GOVERNMENT OF GUAM

DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES

DIPATTAMENTON SALUT PUPBLEKO YAN SETBISION SUSIAT

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FEB 2 0 2013

Hon. Tina Rose Muña Barnes
Legislative Secretary
31ST Guam Legislature
155 Hesler St., Suite 101
Hagåtña, Guam 96910

Office of the Speaker
Judith T. Won Pat, Ed. D.
Date 2/25/13
Time 11:58AM
Received by Faith
32-13-141

Dear Senator Barnes:

Re: Interim DPHSS Radiological Health Regulations

Hafa Adai. Enclosed herewith is an Interim Radiological Health Regulations that is hereby filed with your office pursuant to 10 GCA §§31108 and 9302. The enclosed Federal regulations are being adopted as emergency regulations based upon the absence of applicable guidelines for the operation of x-ray equipment on Guam and the urgency to safeguard the public health from the lack thereof, considering the numerous facilities using such equipment on the Island.

Upon filing with your office, the Department of Public Health and Social Services (DPHSS) shall notify all appropriate parties of the interim regulations. Within 180 days of this filing, DPHSS shall publish its own administrative regulations on this subject.

Your assistance and courtesy in accepting the enclosures for filing is much appreciated.

Senseramente,

JAMES W. GILLAN
Director

Enclosure

0141

Office of the Legislative Secretary
Senator Tina Rose Muña Barnes
Date 2-25-13
Time 11:30
Received by

2013 FEB 25 PM 12:56

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INTERIM
DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES (DPHSS) RADIOLOGICAL HEALTH REGULATIONS

Department of Public Health and Social Services
Division of Environmental Health

"Interim DPHSS Radiological Health Regulations"

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA) STANDARDS

Source:
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10098

1910.1096(a). ***Definitions applicable to this section.***

1910.1096(a)(1). ***Radiation*** includes alpha rays, beta rays, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other atomic particles; but such term does not include sound or radio waves, or visible light, or infrared or ultraviolet light.

1910.1096(a)(2). ***Radioactive material*** means any material which emits, by spontaneous nuclear disintegration, corpuscular or electromagnetic emanations.

1910.1096(a)(3). ***Restricted area*** means any area access to which is controlled by the employer for purposes of protection of individuals from exposure to radiation or radioactive materials.

1910.1096(a)(4). ***Unrestricted area*** means any area access to which is not controlled by the employer for purposes of protection of individuals from exposure to radiation or radioactive materials.

1910.1096(a)(5). ***Dose*** means the quantity of ionizing radiation absorbed, per unit of mass, by the body or by any portion of the body. When the provisions in this section specify a dose during a period of time, the dose is the total quantity of radiation absorbed, per unit of mass, by the body or by any portion of the body during such period of time. Several different units of dose are in current use. Definitions of units used in this section are set forth in paragraphs (a)(6) and (7) of this section.

1910.1096(a)(6). ***Rad*** means a measure of the dose of any ionizing radiation to body tissues in terms of the energy absorbed per unit of mass of the tissue. One rad is the dose corresponding to the absorption of 100 ergs per gram of tissue (1 millirad (mrad)=0.001 rad).

1910.1096(a)(7). ***Rem*** means a measure of the dose of any ionizing radiation to body tissue in terms of its estimated biological effect relative to a dose of 1 roentgen (r) of X-rays (1 millirem (mrem)=0.001 rem). The relation of the rem to other dose units depends upon the biological effect under consideration and upon the conditions for irradiation. Each of the following is considered to be equivalent to a dose of 1 rem:

1910.1096(a)(7)(i). A dose of 1 roentgen due to X- or gamma radiation;

1910.1096(a)(7)(ii). A dose of 1 rad due to X-, gamma, or beta radiation;

1910.1096(a)(7)(iii). A dose of 0.1 rad due to neutrons or high energy protons;

1910.1096(a)(7)(iv). A dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye;

1910.1096(a)(7)(v). If it is more convenient to measure the neutron flux, or equivalent, than to determine the neutron dose in rads, as provided in paragraph (a)(7)(iii) of this section, 1 rem of neutron radiation may, for purposes of the provisions in this section be assumed to be equivalent to 14 million neutrons per square centimeter incident upon the body; or, if there is sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to 1 rem may be estimated from Table G-17:

TABLE G-17 - NEUTRON FLUX DOSE EQUIVALENTS

Neutron energy (million electron volts (Mev))	**Number of neutrons per square centimeter equivalent to a dose of 1 rem (neutrons/cm(2))**	**Average flux to deliver 100 millirem in 40 hours (neutrons/cm(2) per sec)**
Thermal	970 X 10(6)	670
0.0001	720 X 10(6)	500
0.005	820 X 10(6)	570
0.02	400 X 10(6)	280
0.1	120 X 10(6)	80
0.5	43 X 10(6)	30
1.0	26 X 10(6)	18
2.5	29 X 10(6)	20
5.0	26 X 10(6)	18
7.5	24 X 10(6)	17
10	24 X 10(6)	17
10 to 30	14 X 10(6)	10

1910.1096(a)(8). For determining exposures to X- or gamma rays up to 3 Mev., the dose

limits specified in this section may be assumed to be equivalent to the "air dose". For the purpose of this section ***air dose*** means that the dose is measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dosage rate.

1910.1096(b). ***Exposure of individuals to radiation in restricted areas.***

1910.1096(b)(1). Except as provided in paragraph (b)(2) of this section, no employer shall possess, use, or transfer sources of ionizing radiation in such a manner as to cause any individual in a restricted area to receive in any period of one calendar quarter from sources in the employer's possession or control a dose in excess of the limits specified in Table G-18:

TABLE G-18

	Rems per calendar quarter
Whole body: Head and trunk; active blood-forming organs; lens of eyes; or gonads	1 1/4
Hands and forearms; feet and ankles	18 3/4
Skin of whole body	7 1/2

1910.1096(b)(2). An employer may permit an individual in a restricted area to receive doses to the whole body greater than those permitted under subparagraph (1) of this paragraph, so long as:

1910.1096(b)(2)(i). During any calendar quarter the dose to the whole body shall not exceed 3 rems; and

1910.1096(b)(2)(ii). The dose to the whole body, when added to the accumulated occupational dose to the whole body, shall not exceed 5 (N-18) rems, where "N" equals the individual's age in years at his last birthday; and

1910.1096(b)(2)(iii). The employer maintains adequate past and current exposure records which show that the addition of such a dose will not cause the individual to exceed the amount authorized in this subparagraph. As used in this subparagraph ***Dose to the whole body*** shall be deemed to include any dose to the whole body, gonad, active bloodforming organs, head and trunk, or lens of the eye.

1910.1096(b)(3). No employer shall permit any employee who is under 18 years of age to receive in any period of one calendar quarter a dose in excess of 10 percent of the limits

specified in Table G-18.

1910.1096(b)(4). ***Calendar quarter*** means any 3-month period determined as follows:

1910.1096(b)(4)(i). The first period of any year may begin on any date in January: ***Provided***, That the second, third, and fourth periods accordingly begin on the same date in April, July, and October, respectively, and that the fourth period extends into January of the succeeding year, if necessary to complete a 3-month quarter. During the first year of use of this method of determination, the first period for that year shall also include any additional days in January preceding the starting date for the first period; or

1910.1096(b)(4)(ii). The first period in a calendar year of 13 complete, consecutive calendar weeks; the second period in a calendar year of 13 complete, consecutive weeks; the third period in a calendar year of 13 complete, consecutive calendar weeks; the fourth period in a calendar year of 13 complete, consecutive calendar weeks. If at the end of a calendar year there are any days not falling within a complete calendar week of that year, such days shall be included within the last complete calendar week of that year. If at the beginning of any calendar year there are days not falling within a complete calendar week of that year, such days shall be included within the last complete calendar week of the previous year; or

1910.1096(b)(4)(iii). The four periods in a calendar year may consist of the first 14 complete, consecutive calendar weeks; the next 12 complete, consecutive calendar weeks, the next 14 complete, consecutive calendar weeks, and the last 12 complete, consecutive calendar weeks. If at the end of a calendar year there are any days not falling within a complete calendar week of that year, such days shall be included (for purposes of this section) within the last complete calendar week of the year. If at the beginning of any calendar year there are days not falling within a complete calendar week of that year, such days shall be included (for purposes of this section) within the last complete week of the previous year.

1910.1096(c). ***Exposure to airborne radioactive material.***

1910.1096(c)(1). No employer shall possess, use or transport radioactive material in such a manner as to cause any employee, within a restricted area, to be exposed to airborne radioactive material in an average concentration in excess of the limits specified in Table 1 of appendix B to 10 CFR part 20. The limits given in Table 1 are for exposure to the concentrations specified for 40 hours in any workweek of 7 consecutive days. In any such period where the number of hours of exposure is less than 40, the limits specified in the table may be increased proportionately. In any such period where the number of hours of exposure is greater than 40, the limits specified in the table shall be decreased proportionately.

1910.1096(c)(2). No employer shall possess, use, or transfer radioactive material in such a manner as to cause any individual within a restricted area, who is under 18 years of age, to

be exposed to airborne radioactive material in an average concentration in excess of the limits specified in Table II of appendix B to 10 CFR part 20. For purposes of this paragraph, concentrations may be averaged over periods not greater than 1 week.

1910.1096(c)(3). ***Exposed*** as used in this paragraph means that the individual is present in an airborne concentration. No allowance shall be made for the use of protective clothing or equipment, or particle size.

1910.1096(d). ***Precautionary procedures and personal monitoring.***

1910.1096(d)(1). Every employer shall make such surveys as may be necessary for him to comply with the provisions in this section. ***Survey*** means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions. When appropriate, such evaluation includes a physical survey of the location of materials and equipment, and measurements of levels of radiation or concentrations of radioactive material present.

1910.1096(d)(2). Every employer shall supply appropriate personnel monitoring equipment, such as film badges, pocket chambers, pocket dosimeters, or film rings, and shall require the use of such equipment by:

1910.1096(d)(2)(i). Each employee who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 25 percent of the applicable value specified in paragraph (b)(1) of this section; and

1910.1096(d)(2)(ii). Each employee under 18 years of age who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 5 percent of the applicable value specified in paragraph (b)(1) of this section; and

1910.1096(d)(2)(iii). Each employee who enters a high radiation area.

