacturers.
- 1002.31 Preservation and inspection of records.

Subpart E—Dealer and Distributor Records

- 1002.40 Records to be obtained by dealers and distributors.
- 1002.41 Disposition of records obtained by dealers and distributors.
- 1002.42 Confidentiality of records furnished by dealers and distributors.

Subpart F—Exemptions From Records and Reports Requirements

- 1002.50 Special exemptions.
- 1002.51 Exemptions for manufacturers of products intended for the U.S. Government.

AUTHORITY: 21 U.S.C. 352, 360, 360i, 360j, 360hh-360ss, 371, 374.

SOURCE: 38 FR 28625, Oct. 15, 1973, unless otherwise noted.

Subpart A—General Provisions

§ 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

Products	Manufacturer						Dealer & Distributor
	Product reports § 1002.10	Supplemental reports § 1002.11	Abbreviated reports § 1002.12	Annual reports § 1002.13	Test records § 1002.30(a) ¹	Distribution records § 1002.30(b) ²	Distribution records §§ 1002.40 and 1002.41
DIAGNOSTIC X-RAY ³ (1020.30, 1020.31, 1020.32, 1020.33)							
Computed tomography	X	X		X	X	X	X
X-ray system ⁴	X	X		X	X	X	X
Tube housing assembly	X	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	X
Vertical cassette holders mounted in a fixed location and cassette holders with front panels			X		X	X	X
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 5, 1978			X		X	X	X
CABINET X RAY (§ 1020.40)							
Baggage inspection	X	X		X	X	X	X
Other	X	X		X	X	X	
PRODUCTS INTENDED TO PRODUCE PARTICULATE RADIATION OR X-RAYS OTHER THAN DIAGNOSTIC OR CABINET DIAGNOSTIC X-RAY							
Medical							
Analytical			X	X	X	X	
Industrial			X	X	X	X	
TELEVISION PRODUCTS (§ 1020.10)							
<25 kilovolt (kV) and <0.1 milliroentgen per hour (mR/hr IRLC ^{5,6}			X	X ⁶			
≥25kV and <0.1mR/hr IRLC ⁵	X	X		X			
≥0.1mR/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, electromagnetic induction and heating equipment, dielectric heaters (2–500 megahertz)			X				
OPTICAL							
Phototherapy products							
Laser products (§§ 1040.10, 1040.11)		X					
Class I lasers and products containing such lasers ⁷	X			X	X		
Class I laser products containing class IIa, II, IIIa, lasers ⁷	X			X	X	X	
Class IIa, II, IIIa lasers and products other than class I products containing such lasers ⁷	X	X		X	X	X	X
Class IIIb and IV lasers and products containing such lasers ⁷	X	X		X	X	X	X

§ 1002.1

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

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			

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

²The requirement includes §§ 1002.31 and 1002.42, if applicable.

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

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

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

⁶Annual report is for production status information only.

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

[60 FR 48382, Sept. 19, 1995; 61 FR 13423, Mar. 27, 1996]