SUBCHAPTER J—RADIOLOGICAL HEALTH

PART 1000—GENERAL

Subpart A—General Provisions

Subpart B—Statements of Policy and Interpretation

Subpart C—Radiation Protection Recommendations

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.

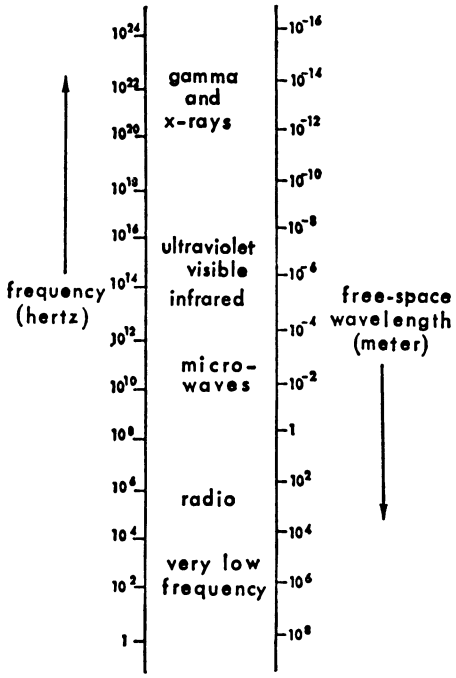

Figure 1. The Electromagnetic Spectrum

(j) *Electronic product* means:

(1) Any manufactured or assembled product which, when in operation:

(i) Contains or acts as part of an electronic circuit and

(ii) Emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or

(2) Any manufactured or assembled article that is intended for use as a component, part, or accessory of a product described in paragraph (j)(1) of this section and which, when in operation, emits (or in the absence of effective shielding or other controls would emit) such radiation.

(k) *Electronic product radiation* means:

(1) Any ionizing or nonionizing electromagnetic or particulate radiation, or

(2) Any sonic, infrasonic, or ultrasonic wave that is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

(l) *Federal standard* means a performance standard issued pursuant to section 534 of the Federal Food, Drug, and Cosmetic Act.

(m) *Infrasonic, sonic (or audible) and ultrasonic waves* refer to energy transmitted as an alteration (pressure, particle displacement or density) in a property of an elastic medium (gas, liquid or solid) that can be detected by an instrument or listener.

(n) *Manufacturer* means any person engaged in the business of manufacturing, assembling, or importing electronic products.

(o) *Model* means any identifiable, unique electronic product design, and refers to products having the same structural and electrical design characteristics and to which the manufacturer has assigned a specific designation to differentiate between it and other products produced by that manufacturer.

(p) *Model family* means products having similar design and radiation characteristics but different manufacturer model numbers.

(q) *Modified model* means a product that is redesigned so that actual or potential radiation emission, the manner of compliance with a standard, or the manner of radiation safety testing is affected.

(r) *Particulate radiation* is defined as:

(1) Charged particles, such as protons, electrons, alpha particles, or heavy particles, which have sufficient kinetic energy to produce ionization or atomic or electron excitation by collision, electrical attractions or electrical repulsion; or

(2) Uncharged particles, such as neutrons, which can initiate a nuclear transformation or liberate charged particles having sufficient kinetic energy to produce ionization or atomic or electron excitation.

(s) *Phototherapy product* means any ultraviolet lamp, or product containing such lamp, that is intended for irradiation of any part of the living human body by light in the wavelength range of 200 to 400 nanometers, in order to perform a therapeutic function.

(t) *Purchaser* means the first person who, for value, or as an award or prize, acquires an electronic product for purposes other than resale, and includes a person who leases an electronic product for purposes other than subleasing.

(u) *State* means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

[60 FR 48380, Sept. 19, 1995; 61 FR 13422, Mar. 27, 1996]

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.

The following listed electronic products are intended to serve as illustrative examples of sources of electronic product radiation to which the regulations of this part apply.

(a) Examples of electronic products which may emit x-rays and other ionizing electromagnetic radiation, electrons, neutrons, and other particulate radiation include:

Ionizing electromagnetic radiation:
- Television receivers.
- Accelerators.
- X-ray machines (industrial, medical, research, educational).

Particulate radiation and ionizing electromagnetic radiation:
- Electron microscopes.
- Neutron generators.

(b) Examples of electronic products which may emit ultraviolet, visible, infrared, microwaves, radio and low frequency electromagnetic radiation include:

Ultraviolet:
- Biochemical and medical analyzers.
- Tanning and therapeutic lamps.
- Sanitizing and sterilizing devices.
- Black light sources.
- Welding equipment.

Visible:
- White light devices.

Infrared:
- Alarm systems.
- Diathermy units.
- Dryers, ovens, and heaters.

Microwave:
- Alarm systems.
- Diathermy units.
- Dryers, ovens, and heaters.
- Medico-biological heaters.
- Microwave power generating devices.
- Radar devices.
- Remote control devices.
- Signal generators.

Radio and low frequency:
- Cauterizers.
- Diathermy units.
- Power generation and transmission equipment.
- Signal generators.
- Electromedical equipment.

(c) Examples of electronic products which may emit coherent electromagnetic radiation produced by stimulated emission include:

Laser:
- Art-form, experimental and educational devices.
- Biomedical analyzers.
- Cauterizing, burning and welding devices.
- Cutting and drilling devices.
- Communications transmitters.
- Rangefinding devices.

Maser:
- Communications transmitters.

(d) Examples of electronic products which may emit infrasonic, sonic, and ultrasonic vibrations resulting from operation of an electronic circuit include:

Infrasonic:
- Vibrators.