1910.1096(d)(3). As used in this section:

1910.1096(d)(3)(i). ***Personnel monitoring equipment*** means devices designed to be worn or carried by an individual for the purpose of measuring the dose received (e.g., film badges, pocket chambers, pocket dosimeters, film rings, etc.);

1910.1096(d)(3)(ii). ***Radiation area*** means any area, accessible to personnel, in which there exists radiation at such levels that a major portion of the body could receive in any 1 hour a dose in excess of 5 millirem, or in any 5 consecutive days a dose in excess of 100 millirem; and

1910.1096(d)(3)(iii). ***High radiation area*** means any area, accessible to personnel, in which there exists radiation at such levels that a major portion of the body could

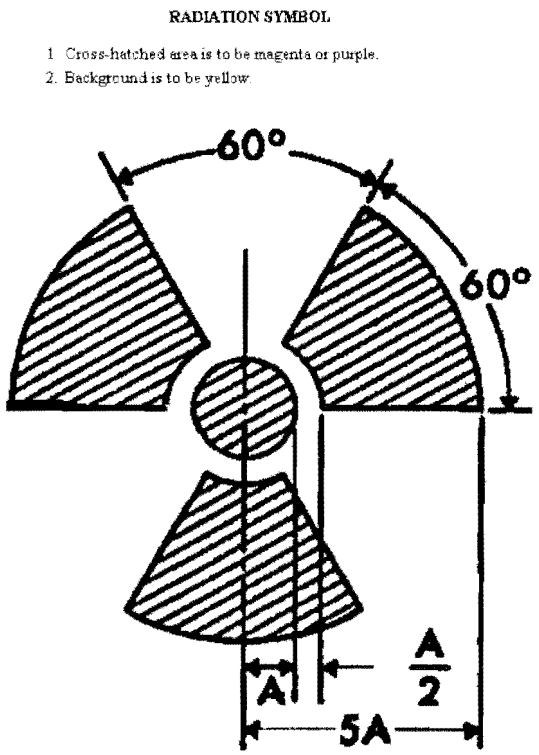
receive in any one hour a dose in excess of 100 millirem.

1910.1096(e). ***Caution signs, labels, and signals*** -

1910.1096(e)(1). ***General.***

1910.1096(e)(1)(i). Symbols prescribed by this paragraph shall use the conventional radiation caution colors (magenta or purple on yellow background). The symbol prescribed by this paragraph is the conventional three-bladed design:

FIGURE G-10 RADIATION SYMBOL



1910.1096(e)(2). ***Radiation area.*** Each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol described in subparagraph (1) of this paragraph and the words:

CAUTION

RADIATION AREA

1910.1096(e)(3). ***High radiation area.***

1910.1096(e)(3)(i). Each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION

HIGH RADIATION AREA

1910.1096(e)(3)(ii). Each high radiation area shall be equipped with a control device which shall either cause the level of radiation to be reduced below that at which an individual might receive a dose of 100 millirems in 1 hour upon entry into the area or shall energize a conspicuous visible or audible alarm signal in such a manner that the individual entering and the employer or a supervisor of the activity are made aware of the entry. In the case of a high radiation area established for a period of 30 days or less, such control device is not required.

1910.1096(e)(4). ***Airborne radioactivity area***.

1910.1096(e)(4)(i). As used in the provisions of this section, ***airborne radioactivity area*** means:

1910.1096(e)(4)(i)(a). Any room, enclosure, or operating area in which airborne radioactive materials, composed wholly or partly of radioactive material, exist in concentrations in excess of the amounts specified in column 1 of Table 1 of appendix B to 10 CFR part 20 or

1910.1096(e)(4)(i)(b). Any room, enclosure, or operating area in which airborne radioactive materials exist in concentrations which, averaged over the number of hours in any week during which individuals are in the area, exceed 25 percent of the amounts specified in column 1 of Table 1 of appendix B to 10 CFR part 20.

1910.1096(e)(4)(ii). Each airborne radioactivity area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol described in paragraph (e)(1) of this section and the words:

CAUTION

AIRBORNE RADIOACTIVITY AREA

1910.1096(e)(5). ***Additional requirements***.

1910.1096(e)(5)(i). Each area or room in which radioactive material is used or stored and which contains any radioactive material (other than natural uranium or thorium) in any amount exceeding 10 times the quantity of such material specified in appendix C to 10 CFR part 20 shall be conspicuously posted with a sign or signs

bearing the radiation caution symbol described in paragraph (e)(1) of this section and the words:

CAUTION

RADIOACTIVE MATERIALS

1910.1096(e)(5)(ii). Each area or room in which natural uranium or thorium is used or stored in an amount exceeding 100 times the quantity of such material specified in 10 CFR part 20 shall be conspicuously posted with a sign or signs bearing the radiation caution symbol described in paragraph (e)(1) of this section and the words:

CAUTION

RADIOACTIVE MATERIALS

1910.1096(e)(6). ***Containers.***

1910.1096(e)(6)(i). Each container in which is transported, stored, or used a quantity of any radioactive material (other than natural uranium or thorium) greater than the quantity of such material specified in appendix C to 10 CFR part 20 shall bear a durable, clearly visible label bearing the radiation caution symbol described in paragraph (e)(1) of this section and the words:

CAUTION

RADIOACTIVE MATERIALS

1910.1096(e)(6)(ii). Each container in which natural uranium or thorium is transported, stored, or used in a quantity greater than 10 times the quantity specified in appendix C to 10 CFR part 20 shall bear a durable, clearly visible label bearing the radiation caution symbol described in paragraph (e)(1) of this section and the words:

1910.1096(i). ***"Instruction of personnel, posting."***

1910.1096(i)(1). Employers regulated by the Nuclear Regulatory Commission shall be governed by 10 CFR part 20 standards. Employers in a State named in paragraph (p)(3) of this section shall be governed by the requirements of the laws and regulations of that State. All other employers shall be regulated by the following:

1910.1096(i)(2). All individuals working in or frequenting any portion of a radiation area shall be informed of the occurrence of radioactive materials or of radiation in such portions of the radiation area; shall be instructed in the safety problems associated with exposure to

such materials or radiation and in precautions or devices to minimize exposure; shall be instructed in the applicable provisions of this section for the protection of employees from exposure to radiation or radioactive materials; and shall be advised of reports of radiation exposure which employees may request pursuant to the regulations in this section.

1910.1096(i)(3). Each employer to whom this section applies shall post a current copy of its provisions and a copy of the operating procedures applicable to the work conspicuously in such locations as to insure that employees working in or frequenting radiation areas will observe these documents on the way to and from their place of employment, or shall keep such documents available for examination of employees upon request.

1910.1096(j). ***Storage of radioactive materials***. Radioactive materials stored in a non-radiation area shall be secured against unauthorized removal from the place of storage.

1910.1096(k). ***Waste disposal.*** No employer shall dispose of radioactive material except by transfer to an authorized recipient, or in a manner approved by the Nuclear Regulatory Commission or a State named in paragraph (p)(3) of this section.

1910.1096(l). ***Notification of incidents*** -

1910.1096(l)(1). ***Immediate notification.*** Each employer shall immediately notify the Assistant Secretary of Labor or his duly authorized representative, for employees not protected by the Nuclear Regulatory Commission by means of 10 CFR part 20; paragraph (p)(2) of this section, or the requirements of the laws and regulations of States named in paragraph (p)(3) of this section, by telephone or telegraph of any incident involving radiation which may have caused or threatens to cause:

1910.1096(l)(1)(i). Exposure of the whole body of any individual to 25 rems or more of radiation; exposure of the skin of the whole body of any individual to 150 rems or more of radiation; or exposure of the feet, ankles, hands, or forearms of any individual to 375 rems or more of radiation; or

1910.1096(l)(1)(ii). The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 5,000 times the limit specified for such materials in Table II of appendix B to 10 CFR part 20.

1910.1096(n). ***"Records."***

1910.1096(n)(1). Every employer shall maintain records of the radiation exposure of all employees for whom personnel monitoring is required under paragraph (d) of this section and advise each of his employees of his individual exposure on at least an annual basis.

1910.1096(n)(2). Every employer shall maintain records in the same units used in tables in paragraph (b) of this section and appendix B to 10 CFR Part 20.

1910.1096(p). ***"Nuclear Regulatory Commission licensees - NRC contractors operating NRC***

plants and facilities - NRC Agreement State licensees or registrants."

1910.1096(p)(1). Any employer who possesses or uses source material, byproduct material, or special nuclear material, as defined in the Atomic Energy Act of 1954, as amended, under a license issued by the Nuclear Regulatory Commission and in accordance with the requirements of 10 CFR part 20 shall be deemed to be in compliance with the requirements of this section with respect to such possession and use.

1910.1096(p)(2). NRC contractors operating NRC plants and facilities: Any employer who possesses or uses source material, byproduct material, special nuclear material, or other radiation sources under a contract with the Nuclear Regulatory Commission for the operation of NRC plants and facilities and in accordance with the standards, procedures, and other requirements for radiation protection established by the Commission for such contract pursuant to the Atomic Energy Act of 1954 as amended (42 U.S.C. 2011 et seq.), shall be deemed to be in compliance with the requirements of this section with respect to such possession and use.

1910.1096(p)(3). NRC-agreement State licensees or registrants:

1910.1096(p)(3)(i). "Atomic Energy Act sources." Any employer who possesses or uses source material, byproduct material, or special nuclear material, as defined in the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.), and has either registered such sources with, or is operating under a license issued by, a State which has an agreement in effect with the Nuclear Regulatory Commission pursuant to section 274(b) (42 U.S.C. 2021(b)) of the Atomic Energy Act of 1954, as amended, and in accordance with the requirements of that State's laws and regulations shall be deemed to be in compliance with the radiation requirements of this section, insofar as his possession and use of such material is concerned, unless the Secretary of Labor, after conference with the Nuclear Regulatory Commission, shall determine that the State's program for control of these radiation sources is incompatible with the requirements of this section. Such agreements currently are in effect only in the States of Alabama, Arkansas, California, Kansas, Kentucky, Florida, Mississippi, New Hampshire, New York, North Carolina, Texas, Tennessee, Oregon, Idaho, Arizona, Colorado, Louisiana, Nebraska, Washington, Maryland, North Dakota, South Carolina, and Georgia.

1910.1096(p)(3)(ii). "Other sources." Any employer who possesses or uses radiation sources other than source material, byproduct material, or special nuclear material, as defined in the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.), and has either registered such sources with, or is operating under a license issued by a State which has an agreement in effect with the Nuclear Regulatory Commission pursuant to section 274(b) (42 U.S.C. 2021(b)) of the Atomic Energy Act of 1954, as amended, and in accordance with the requirements of that State's laws and regulations shall be deemed to be in compliance with the radiation requirements of this section, insofar as his possession and use of such material is concerned, provided the State's program for control of these radiation sources is the

subject of a currently effective determination by the Assistant Secretary of Labor that such program is compatible with the requirements of this section. Such determinations currently are in effect only in the States of Alabama, Arkansas, California, Kansas, Kentucky, Florida, Mississippi, New Hampshire, New York, North Carolina, Texas, Tennessee, Oregon, Idaho, Arizona, Colorado, Louisiana, Nebraska, Washington, Maryland, North Dakota, South Carolina, and Georgia.

[39 FR 23502, June 27, 1974, as amended at 43 FR 49746, Oct. 24, 1978; 43 FR 51759, Nov. 7, 1978; 49 FR 18295, Apr. 30, 1984; 58 FR 35309, June 30, 1993; 61 FR 5507, Feb. 13, 1996; 61 FR 31427, June 20, 1996]

NUCLEAR REGULATORY COMMISSION (NRC) STANDARDS

Source: http://www.nrc.gov/reading-rm/doc-collections/cfr/part020/

NRC Regulations (10 CFR) > PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

Subpart A—General Provisions
20.1001 Purpose.
20.1002 Scope.
20.1003 Definitions.
20.1004 Units of radiation dose.
20.1005 Units of radioactivity.

