

## SUBCHAPTER J—RADIOLOGICAL HEALTH

### PART 1000—GENERAL

#### Subpart A—General Provisions

Sec.

1000.1 General.

1000.3 Definitions.

#### Subpart B—Statements of Policy and Interpretation

1000.15 Examples of electronic products subject to the Radiation Control for Health and Safety Act of 1968.

#### Subpart C—Radiation Protection Recommendations

1000.50 Recommendation for the use of specific area gonad shielding on patients during medical diagnostic x-ray procedures.

1000.55 Recommendation for quality assurance programs in diagnostic radiology facilities.

1000.60 Recommendation on administratively required dental x-ray examinations.

AUTHORITY: 21 U.S.C. 360hh-360ss.

SOURCE: 38 FR 28624, Oct. 15, 1973, unless otherwise noted.

#### Subpart A—General Provisions

##### § 1000.1 General.

References in this subchapter J to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

[50 FR 33688, Aug. 20, 1985]

##### § 1000.3 Definitions.

As used in this subchapter J:

(a) *Accidental radiation occurrence* means a single event or series of events that has/have resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a result of the manufacturing, testing, or use of an electronic product.

(b) *Act* means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360hh-360ss).

(c) *Chassis family* means a group of one or more models with all of the following common characteristics:

(1) The same circuitry in the high voltage, horizontal oscillator, and power supply sections;

(2) The same worst component failures;

(3) The same type of high voltage hold-down or safety circuits; and

(4) The same design and installation.

(d) *Commerce* means:

(1) Commerce between any place in any State and any place outside thereof, and

(2) Commerce wholly within the District of Columbia.

(e) *Component*, for the purposes of this part, means an essential functional part of a subassembly or of an assembled electronic product, and which may affect the quantity, quality, direction, or radiation emission of the finished product.

(f) *Dealer* means a person engaged in the business of offering electronic products for sale to purchasers, without regard to whether such person is or has been primarily engaged in such business, and includes persons who offer such products for lease or as prizes or awards.

(g) *Director* means the Director of the Center for Devices and Radiological Health.

(h) *Distributor* means a person engaged in the business of offering electronic products for sale to dealers, without regard to whether such person is or has been primarily or customarily engaged in such business.

(i) *Electromagnetic radiation* includes the entire electromagnetic spectrum of radiation of any wavelength. The electromagnetic spectrum illustrated in figure 1 includes, but is not limited to, gamma rays, x-rays, ultra-violet, visible, infrared, microwave, radiowave, and low frequency radiation.