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



### Subpart C—Manufacturers' Reports on Accidental Radiation Occurrences



### Subpart D—Manufacturers' Records



### Subpart E—Dealer and Distributor Records



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



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-ray control | X | X | | X | X | X | X |
| X-ray high voltage generator | X | X | | X | X | X | X |

TABLE 1—RECORD AND REPORTING REQUIREMENTS BY PRODUCT—Continued

| 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 |
| X-ray table or cradle | | | X | | X | X | X |
| X-ray film changer | | | 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 | | | X | X | X | X | |
| 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 | X | X | | | | | |
| Laser products (§§ 1040.10, 1040.11) | | | | | | | |
| 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 |
| 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 | | | | |

TABLE 1—RECORD AND REPORTING REQUIREMENTS BY PRODUCT—Continued

| 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 |
| Medical ultrasound other than therapy or diagnostic | X | X | | | | | |
| Nonmedical ultrasound | | | X | | | | |

[1]However, authority to inspect all appropriate documents supporting the adequacy of a manufacturer's compliance testing program is retained.
[2]The requirement includes §§ 1002.31 and 1002.42, if applicable.
[3]Report of Assembly (Form FDA 2579) is required for diagnostic x-ray components; see 21 CFR 1020.30(d)(1) through (d)(3).
[4]Systems records and reports are required if a manufacturer exercises the option and certifies the system as permitted in 21 CFR 1020.30(c).
[5]Determined using the isoexposure rate limit curve (IRLC) under phase III test conditions (1020.10(c)(3)(iii)).
[6]Annual report is for production status information only.
[7]Determination 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]

### § 1002.2 [Reserved]

### § 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.

[69 FR 17292, Apr. 2, 2004]

### § 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.

### § 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 Center for Devices and Radiological Health, ATTN: Electronic Product Reports, Radiological Health Document Control (HFZ–309), Office of Communication, Education, and Radiation Programs, 9200 Corporate Blvd., Rockville, MD 20850.

(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