Subpart B—Radiation Protection Programs
20.1101 Radiation protection programs.

Subpart C—Occupational Dose Limits
20.1201 Occupational dose limits for adults.
20.1207 Occupational dose limits for minors.
20.1208 Dose equivalent to an embryo/fetus.

Subpart D—Radiation Dose Limits for Individual Members of the Public
20.1301 Dose limits for individual members of the public.
20.1302 Compliance with dose limits for individual members of the public.

Subpart F—Surveys and Monitoring
20.1501 General.
20.1502 Conditions requiring individual monitoring of external and internal occupational dose.

Authority: Atomic Energy Act secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 223, 234, 1701 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2273, 2282, 2297f), Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846);

Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005 sec. 651(e), Pub. L. 109–58, 119 Stat. 549 (2005) (42 U.S.C. 2014, 2021, 2021b, 2111).

[72 FR 55921, Oct. 1, 2007; 76 FR 35564, Jun. 17, 2011; 77 FR 39904, Jul. 6, 2012]

Subpart A—General Provisions

Source: 56 FR 23391, May 21, 1991, unless otherwise noted.

§ 20.1001 Purpose.

(a) The regulations in this part establish standards for protection against ionizing radiation resulting from activities conducted under licenses issued by the Nuclear Regulatory Commission. These regulations are issued under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

(b) It is the purpose of the regulations in this part to control the receipt, possession, use, transfer, and disposal of licensed material by any licensee in such a manner that the total dose to an individual (including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation) does not exceed the standards for protection against radiation prescribed in the regulations in this part. However, nothing in this part shall be construed as limiting actions that may be necessary to protect health and safety.

§ 20.1002 Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material or to operate a production or utilization facility under parts 30 through 36, 39, 40, 50, 52, 60, 61, 63, 70, or 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released under § 35.75, or to exposure from voluntary participation in medical research programs.

[67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002, as amended at 67 FR 77652, Dec. 19, 2002; 72 FR 49485, Aug. 28, 2007]

§ 20.1003 Definitions.

As used in this part:

Absorbed dose means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).

Accelerator-produced radioactive material means any material made radioactive by a particle accelerator.

Act means the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.), as amended.

Activity is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).

Adult means an individual 18 or more years of age.

Airborne radioactive material means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

Airborne radioactivity area means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations—

(1) In excess of the derived air concentrations (DACs) specified in appendix B, to §§ 20.1001-20.2401, or

(2) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

Air-purifying respirator means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

ALARA (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

Annual limit on intake **(ALI)** means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. (ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table 1, Columns 1 and 2, of appendix B to §§ 20.1001-20.2401).

Assigned protection factor (APF) means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

Atmosphere-supplying respirator means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

Background radiation means radiation from cosmic sources; naturally occurring radioactive material, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "*Background radiation*" does not include radiation from source, byproduct, or special nuclear materials regulated by the Commission.

Bioassay ***(radiobioassay)*** means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

Byproduct material means—

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore

bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

(3)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(4) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

***Class* (or *lung class* or *inhalation class*)** means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D (Days) of less than 10 days, for Class W (Weeks) from 10 to 100 days, and for Class Y Years) of greater than 100 days.

Collective dose is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

Commission means the Nuclear Regulatory Commission or its duly authorized representatives.

***Committed dose equivalent* ($H_{T,50}$)** means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

***Committed effective dose equivalent* ($H_{E,50}$)** is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \Sigma W_T H_{T,50}$).

Constraint (dose constraint) means a value above which specified licensee actions are required.

Controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

Critical Group means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

Declared pregnant woman means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

Decommission means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits—

(1) Release of the property for unrestricted use and termination of the license; or
(2) Release of the property under restricted conditions and termination of the license.

Deep-dose equivalent **(H_d),** which applies to external whole-body exposure, is the dose equivalent at a tissue depth of 1 cm (1000 mg/cm^2).

Demand respirator means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

Department means the Department of Energy established by the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565, 42 U.S.C. 7101 et seq.) to the extent that the Department, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers, and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104 (b), (c), and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat 565 at 577-578, 42 U.S.C. 7151).

Derived air concentration (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of one ALI. DAC values are given in Table 1, Column 3, of appendix B to §§ 20.1001-20.2401.

Derived air concentration-hour **(DAC-hour)** is the product of the concentration of radioactive material in air (expressed as a fraction or multiple of the derived air concentration for each radionuclide) and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 5 rems (0.05 Sv).

Discrete source means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

Disposable respirator means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

Distinguishable from background means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

Dose* or *radiation dose is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in other paragraphs of this section.

Dose equivalent **(H_T)** means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

Dosimetry processor means an individual or organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.

Effective dose equivalent **(H_E)** is the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma W_T H_T$).

Embryo/fetus means the developing human organism from conception until the time of birth.

Entrance or access point means any location through which an individual could gain access to radiation areas or to radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

Exposure means being exposed to ionizing radiation or to radioactive material.

External dose means that portion of the dose equivalent received from radiation sources outside the body.

Extremity means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

Filtering facepiece (dust mask) means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

Fit factor means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

Fit test means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

Generally applicable environmental radiation standards means standards issued by the Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

Government agency means any executive department, commission, independent establishment, corporation wholly or partly owned by the United States of America, which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

Gray [See § 20.1004].

Helmet means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

High radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

Hood means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

Individual means any human being.

Individual monitoring means—

(1) The assessment of dose equivalent by the use of devices designed to be worn by an individual;

(2) The assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or

(3) The assessment of dose equivalent by the use of survey data.

Individual monitoring devices (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges,

thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

Internal dose means that portion of the dose equivalent received from radioactive material taken into the body.

Lens dose equivalent (LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

License means a license issued under the regulations in parts 30 through 36, 39, 40, 50, 60, 61, 63, 70, or 72 of this chapter.

Licensed material means source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general or specific license issued by the Commission.

Licensee means the holder of a license.

Limits (dose limits) means the permissible upper bounds of radiation doses.

Loose-fitting facepiece means a respiratory inlet covering that is designed to form a partial seal with the face.

Lost or missing licensed material means licensed material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

Member of the public means any individual except when that individual is receiving an occupational dose.

Minor means an individual less than 18 years of age.

Monitoring (radiation monitoring, radiation protection monitoring) means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

Negative pressure respirator (tight fitting) means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Nonstochastic effect means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect (also called a deterministic effect).

NRC means the Nuclear Regulatory Commission or its duly authorized representatives.

Occupational dose means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under § 35.75, from voluntary participation in medical research programs, or as a member of the public.

Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, "accelerator" is an equivalent term.

Person means—

(1) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department of Energy (except that the Department shall be considered a person within the meaning of the regulations in 10 CFR chapter I to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission under section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), the Nuclear Waste Policy Act of 1982 (96 Stat. 2201), and section 3(b)(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (99 Stat. 1842)), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and

(2) Any legal successor, representative, agent, or agency of the foregoing.

Planned special exposure means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

Positive pressure respirator means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

Powered air-purifying respirator (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

Pressure demand respirator means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

Public dose means the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to

individuals administered radioactive material and released under § 35.75, or from voluntary participation in medical research programs.

Qualitative fit test (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

Quality Factor (Q) means the modifying factor (listed in tables 1004(b).1 and 1004(b).2 of § 20.1004) that is used to derive dose equivalent from absorbed dose.

Quantitative fit test (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Quarter means a period of time equal to one-fourth of the year observed by the licensee (approximately 13 consecutive weeks), providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

Rad (See § 20.1004).

Radiation (ionizing radiation) means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation, as used in this part, does not include non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light.

Radiation area means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Reference man means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

Rem (See § 20.1004).

Residual radioactivity means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 10 CFR part 20.

Respiratory protective device means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

Restricted area means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

Sanitary sewerage means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

Self-contained breathing apparatus (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Shallow-dose equivalent (H_S), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

Sievert (See § 20.1004).

Site boundary means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

Source material means—

(1) Uranium or thorium or any combination of uranium and thorium in any physical or chemical form; or

(2) Ores that contain, by weight, one-twentieth of 1 percent (0.05 percent), or more, of uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

Special nuclear material means—

(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material, but does not include source material; or

(2) Any material artificially enriched by any of the foregoing but does not include source material.

Stochastic effects means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

Supplied-air respirator (SAR) **or** ***airline respirator*** means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

Survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

Tight-fitting facepiece means a respiratory inlet covering that forms a complete seal with the face.

Total Effective Dose Equivalent **(TEDE)** means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Uranium fuel cycle means the operations of milling of uranium ore, chemical conversion of uranium, isotopic enrichment of uranium, fabrication of uranium fuel, generation of electricity by a light-water-cooled nuclear power plant using uranium fuel, and reprocessing of spent uranium fuel to the extent that these activities directly support the production of electrical power for public use. Uranium fuel cycle does not include mining operations, operations at waste disposal sites, transportation of radioactive material in support of these operations, and the reuse of recovered non-uranium special nuclear and byproduct materials from the cycle.

User seal check (fit check) means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

Very high radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in 1 hour at 1 meter from a radiation source or 1 meter from any surface that the radiation penetrates.

(Note: At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts)).

Waste means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in this section.

Week means 7 consecutive days starting on Sunday.

Weighting factor W_T, for an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the

whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of W_T are:

Organ Dose Weighting Factors

Organ or Tissue	W_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	[1]0.30
Whole Body	[2]1.00

[1] 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.

[2] For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, w_T=1.0, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

Whole body means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

Working level (WL) is any combination of short-lived radon daughters (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in 1 liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha particle energy.

Working level month (WLM) means an exposure to 1 working level for 170 hours (2,000 working hours per year/12 months per year=approximately 170 hours per month).

Year means the period of time beginning in January used to determine compliance with the provisions of this part. The licensee may change the starting date of the year used to determine compliance by the licensee provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

[56 FR 23391, May 21, 1991, as amended at 57 FR 57878, Dec. 8, 1992; 58 FR 7736, Feb. 9, 1993; 60 FR 36043, July 13, 1995; 60 FR 48625, Sept. 20, 1995; 61 FR 65127, Dec. 10, 1996; 62 FR 4133, Jan. 29, 1997; 62 FR 39087, July 21, 1997; 63 FR 39481, July 23, 1998; 64 FR 54556, Oct. 7, 1999; 66 FR 55789, Nov. 2, 2001; 67 FR 16304, Apr. 5, 2002; 67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002; 72 FR 55921, Oct. 1, 2007; 72 FR 68058, Dec. 4, 2007; 74 FR 62680, Dec. 1, 2009]

§ 20.1004 Units of radiation dose.

(a) Definitions. As used in this part, the units of radiation dose are:

Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 Joule/kilogram (100 rads).

Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray).

Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem=0.01 sievert).

Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv=100 rems).

(b) As used in this part, the quality factors for converting absorbed dose to dose equivalent are shown in table 1004(b).1.

Table 1004(b).1-Quality Factors and Absorbed Dose Equivalencies

Type of radiation	Quality factor (Q)	Absorbed dose equal to a unit dose equivalent[a]
X-, gamma, or beta radiation	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

[a] Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

(c) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, as provided in paragraph (b) of this section, 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of the regulations in this part, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee may use the fluence rate per unit dose equivalent or the appropriate Q value from table 1004(b).2 to convert a measured tissue dose in rads to dose equivalent in rems.

Table 1004(b).2.—Mean Quality Factors, Q, and Fluence Per Unit Dose Equivalent for Monoenergetic Neutrons

	Neutron energy (MeV)	Quality factor[a] (Q)	Fluence per unit dose equivalent[b] (neutrons cm^{-2} rem^{-1})

(thermal).....	2.5×10^{-8}	2	980×10^{6}
	1×10^{-7}	2	980×10^{6}
	1×10^{-6}	2	810×10^{6}
	1×10^{-5}	2	810×10^{6}
	1×10^{-4}	2	840×10^{6}
	1×10^{-3}	2	980×10^{6}
	1×10^{-2}	2.5	1010×10^{6}
	1×10^{-1}	7.5	170×10^{6}
	5×10^{-1}	11	39×10^{6}
	1	11	27×10^{6}
	2.5	9	29×10^{6}
	5	8	23×10^{6}
	7	7	24×10^{6}
	10	6.5	24×10^{6}
	14	7.5	17×10^{6}
	20	8	16×10^{6}
	40	7	14×10^{6}
	60	5.5	16×10^{6}
	1×10^{2}	4	20×10^{6}
	2×10^{2}	3.5	19×10^{6}
	3×10^{2}	3.5	16×10^{6}
	4×10^{2}	3.5	14×10^{6}

[a] Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-cm diameter cylinder tissue-equivalent phantom.
[b] Monoenergetic neutrons incident normally on a 30-cm diameter cylinder tissue-equivalent phantom.

§ 20.1005 Units of radioactivity.

For the purposes of this part, activity is expressed in the special unit of curies (Ci) or in the SI unit of becquerels (Bq), or their multiples, or disintegrations (transformations) per unit of time.

(a) One becquerel=1 disintegration per second (s^{-1}).

(b) One curie=3.7×10^{10} disintegrations per second=3.7×10^{10} becquerels=2.22×10^{12} disintegrations per minute.

[56 FR 23391, May 21, 1991; 56 FR 61352, Dec. 3, 1991]

Subpart B--Radiation Protection Programs

Source: 56 FR 23396, May 21, 1991, unless otherwise noted.

§ 20.1101 Radiation protection programs.

(a) Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part. (See § 20.2102 for recordkeeping requirements relating to these programs.)

(b) The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

(c) The licensee shall periodically (at least annually) review the radiation protection program content and implementation.

(d) To implement the ALARA requirements of § 20.1101 (b), and notwithstanding the requirements in § 20.1301 of this part, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees other than those subject to § 50.34a, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in § 20.2203 and promptly take appropriate corrective action to ensure against recurrence.

[56 FR 23396, May 21, 1991, as amended at 61 FR 65127, Dec. 10, 1996; 63 FR 39482, July 23, 1998]

Subpart C--Occupational Dose Limits

Source: 56 FR 23396, May 21, 1991, unless otherwise noted.

§ 20.1201 Occupational dose limits for adults.

(a) The licensee shall control the occupational dose to individual adults, except for planned special exposures under § 20.1206, to the following dose limits.

(1) An annual limit, which is the more limiting of--

(i) The total effective dose equivalent being equal to 5 rems (0.05 Sv); or
(ii) The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).

(2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

(i) A lens dose equivalent of 15 rems (0.15 Sv), and
(ii) A shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

(b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures that the individual may receive during the current year (see § 20.1206(e)(1)) and during the individual's lifetime (see § 20.1206(e)(2)).

(c) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

(d) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table 1 of appendix B to part 20 and may be used to determine the individual's dose (see § 20.2106) and to demonstrate compliance with the occupational dose limits.

(e) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity (see footnote 3 of appendix B to part 20).

(f) The licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person (see § 20.2104(e)).

[56 FR 23396, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995; 63 FR 39482, July 23, 1998; 67 FR 16304, Apr. 5, 2002; 72 FR 68059, Dec. 4, 2007]

§ 20.1207 Occupational dose limits for minors.

The annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers in § 20.1201.

§ 20.1208 Dose equivalent to an embryo/fetus.

(a) The licensee shall ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). (For recordkeeping requirements, see § 20.2106.)

(b) The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph (a) of this section.

(c) The dose equivalent to the embryo/fetus is the sum of--

(1) The deep-dose equivalent to the declared pregnant woman; and

(2) The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

(d) If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee, the licensee shall be deemed to be in compliance with paragraph (a) of this section if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

[56 FR 23396, May 21, 1991, as amended at 63 FR 39482, July 23, 1998]

Subpart D--Radiation Dose Limits for Individual Members of the Public

Source: 56 FR 23398, May 21, 1991, unless otherwise noted.

§ 20.1301 Dose limits for individual members of the public.

(a) Each licensee shall conduct operations so that -

(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from background radiation, from any administration the individual has received, from exposure to individuals administered radioactive material and released under § 35.75, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.2003, and

(2) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with § 35.75, does not exceed 0.002 rem (0.02 millisievert) in any one hour.

(b) If the licensee permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(c) Notwithstanding paragraph (a)(1) of this section, a licensee may permit visitors to an individual who cannot be released, under § 35.75, to receive a radiation dose greater than 0.1 rem (1 mSv) if-

(1) The radiation dose received does not exceed 0.5 rem (5 mSv); and

(2) The authorized user, as defined in 10 CFR Part 35, has determined before the visit that it is appropriate.

(d) A licensee or license applicant may apply for prior NRC authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). The licensee or license applicant shall include the following information in this application:

(1) Demonstration of the need for and the expected duration of operations in excess of the limit in paragraph (a) of this section;

(2) The licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

(3) The procedures to be followed to maintain the dose as low as is reasonably achievable.

(e) In addition to the requirements of this part, a licensee subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR part 190 shall comply with those standards.

(f) The Commission may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

[56 FR 23398, May 21, 1991, as amended at 60 FR 48625, Sept. 20, 1995; 62 FR 4133, Jan. 29, 1997; 67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002]

§ 20.1302 Compliance with dose limits for individual members of the public.

(a) The licensee shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in § 20.1301.

(b) A licensee shall show compliance with the annual dose limit in § 20.1301 by--

(1) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual dose limit; or

(2) Demonstrating that—

(i) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in table 2 of appendix B to part 20; and

(ii) If an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

(c) Upon approval from the Commission, the licensee may adjust the effluent concentration values in appendix B to part 20, table 2, for members of the public, to take into account the actual physical and chemical characteristics of the effluents (e.g., aerosol size distribution, solubility, density, radioactive decay equilibrium, chemical form).

[56 FR 23398, May 21, 1991; 56 FR 61352, Dec. 3, 1991, as amended at 57 FR 57878, Dec. 8, 1992; 60 FR 20185, Apr. 25, 1995]

Subpart F--Surveys and Monitoring

Source: 56 FR 23398, May 21, 1991, unless otherwise noted.

§ 20.1501 General.

(a) Each licensee shall make or cause to be made, surveys of areas, including the subsurface, that —

(1) May be necessary for the licensee to comply with the regulations in this part; and

(2) Are reasonable under the circumstances to evaluate—

(i) The magnitude and extent of radiation levels; and

(ii) Concentrations or quantities of residual radioactivity; and

(iii) The potential radiological hazards of the radiation levels and residual radioactivity detected.

(b) Notwithstanding § 20.2103(a) of this part, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with §§ 30.35(g), 40.36(f), 50.75(g), 70.25(g), or 72.30(d), as applicable.

(c) The licensee shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically for the radiation measured.

(d) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees to comply with § 20.1201, with other applicable provisions of this chapter, or with conditions specified in a license must be processed and evaluated by a dosimetry processor--

(1) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(2) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

[56 FR 23398, May 21, 1991, as amended at 63 FR 39482, July 23, 1998; 76 FR 35564 Jun. 17, 2011]

§ 20.1502 Conditions requiring individual monitoring of external and internal occupational dose.

Each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this part. As a minimum—

(a) Each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by—

(1) Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in § 20.1201(a),

(2) Minors likely to receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);

(3) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv);[2] and

(4) Individuals entering a high or very high radiation area.

(b) Each licensee shall monitor (see § 20.1204) the occupational intake of radioactive material by and assess the committed effective dose equivalent to—

(1) Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) in table 1, Columns 1 and 2, of appendix B to §§ 20.1001-20.2402;

(2) Minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.1 rem (1 mSv); and

(3) Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

[56 FR 23398, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995; 63 FR 39482, July 23, 1998]

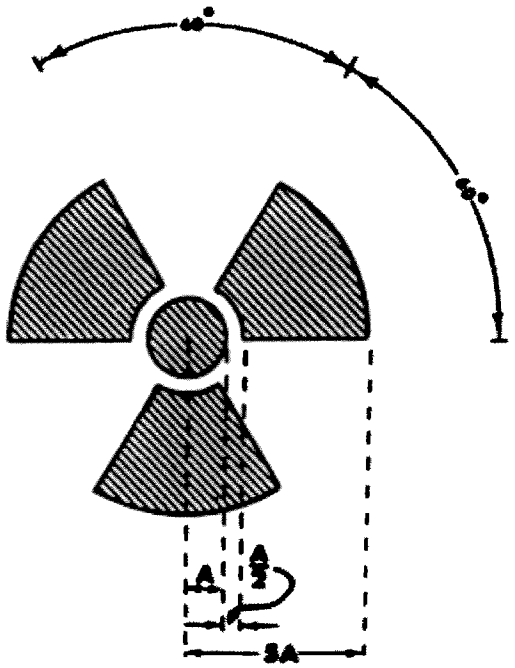
[2] All of the occupational doses in § 20.1201 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.

Subpart J--Precautionary Procedures

Source: 56 FR 23401, May 21, 1991, unless otherwise noted.

§ 20.1901 Caution signs.

(a) *Standard radiation symbol.* Unless otherwise authorized by the Commission, the symbol prescribed by this part shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed by this part is the three-bladed design:



RADIATION SYMBOL

(1) Cross-hatched area is to be magenta, or purple, or black, and

(2) The background is to be yellow.

(b) *Exception to color requirements for standard radiation symbol.* Notwithstanding the requirements of paragraph (a) of this section, licensees are authorized to label sources, source holders, or device components containing sources of licensed materials that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(c) *Additional information on signs and labels.* In addition to the contents of signs and labels prescribed in this part, the licensee may provide, on or near the required signs and labels,

additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

§ 20.1902 Posting requirements.

(a) *Posting of radiation areas.* The licensee shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

(b) *Posting of high radiation areas.* The licensee shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

(c) *Posting of very high radiation areas.* The licensee shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

(d) *Posting of airborne radioactivity areas.* The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

(e) *Posting of areas or rooms in which licensed material is used or stored.* The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in appendix C to part 20 with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

[56 FR 23401, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995]

§ 20.1903 Exceptions to posting requirements.

(a) A licensee is not required to post caution signs in areas or rooms containing radioactive materials for periods of less than 8 hours, if each of the following conditions is met:

(1) The materials are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to radiation or radioactive materials in excess of the limits established in this part; and

(2) The area or room is subject to the licensee's control.

(b) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to § 20.1902 provided that the patient could be released from licensee control pursuant to § 35.75 of this chapter.

(c) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the source container or housing does not exceed 0.005 rem (0.05 mSv) per hour.

(d) Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under § 20.1902 if--

(1) Access to the room is controlled pursuant to 10 CFR 35.615; and

(2) Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this part.

[56 FR 23401, May 21, 1991, as amended at 57 FR 39357, Aug. 31, 1992; 62 FR 4133, Jan. 29, 1997; 63 FR 39482, July 23, 1998]

Subpart K--Waste Disposal

Source: 56 FR 23403, May 21, 1991, unless otherwise noted.

§ 20.2007 Compliance with environmental and health protection regulations.

Nothing in this subpart relieves the licensee from complying with other applicable Federal, State, and local regulations governing any other toxic or hazardous properties of materials that may be disposed of under this subpart.

Subpart L--Records

Source: 56 FR 23404, May 21, 1991, unless otherwise noted.

§ 20.2101 General provisions.

(a) Each licensee shall use the units: curie, rad, rem, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this part.

(b) In the records required by this part, the licensee may record quantities in SI units in parentheses following each of the units specified in paragraph (a) of this section. However, all quantities must be recorded as stated in paragraph (a) of this section.

(d) The licensee shall make a clear distinction among the quantities entered on the records required by this part (e.g., total effective dose equivalent, shallow-dose equivalent, lens dose equivalent, deep-dose equivalent, committed effective dose equivalent).

[56 FR 23404, May 21, 1991, as amended at 60 FR 15663, Mar. 27, 1995; 63 FR 39483, July 23, 1998]

§ 20.2102 Records of radiation protection programs.

(a) Each licensee shall maintain records of the radiation protection program, including:

(1) The provisions of the program; and

(2) Audits and other reviews of program content and implementation.

(b) The licensee shall retain the records required by paragraph (a)(1) of this section until the Commission terminates each pertinent license requiring the record. The licensee shall retain the records required by paragraph (a)(2) of this section for 3 years after the record is made.

§ 20.2103 Records of surveys.

(a) Each licensee shall maintain records showing the results of surveys and calibrations required by §§ 20.1501 and 20.1906(b). The licensee shall retain these records for 3 years after the record is made.

(b) The licensee shall retain each of the following records until the Commission terminates each pertinent license requiring the record:

(1) Records of the results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents. This includes those records of results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents required under the standards for protection against radiation in effect prior to January 1, 1994; and

(2) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose. This includes those records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose required under the standards for protection against radiation in effect prior to January 1, 1994; and

(3) Records showing the results of air sampling, surveys, and bioassays required pursuant to § 20.1703(c)(1) and (2). This includes those records showing the results of air sampling, surveys, and bioassays required under the standards for protection against radiation in effect prior to January 1, 1994; and

(4) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment. This includes those records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment required under the standards for protection against radiation in effect prior to January 1, 1994.

[56 FR 23404, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995; 66 FR 64737, Dec. 14, 2001]

§ 20.2106 Records of individual monitoring results.

(a) *Recordkeeping requirement.* Each licensee shall maintain records of doses received by all individuals for whom monitoring was required pursuant to § 20.1502, and records of doses received during planned special exposures, accidents, and emergency conditions. These records[5] must include, when applicable—

(1) The deep-dose equivalent to the whole body, lens dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities;

(2) The estimated intake of radionuclides (see § 20.1202);

(3) The committed effective dose equivalent assigned to the intake of radionuclides;

(4) The specific information used to assess the committed effective dose equivalent pursuant to § 20.1204(a) and (c), and when required by § 20.1502;

(5) The total effective dose equivalent when required by § 20.1202; and

(6) The total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose.

(b) *Recordkeeping frequency.* The licensee shall make entries of the records specified in paragraph (a) of this section at least annually.

(e) The licensee shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy shall also be kept on file, but may be maintained separately from the dose records.

[56 FR 23404, May 21, 1991, as amended at 60 FR 20186, Apr. 25, 1995; 63 FR 39483, July 23, 1998]

[5] Assessments of dose equivalent and records made using units in effect before the licensee's adoption of this part need not be changed.

§ 20.2107 Records of dose to individual members of the public.

(a) Each licensee shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public (see § 20.1301).

§ 20.2110 Form of records.

Each record required by this part must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

Subpart O—Enforcement

§ 20.2402 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in §§ 20.1001 through 20.2402 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) this section.

(b) The regulations in §§ 20.1001 through 20.2402 that are not issued under Sections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 20.1001, 20.1002, 20.1003, 20.1004, 20.1005, 20.1006, 20.1007, 20.1008, 20.1009, 20.1405, 20.1704, 20.1903, 20.1905, 20.2002, 20.2007, 20.2301, 20.2302, 20.2401, and 20.2402.

[57 FR 55071, Nov. 24, 1992]

Appendix C to Part 20—Quantities[1] of Licensed Material Requiring Labeling

Radionuclide	Abbreviation	Quantity (μCi)
Hydrogen-3	H-3	1,000
Beryllium-7	Be-7	1,000
Beryllium-10	Be-10	1
Carbon-11	C-11	1,000
Carbon-14	C-14	100
Fluorine-18	F-18	1,000
Sodium-22	Na-22	10
Sodium-24	Na-24	100
Magnesium-28	Mg-28	100
Aluminum-26	Al-26	10
Silicon-31	Si-31	1,000
Silicon-32	Si-32	1
Phosphorus-32	P-32	10
Phosphorus-33	P-33	100
Sulfur-35	S-35	100

Chlorine-36	Cl-36	10
Chlorine-38	Cl-38	1,000
Chlorine-39	Cl-39	1,000
Argon-39	Ar-39	1,000
Argon-41	Ar-41	1,000
Potassium-40	K-40	100
Potassium-42	K-42	1,000
Potassium-43	K-43	1,000
Potassium-44	K-44	1,000
Potassium-45	K-45	1,000
Calcium-41	Ca-41	100
Calcium-45	Ca-45	100
Calcium-47	Ca-47	100
Scandium-43	Sc-43	1,000
Scandium-44m	Sc-44m	100
Scandium-44	Sc-44	100
Scandium-46	Sc-46	10
Scandium-47	Sc-47	100
Scandium-48	Sc-48	100
Scandium-49	Sc-49	1,000
Titanium-44	Ti-44	1
Titanium-45	Ti-45	1,000
Vanadium-47	V-47	1,000
Vanadium-48	V-48	100
Vanadium-49	V-49	1,000
Chromium-48	Cr-48	1,000
Chromium-49	Cr-49	1,000
Chromium-51	Cr-51	1,000
Manganese-51	Mn-51	1,000
Manganese-52m	Mn-52m	1,000
Manganese-52	Mn-52	100
Manganese-53	Mn-53	1,000
Manganese-54	Mn-54	100
Manganese-56	Mn-56	1,000
Iron-52	Fe-52	100
Iron-55	Fe-55	100
Iron-59	Fe-59	10
Iron-60	Fe-60	1
Cobalt-55	Co-55	100
Cobalt-56	Co-56	10
Cobalt-57	Co-57	100

Cobalt-58m	Co-58m	1,000
Cobalt-58	Co-58	100
Cobalt-60m	Co-60m	1,000
Cobalt-60	Co-60	1
Cobalt-61	Co-61	1,000
Cobalt-62m	Co-62m	1,000
Nickel-56	Ni-56	100
Nickel-57	Ni-57	100
Nickel-59	Ni-59	100
Nickel-63	Ni-63	100
Nickel-65	Ni-65	1,000
Nickel-66	Ni-66	10
Copper-60	Cu-60	1,000
Copper-61	Cu-61	1,000
Copper-64	Cu-64	1,000
Copper-67	Cu-67	1,000
Zinc-62	Zn-62	100
Zinc-63	Zn-63	1,000
Zinc-65	Zn-65	10
Zinc-69m	Zn-69m	100
Zinc-69	Zn-69	1,000
Zinc-71m	Zn-71m	1,000
Zinc-72	Zn-72	100
Gallium-65	Ga-65	1,000
Gallium-66	Ga-66	100
Gallium-67	Ga-67	1,000
Gallium-68	Ga-68	1,000
Gallium-70	Ga-70	1,000
Gallium-72	Ga-72	100
Gallium-73	Ga-73	1,000
Germanium-66	Ge-66	1,000
Germanium-67	Ge-67	1,000
Germanium-68	Ge-68	10
Germanium-69	Ge-69	1,000
Germanium-71	Ge-71	1,000
Germanium-75	Ge-75	1,000
Germanium-77	Ge-77	1,000
Germanium-78	Ge-78	1,000
Arsenic-69	As-69	1,000
Arsenic-70	As-70	1,000
Arsenic-71	As-71	100

Arsenic-72	As-72	100
Arsenic-73	As-73	100
Arsenic-74	As-74	100
Arsenic-76	As-76	100
Arsenic-77	As-77	100
Arsenic-78	As-78	1,000
Selenium-70	Se-70	1,000
Selenium-73m	Se-73m	1,000
Selenium-73	Se-73	100
Selenium-75	Se-75	100
Selenium-79	Se-79	100
Selenium-81m	Se-81m	1,000
Selenium-81	Se-81	1,000
Selenium-83	Se-83	1,000
Bromine-74m	Br-74m	1,000
Bromine-74	Br-74	1,000
Bromine-75	Br-75	1,000
Bromine-76	Br-76	100
Bromine-77	Br-77	1,000
Bromine-80m	Br-80m	1,000
Bromine-80	Br-80	1,000
Bromine-82	Br-82	100
Bromine-83	Br-83	1,000
Bromine-84	Br-84	1,000
Krypton-74	Kr-74	1,000
Krypton-76	Kr-76	1,000
Krypton-77	Kr-77	1,000
Krypton-79	Kr-79	1,000
Krypton-81	Kr-81	1,000
Krypton-83m	Kr-83m	1,000
Krypton-85m	Kr-85m	1,000
Krypton-85	Kr-85	1,000
Krypton-87	Kr-87	1,000
Krypton-88	Kr-88	1,000
Rubidium-79	Rb-79	1,000
Rubidium-81m	Rb-81m	1,000
Rubidium-81	Rb-81	1,000
Rubidium-82m	Rb-82m	1,000
Rubidium-83	Rb-83	100
Rubidium-84	Rb-84	100
Rubidium-86	Rb-86	100

Rubidium-87	Rb-87	100
Rubidium-88	Rb-88	1,000
Rubidium-89	Rb-89	1,000
Strontium-80	Sr-80	100
Strontium-81	Sr-81	1,000
Strontium-83	Sr-83	100
Strontium-85m	Sr-85m	1,000
Strontium-85	Sr-85	100
Strontium-87m	Sr-87m	1,000
Strontium-89	Sr-89	10
Strontium-90	Sr-90	0.1
Strontium-91	Sr-91	100
Strontium-92	Sr-92	100
Yttrium-86m	Y-86m	1,000
Yttrium-86	Y-86	100
Yttrium-87	Y-87	100
Yttrium-88	Y-88	10
Yttrium-90m	Y-90m	1,000
Yttrium-90	Y-90	10
Yttrium-91m	Y-91m	1,000
Yttrium-91	Y-91	10
Yttrium-92	Y-92	100
Yttrium-93	Y-93	100
Yttrium-94	Y-94	1,000
Yttrium-95	Y-95	1,000
Zirconium-86	Zr-86	100
Zirconium-88	Zr-88	10
Zirconium-89	Zr-89	100
Zirconium-93	Zr-93	1
Zirconium-95	Zr-95	10
Zirconium-97	Zr-97	100
Niobium-88	Nb-88	1,000
Niobium-89m (66 min)	Nb-89m	1,000
Niobium-89 (122 min)	Nb-89	1,000
Niobium-89	Nb-89	1,000
Niobium-90	Nb-90	100
Niobium-93m	Nb-93m	10
Niobium-94	Nb-94	1
Niobium-95m	Nb-95m	100
Niobium-95	Nb-95	100
Niobium-96	Nb-96	100

Niobium-97	Nb-97	1,000
Niobium-98	Nb-98	1,000
Molybdenum-90	Mo-90	100
Molybdenum-93m	Mo-93m	100
Molybdenum-93	Mo-93	10
Molybdenum-99	Mo-99	100
Molybdenum-101	Mo-101	1,000
Technetium-93m	Tc-93m	1,000
Technetium-93	Tc-93	1,000
Technetium-94m	Tc-94m	1,000
Technetium-94	Tc-94	1,000
Technetium-96m	Tc-96	1,000
Technetium-96	Tc-96	100
Technetium-97m	Tc-97m	100
Technetium-97	Tc-97	1,000
Technetium-98	Tc-98	10
Technetium-99m	Tc-99m	1,000
Technetium-99	Tc-99	100
Technetium-101	Tc-101	1,000
Technetium-104	Tc-104	1,000
Ruthenium-94	Ru-94	1,000
Ruthenium-97	Ru-97	1,000
Ruthenium-103	Ru-103	100
Ruthenium-105	Ru-105	1,000
Ruthenium-106	Ru-106	1
Rhodium-99m	Rh-99m	1,000
Rhodium-99	Rh-99	100
Rhodium-100	Rh-100	100
Rhodium-101m	Rh-101m	1,000
Rhodium-101	Rh-101	10
Rhodium-102m	Rh-102m	10
Rhodium-102	Rh-102	10
Rhodium-103m	Rh-103m	1,000
Rhodium-105	Rh-105	100
Rhodium-106m	Rh-106m	1,000
Rhodium-107	Rh-107	1,000
Palladium-100	Pd-100	100
Palladium-101	Pd-101	1,000
Palladium-103	Pd-103	100
Palladium-107	Pd-107	10
Palladium-109	Pd-109	100

Silver-102	Ag-102	1,000
Silver-103	Ag-103	1,000
Silver-104m	Ag-104m	1,000
Silver-104	Ag-104	1,000
Silver-105	Ag-105	100
Silver-106m	Ag-106m	100
Silver-106	Ag-106	1,000
Silver-108m	Ag-108m	1
Silver-110m	Ag-110m	10
Silver-111	Ag-111	100
Silver-112	Ag-112	100
Silver-115	Ag-115	1,000
Cadmium-104	Cd-104	1,000
Cadmium-107	Cd-107	1,000
Cadmium-109	Cd-109	1
Cadmium-113m	Cd-113m	0.1
Cadmium-113	Cd-113	100
Cadmium-115m	Cd-115m	10
Cadmium-115	Cd-115	100
Cadmium-117m	Cd-117m	1,000
Cadmium-117	Cd-117	1,000
Indium-109	In-109	1,000
Indium-110 (69.1 min.)	In-110	1,000
Indium-110 (4.9h)	In-110	1,000
Indium-111	In-111	100
Indium-112	In-112	1,000
Indium-113m	In-113m	1,000
Indium-114m	In-114m	10
Indium-115m	In-115m	1,000
Indium-115	In-115	100
Indium-116m	In-116m	1,000
Indium-117m	In-117m	1,000
Indium-117	In-117	1,000
Indium-119m	In-119m	1,000
Tin-110	Sn-110	100
Tin-111	Sn-111	1,000
Tin-113	Sn-113	100
Tin-117m	Sn-117m	100
Tin-119m	Sn-119m	100
Tin-121m	Sn-121m	100
Tin-121	Sn-121	1,000

Tin-123m	Sn-123m	1,000
Tin-123	Sn-123	10
Tin-125	Sn-125	10
Tin-126	Sn-126	10
Tin-127	Sn-127	1,000
Tin-128	Sn-128	1,000
Antimony-115	Sb-115	1,000
Antimony-116m	Sb-116m	1,000
Antimony-116	Sb-116	1,000
Antimony-117	Sb-117	1,000
Antimony-118m	Sb-118m	1,000
Antimony-119	Sb-119	1,000
Antimony-120 (16 min.)	Sb-120	1,000
Antimony-120 (5.76d)	Sb-120	100
Antimony-122	Sb-122	100
Antimony-124m	Sb-124m	1,000
Antimony-124	Sb-124	10
Antimony-125	Sb-125	100
Antimony-126m	Sb-126m	1,000
Antimony-126	Sb-126	100
Antimony-127	Sb-127	100
Antimony-128 (10.4 min.)	Sb-128	1,000
Antimony-128 (9.01h)	Sb-128	100
Antimony-129	Sb-129	100
Antimony-130	Sb-130	1,000
Antimony-131	Sb-131	1,000
Tellurium-116	Te-116	1,000
Tellurium-121m	Te-121m	10
Tellurium-121	Te-121	100
Tellurium-123m	Te-123m	10
Tellurium-123	Te-123	100
Tellurium-125m	Te-125m	10
Tellurium-127m	Te-127m	10
Tellurium-127	Te-127	1,000
Tellurium-129m	Te-129m	10
Tellurium-129	Te-129	1,000
Tellurium-131m	Te-131m	10
Tellurium-131	Te-131	100
Tellurium-132	Te-132	10
Tellurium-133m	Te-133m	100
Tellurium-133	Te-133	1,000

Tellurium-134	Te-134	1,000
Iodine-120m	I-120m	1,000
Iodine-120	I-120	100
Iodine-121	I-121	1,000
Iodine-123	I-123	100
Iodine-124	I-124	10
Iodine-125	I-125	1
Iodine-126	I-126	1
Iodine-128	I-128	1,000
Iodine-129	I-129	1
Iodine-130	I-130	10
Iodine-131	I-131	1
Iodine-132m	I-132m	100
Iodine-132	I-132	100
Iodine-133	I-133	10
Iodine-134	I-134	1,000
Iodine-135	I-135	100
Xenon-120	Xe-120	1,000
Xenon-121	Xe-121	1,000
Xenon-122	Xe-122	1,000
Xenon-123	Xe-123	1,000
Xenon-125	Xe-125	1,000
Xenon-127	Xe-127	1,000
Xenon-129m	Xe-129m	1,000
Xenon-131m	Xe-131m	1,000
Xenon-133m	Xe-133m	1,000
Xenon-133	Xe-133	1,000
Xenon-135m	Xe-135m	1,000
Xenon-135	Xe-135	1,000
Xenon-138	Xe-138	1,000
Cesium-125	Cs-125	1,000
Cesium-127	Cs-127	1,000
Cesium-129	Cs-129	1,000
Cesium-130	Cs-130	1,000
Cesium-131	Cs-131	1,000
Cesium-132	Cs-132	100
Cesium-134m	Cs-134m	1,000
Cesium-134	Cs-134	10
Cesium-135m	Cs-135m	1,000
Cesium-135	Cs-135	100
Cesium-136	Cs-136	10

Cesium-137	Cs-137	10
Cesium-138	Cs-138	1,000
Barium-126	Ba-126	1,000
Barium-128	B-128	100
Barium-131m	Ba-131m	1,000
Barium-131	Ba-131	100
Barium-133m	Ba-133m	100
Barium-133	Ba-133	100
Barium-135m	Ba-135m	100
Barium-139	Ba-139	1,000
Barium-140	Ba-140	100
Barium-141	Ba-141	1,000
Barium-142	Ba-142	1,000
Lanthanum-131	La-131	1,000
Lanthanum-132	La-132	100
Lanthanum-135	La-135	1,000
Lanthanum-137	La-137	10
Lanthanum-138	La-138	100
Lanthanum-140	La-140	100
Lanthanum-141	La-141	100
Lanthanum-142	La-142	1,000
Lanthanum-143	La-143	1,000
Cerium-134	Ce-134	100
Cerium-135	Ce-135	100
Cerium-137m	Ce-137m	100
Cerium-137	Ce-137	1,000
Cerium-139	Ce-139	100
Cerium-141	Ce-141	100
Cerium-143	Ce-143	100
Cerium-144	Ce-144	1
Praseodymium-136	Pr-136	1,000
Praseodymium-137	Pr-137	1,000
Praseodymium-138m	Pe-138m	1,000
Praseodymium-139	Pe-139	1,000
Praseodymium-142m	Pe-142m	1,000
Praseodymium-142	Pe-142	100
Praseodymium-143	Pe-143	100
Praseodymium-144	Pe-144	1,000
Praseodymium-145	Pe-145	100
Praseodymium-147	Pe-147	1,000
Neodymium-136	Nd-136	1,000

Neodymium-138	Nd-138	100
Neodymium-139m	Nd-139m	1,000
Neodymium-139	Nd-139	1,000
Neodymium-141	Nd-141	1,000
Neodymium-147	Nd-147	100
Neodymium-149	Nd-149	1,000
Neodymium-151	Nd-151	1,000
Promethium-141	Pm-141	1,000
Promethium-143	Pm-143	100
Promethium-144	Pm-144	10
Promethium-145	Pm-145	10
Promethium-146	Pm-146	1
Promethium-147	Pm-147	10
Promethium-148m	Pm-148m	10
Promethium-148	Pm-148	10
Promethium-149	Pm-149	100
Promethium-150	Pm-150	1,000
Promethium-151	Pm-151	100
Samarium-141m	Sm-141m	1,000
Samarium-141	Sm-141	1,000
Samarium-142	Sm-142	1,000
Samarium-145	Sm-145	100
Samarium-146	Sm-146	1
Samarium-147	Sm-147	100
Samarium-151	Sm-151	10
Samarium-153	Sm-153	100
Samarium-155	Sm-155	1,000
Samarium-156	Sm-156	1,000
Europium-145	Eu-145	100
Europium-146	Eu-146	100
Europium-147	Eu-147	100
Europium-148	Eu-148	10
Europium-149	Eu-149	100
Europium-150 (12.62h)	Eu-150	100
Europium-150 (34.2y)	Eu-150	1
Europium-152m	Eu-152m	100
Europium-152	Eu-152	1
Europium-154	Eu-154	1
Europium-155	Eu-155	10
Europium-156	Eu-156	100
Europium-157	Eu-157	100

Europium-158	Eu-158	1,000
Gadolinium-145	Gd-145	1,000
Gadolinium-146	Gd-146	10
Gadolinium-147	Gd-147	100
Gadolinium-148	Gd-148	0.001
Gadolinium-149	Gd-149	100
Gadolinium-151	Gd-151	10
Gadolinium-152	Gd-152	100
Gadolinium-153	Gd-153	10
Gadolinium-159	Gd-159	100
Terbium-147	Tb-147	1,000
Terbium-149	Tb-149	100
Terbium-150	Tb-150	1,000
Terbium-151	Tb-151	100
Terbium-153	Tb-153	1,000
Terbium-154	Tb-154	100
Terbium-155	Tb-155	1,000
Terbium-156m (5.0h)	Tb-156m	1,000
Terbium-156m (24.4h)	Tb-156m	1,000
Terbium-156	Tb-156	100
Terbium-157	Tb-157	10
Terbium-158	Tb-158	1
Terbium-160	Tb-160	10
Terbium-161	Tb-161	100
Dysprosium-155	Dy-155	1,000
Dysprosium-157	Dy-157	1,000
Dysprosium-159	Dy-159	100
Dysprosium-165	Dy-165	1,000
Dysprosium-166	Dy-166	100
Holmium-155	Ho-155	1,000
Holmium-157	Ho-157	1,000
Holmium-159	Ho-159	1,000
Holmium-161	Ho-161	1,000
Holmium-162m	Ho-162m	1,000
Holmium-162	Ho-162	1,000
Holmium-164m	Hp-164m	1,000
Holmium-164	Ho-164	1,000
Holmium-166m	Ho-166m	1
Holmium-166	Ho-166	100
Holmium-167	Ho-167	1,000
Erbium-161	Er-161	1,000

Erbium-165	Er-165	1,000
Erbium-169	Er-169	100
Erbium-171	Er-171	100
Erbium-172	Er-172	100
Thulium-162	Tm-162	1,000
Thulium-166	Tm-166	100
Thulium-167	Tm-167	100
Thulium-170	Tm-170	10
Thulium-171	Tm-171	10
Thulium-172	Tm-172	100
Thulium-173	Tm-173	100
Thulium-175	Tm-175	1,000
Ytterbium-162	Yb-162	1,000
Ytterbium-166	Yb-166	100
Ytterbium-167	Yb-167	1,000
Ytterbium-169	Yb-169	100
Ytterbium-175	Yb-175	100
Ytterbium-177	Yb-177	1,000
Ytterbium-178	Yb-178	1,000
Lutetium-169	Lu-169	100
Lutetium-170	Lu-170	100
Lutetium-171	Lu-171	100
Lutetium-172	Lu-172	100
Lutetium-173	Lu-173	10
Lutetium-174m	Lu-174m	10
Lutetium-174	Lu-174	10
Lutetium-176m	Lu-176m	1,000
Lutetium-176	Lu-176	100
Lutetium-177m	Lu-177m	10
Lutetium-177	Lu-177	100
Lutetium-178m	Lu-178m	1,000
Lutetium-178	Lu-178	1,000
Lutetium-179	Lu-179	1,000
Hafnium-170	Hf-170	100
Hafnium-172	Hf-172	1
Hafnium-173	Hf-173	1,000
Hafnium-175	Hf-175	100
Hafnium-177m	Hf-177m	1,000
Hafnium-178m	Hf-178m	0.1
Hafnium-179m	Hf-179m	10
Hafnium-180m	Hf-180m	1,000

Hafnium-181	Hf-181	10
Hafnium-182m	Hf-182m	1,000
Hafnium-182	Hf-182	0.1
Hafnium-183	Hf-183	1,000
Hafnium-184	Hf-184	100
Tantalum-172	Ta-172	1,000
Tantalum-173	Ta-173	1,000
Tantalum-174	Ta-174	1,000
Tantalum-175	Ta-175	1,000
Tantalum-176	Ta-176	100
Tantalum-177	Ta-177	1,000
Tantalum-178	Ta-178	1,000
Tantalum-179	Ta-179	100
Tantalum-180m	Ta-180m	1,000
Tantalum-180	Ta-180	100
Tantalum-182m	Ta-182m	1,000
Tantalum-182	Ta-182	10
Tantalum-183	Ta-183	100
Tantalum-184	Ta-184	100
Tantalum-185	Ta-185	1,000
Tantalum-186	Ta-186	1,000
Tungsten-176	W-176	1,000
Tungsten-177	W-177	1,000
Tungsten-178	W-178	1,000
Tungsten-179	W-179	1,000
Tungsten-181	W-181	1,000
Tungsten-185	W-185	100
Tungsten-187	W-187	100
Tungsten-188	W-188	10
Rhenium-177	Re-177	1,000
Rhenium-178	Re-178	1,000
Rhenium-181	Re-181	1,000
Rhenium-182 (12.7h)	Re-182	1,000
Rhenium-182 (64.0h)	Re-182	100
Rhenium-184m	Re-184m	10
Rhenium-184	Re-184	100
Rhenium-186m	Re-186m	10
Rhenium-186	Re-186	100
Rhenium-187	Re-187	1,000
Rhenium-188m	Re-188m	1,000
Rhenium-188	Re-188	100

Rhenium-189	Re-189	100
Osmium-180	Os-180	1,000
Osmium-181	Os-181	1,000
Osmium-182	Os-182	100
Osmium-185	Os-185	100
Osmium-189m	Os-189m	1,000
Osmium-191m	Os-191m	1,000
Osmium-191	Os-191	100
Osmium-193	Os-193	100
Osmium-194	Os-194	1
Iridium-182	Ir-182	1,000
Iridium-184	Ir-184	1,000
Iridium-185	Ir-185	1,000
Iridium-186	Ir-186	100
Iridium-187	Ir-187	1,000
Iridium-188	Ir-188	100
Iridium-189	Ir-189	100
Iridium-190m	Ir-190m	1,000
Iridium-190	Ir-190	100
Iridium-192 (73.8d)	Ir-192	1
Iridium-192m (1.4 min.)	Ir-192m	10
Iridium-194m	Ir-194m	10
Iridium-194	Ir-194	100
Iridium-195m	Ir-195m	1,000
Iridium-195	Ir-95	1,000
Platinum-186	Pt-186	1,000
Platinum-188	Pt-188	100
Platinum-189	Pt-189	1,000
Platinum-191	Pt-191	100
Platinum-193m	Pt-193m	100
Platinum-193	Pt-193	1,000
Platinum-195m	Pt-195m	100
Platinum-197m	Pt-197m	1,000
Platinum-197	Pt-197	100
Platinum-199	Pt-199	1,000
Platinum-200	Pt-200	100
Gold-193	Au-193	1,000
Gold-194	Au-194	100
Gold-195	Au-195	10
Gold-198m	Au-198m	100
Gold-198	Au-198	100

Gold-199	Au-199	100
Gold-200m	Au-200m	100
Gold-200	Au-200	1,000
Gold-201	Au-201	1,000
Mercury-193m	Hg-193m	100
Mercury-193	Hg-193	1,000
Mercury-194	Hg-194	1
Mercury-195m	Hg-195m	100
Mercury-195	Hg-195	1,000
Mercury-197m	Hg-197m	100
Mercury-197	Hg-197	1,000
Mercury-199m	Hg-199m	1,000
Mercury-203	Hg-203	100
Thallium-194m	Tl-194m	1,000
Thallium-194	Tl-194	1,000
Thallium-195	Tl-195	1,000
Thallium-197	Tl-197	1,000
Thallium-198m	Tl-198m	1,000
Thallium-198	Tl-198	1,000
Thallium-199	Tl-199	1,000
Thallium-200	Tl-200	1,000
Thallium-201	Tl-201	1,000
Thallium-202	Tl-202	100
Thallium-204	Tl-204	100
Lead-195m	Pb-195m	1,000
Lead-198	Pb-198	1,000
Lead-199	Pb-199	1,000
Lead-200	Pb-200	100
Lead-201	Pb-201	1,000
Lead-202m	Pb-202m	1,000
Lead-202	Pb-202	10
Lead-203	Pb-2023	1,000
Lead-205	Pb-205	100
Lead-209	Pb-209	1,000
Lead-210	Pb-210	0.01
Lead-211	Pb-211	100
Lead-212	Pb-212	1
Lead-214	Pb-214	100
Bismuth-200	Bi-200	1,000
Bismuth-201	Bi-201	1,000
Bismuth-202	Bi-202	1,000

Bismuth-203	Bi-203	100
Bismuth-205	Bi-205	100
Bismuth-206	Bi-206	100
Bismuth-207	Bi-207	10
Bismuth-210m	Bi-210m	0.1
Bismuth-210	Bi-210	1
Bismuth-212	Bi-212	10
Bismuth-213	Bi-213	10
Bismuth-214	Bi-214	100
Polonium-203	Po-203	1,000
Polonium-205	Po-205	1,000
Polonium-207	Po-207	1,000
Polonium-210	Po-210	0.1
Astatine-207	At-207	100
Astatine-211	At-211	10
Radon-220	Rn-220	1
Radon-222	Rn-222	1
Francium-222	Fr-222	100
Francium-223	Fr-223	100
Radium-223	Ra-223	0.1
Radium-224	Ra-224	0.1
Radium-225	Ra-225	0.1
Radium-226	Ra-226	0.1
Radium-227	Ra-227	1,000
Radium-228	Ra-228	0.1
Actinium-224	Ac-224	1
Actinium-225	Ac-225	0.01
Actinium-226	Ac-226	0.1
Actinium-227	Ac-227	0.001
Actinium-228	Ac-228	1
Thorium-226	Th-226	10
Thorium-227	Th-227	0.01
Thorium-228	Th-228	0.001
Thorium-229	Th-229	0.001
Thorium-230	Th-230	0.001
Thorium-231	Th-231	100
Thorium-232	Th-232	100
Thorium-234	Th-234	10
Thorium-natural		100
Protactinium-227	Pa-227	10
Protactinium-228	Pa-228	1

Protactinium-230	Pa-230	0.01
Protactinium-231	Pa-231	0.001
Protactinium-232	Pa-232	1
Protactinium-233	Pa-233	100
Protactinium-234	Pa-234	100
Uranium-230	U-230	0.01
Uranium-231	U-231	100
Uranium-232	U-232	0.001
Uranium-233	U-233	0.001
Uranium-234	U-234	0.001
Uranium-235	U-235	0.001
Uranium-236	U-236	0.001
Uranium-237	U-237	100
Uranium-238	U-238	100
Uranium-239	U-239	1,000
Uranium-240	U-240	100
Uranium-natural		100
Neptunium-232	Np-232	100
Neptunium-233	Np-233	1,000
Neptunium-234	Np-234	100
Neptunium-235	Np-235	100
Neptunium-236 ($1.15x10^5$y)	Np-236	0.001
Neptunium-236 (22.5h)	Np-236	1
Neptunium-237	Np-237	0.001
Neptunium-238	Np-238	10
Neptunium-239	Np-239	100
Neptunium-240	Np-240	1,000
Plutonium-234	Pu-234	10
Plutonium-235	Pu-235	1,000
Plutonium-236	Pu-236	0.001
Plutonium-237	Pu-237	100
Plutonium-238	Pu-238	0.001
Plutonium-239	Pu-239	0.001
Plutonium-240	Pu-240	0.001
Plutonium-241	Pu-241	0.01
Plutonium-242	Pu-242	0.001
Plutonium-243	Pu-243	1,000
Plutonium-244	Pu-244	0.001
Plutonium-245	Pu-245	100
Americium-237	Am-237	1,000
Americium-238	Am-238	100

Americium-239	Am-239	1,000
Americium-240	Am-240	100
Americium-241	Am-241	0.001
Americium-242m	Am-242m	0.001
Americium-242	Am-242	10
Americium-243	Am-243	0.001
Americium-244m	Am-244m	100
Americium-244	Am-244	10
Americium-245	Am-245	1,000
Americium-246m	Am-246	1,000
Americium-246	Am-246	1,000
Curium-238	Cm-238	100
Curium-240	Cm-240	0.1
Curium-241	Cm-241	1
Curium-242	Cm-242	0.01
Curium-243	Cm-243	0.001
Curium-244	Cm-244	0.001
Curium-245	Cm-245	0.001
Curium-246	Cm-246	0.001
Curium-247	Cm-247	0.001
Curium-248	Cm-248	0.001
Curium-249	Cm-249	1,000
Berkelium-245	Bk-245	100
Berkelium-246	Bk-246	100
Berkelium-247	Bk-247	0.001
Berkelium-249	Bk-249	0.1
Berkelium-250	Bk-250	10
Californium-244	Cf-244	100
Californium-246	Cf-246	1
Californium-248	Cf-248	0.01
Californium-249	Cf-249	0.001
Californium-250	Cf-250	0.001
Californium-251	Cf-251	0.001
Californium-252	Cf-252	0.001
Californium-253	Cf-253	0.1
Californium-254	Cf-254	0.001
Any alpha emitting radionuclide not listed above or mixtures or alpha emitters of unknown composition		0.001
Einsteinium-250	Es-250	100
Einsteinium-251	Es-251	100
Einsteinium-253	Es-253	0.1
Einsteinium-254m	Es-254m	1

Einsteinium-254	Es-254	0.01
Fermium-252	Fm-252	1
Fermium-253	Fm-253	1
Fermium-254	Fm-254	10
Fermium-255	Fm-255	1
Fermium-257	Fm-257	0.01
Mendelevium-257	Md-257	10
Mendelevium-258	Md-258	0.01
Any radionuclide other than alpha emitter radionuclides not listed above, or mixtures of beta emitters of unknown composition		0.01

[1]The quantities listed above were derived by taking $^1/_{10}$th of the most restrictive ALI listed in table 1, columns 1 and 2, of appendix B to §§ 20.1001-20.2401 of this part, rounding to the nearest factor of 10, and arbitrarily constraining the values listed between 0.001 and 1,000 μCi. Values of 100 μCi have been assigned for radionuclides having a radioactive half-life in excess of 10^9 years (except rhenium, 1000 μCi) to take into account their low specific activity.

NOTE: For purposes of §§ 20.1902(e), 20.1905(a), and 20.2201(a) where there is involved a combination of radionuclides in known amounts, the limit for the combination should be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" (i.e., "unity").

[56 FR 23465, May 21, 1991; 56 FR 61352, Dec. 3, 1991. Redesignated and amended at 58 FR 67659, Dec. 22, 1993; 60 FR 20186, Apr. 25, 1995]

APPENDIX D TO PART 20—UNITED STATES NUCLEAR REGULATORY COMMISSION REGIONAL OFFICES

Region	Address	Telephone (24 hour)	E-Mail
NRC Headquarters Operations Center	USNRC, Division of Incident Response Operations, Washington, DC 20555–0001.	(301) 816–5100 (301) 951–0550 (301) 816–5151 (fax)	*H001@nrc.gov*
Region I: Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.	USNRC, Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406–2713.	(610) 337–5000, (800) 432–1156 TDD: (301) 415–5575	*RidsRgn1MailCenter@nrc.gov*
Region II: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina,	USNRC, Region II,	(404) 997–4000, (800) 877–8510	*RidsRgn2MailCenter@nrc.gov*

Puerto Rico, South Carolina, Tennessee, Virginia, Virgin Islands, and West Virginia.	245 Peachtree Center Avenue, NE., Suite 1200, Atlanta, GA 30303–1257.	TDD: (301) 415–5575	
Region III: Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin.	USNRC, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532–4352.	(630) 829–9500 (800) 522–3025 TDD: (301) 415–5575	*RidsRgn3MailCenter@nrc.gov*
Region IV: Alaska, Arizona, Arkansas, California, Colorado, Hawaii, Idaho, Kansas, Louisiana, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington, Wyoming, and the U.S. territories and possessions in the Pacific.	USNRC, Region IV, 1600 E. Lamar Blvd., Arlington, TX 76011–4511.	(817) 860–8100 (800) 952–9677 TDD: (301) 415–5575	*RidsRgn4MailCenter@nrc.gov*

[56 FR 23468, May 21, 1991, as amended at 56 FR 41449, Aug. 21, 1991; 58 FR 64111, Dec. 6, 1993; 59 FR 17465, Apr. 13, 1994; 60 FR 24551, May 9, 1995; 62 FR 22880, Apr. 28, 1997; 67 FR 67099, Nov. 4, 2002; 67 FR 77652, Dec. 19, 2002; 68 FR 58802, Oct. 10, 2003; 71 FR 15007, Mar. 27, 2006; 75 FR 21980, Apr. 27, 2010; 76 FR 72084, Nov. 22, 2011]

U.S. FOOD AND DRUG ADMINISTRATION (FDA) STANDARDS

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[Code of Federal Regulations]
[Title 21, Volume 8]
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TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER J--RADIOLOGICAL HEALTH

PART 1020 -- PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

Sec. 1020.30 Diagnostic x-ray systems and their major components.

(a) **Applicability.**

(1) The provisions of this section are applicable to:

(i) The following components of diagnostic x-ray systems:

(A) Tube housing assemblies, x-ray controls, x-ray high-voltage generators, x-ray tables, cradles, film changers, vertical cassette holders mounted in a fixed location and cassette holders with front panels, and beam-limiting devices manufactured after August 1, 1974.

(B) Fluoroscopic imaging assemblies manufactured after August 1, 1974, and before April 26, 1977, or after June 10, 2006.

(C) Spot-film devices and image intensifiers manufactured after April 26, 1977.

(D) Cephalometric devices manufactured after February 25, 1978.

(E) Image receptor support devices for mammographic x-ray systems manufactured after September 5, 1978.

(F) Image receptors that are electrically powered or connected with the x-ray system manufactured on or after June 10, 2006.

(G) Fluoroscopic air kerma display devices manufactured on or after June 10, 2006.

(ii) Diagnostic x-ray systems, except computed tomography x-ray systems, incorporating one or more of such components; however, such x-ray systems shall be required to comply only with those provisions of this section and 1020.31 and 1020.32, which relate to the components certified in accordance with paragraph (c) of this section and installed into the systems.

(iii) Computed tomography (CT) x-ray systems manufactured before November 29, 1984.

(iv) CT gantries manufactured after September 3, 1985.

(2) The following provisions of this section and 1020.33 are applicable to CT x-ray systems manufactured or remanufactured on or after November 29, 1984:

(i) Section 1020.30(a);

(ii) Section 1020.30(b) "Technique factors";

(iii) Section 1020.30(b) "CT," "Dose," "Scan," "Scan time," and "Tomogram";

(iv) Section 1020.30(h)(3)(vi) through (h)(3)(viii);

(v) Section 1020.30(n);

(vi) Section 1020.33(a) and (b);

(vii) Section 1020.33(c)(1) as it affects 1020.33(c)(2); and

(viii) Section 1020.33(c)(2).

(3) The provisions of this section and 1020.33 in its entirety, including those provisions in paragraph (a)(2) of this section, are applicable to CT x-ray systems manufactured or remanufactured on or after September 3, 1985. The date of manufacture of the CT system is the date of manufacture of the CT gantry.

(b) **Definitions.** As used in this section and 1020.31, 1020.32, and 1020.33, the following definitions apply:

Accessible surface means the external surface of the enclosure or housing provided by the manufacturer.

Accessory component means:

(1) A component used with diagnostic x-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of this subchapter but which requires an initial determination of compatibility with the system; or

(2) A component necessary for compliance of the system with applicable provisions of this subchapter but which may be interchanged with similar compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices; or

(3) A component compatible with all x-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder.

Air kerma means kerma in air (see definition ofKerma).

Air kerma rate (AKR) means the air kerma per unit time.

Aluminum equivalent means the thickness of aluminum (type 1100 alloy)1affording the same attenuation, under specified conditions, as the material in question.

Articulated joint means a joint between two separate sections of a tabletop which joint provides the capacity for one of the sections to pivot on the line segment along which the sections join.

Assembler means any person engaged in the business of assembling, replacing, or installing one or more components into a diagnostic x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

Attenuation block means a block or stack of type 1100 aluminum alloy, or aluminum alloy having equivalent attenuation, with dimensions 20 centimeters (cm) or larger by 20 cm or larger by 3.8 cm, that is large enough to intercept the entire x-ray beam.

Automatic exposure control (AEC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.

Automatic exposure rate control (AERC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation per unit time.

Beam axis means a line from the source through the centers of the x-ray fields.

Beam-limiting device means a device which provides a means to restrict the dimensions of the x-ray field.

C-arm fluoroscope means a fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

Cantilevered tabletop means a tabletop designed such that the unsupported portion can be extended at least 100 cm beyond the support.

Cassette holder means a device, other than a spot-film device, that supports and/or fixes the position of an x-ray film cassette during an x-ray exposure.

Cephalometric device means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

Coefficient of variation means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{S}{\bar{X}} = \frac{1}{\bar{X}}\left[\frac{\sum_{i=1}^{n}(X_i - \bar{X})^2}{n-1}\right]^{\frac{1}{2}}$$

where:

s = Estimated standard deviation of the population.

X= Mean value of observations in sample.

Xi= ith observation sampled.

n = Number of observations sampled.

Computed tomography (CT) means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Control panel means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

Cooling curve means the graphical relationship between heat units stored and cooling time.

Cradle means:

(1) A removable device which supports and may restrain a patient above an x-ray table; or

(2) A device;

(i) Whose patient support structure is interposed between the patient and the image receptor during normal use;

(ii) Which is equipped with means for patient restraint; and

(iii) Which is capable of rotation about its long (longitudinal) axis.

CT gantry means tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers which hold and/or enclose these components.

Cumulative air kerma means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

Diagnostic source assembly means the tube housing assembly with a beam-limiting device attached.

Diagnostic x-ray system means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

Dose means the absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose, D, is the quotient of de by dm, where de is the mean

energy imparted to matter of mass dm; thus D=de/dm, in units of J/kg, where the special name for the unit of absorbed dose is gray (Gy).

Equipment means x-ray equipment.

Exposure (X) means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by photons in air of mass dm are completely stopped in air; thus X=dQ/dm, in units of C/kg. A second meaning of exposure is the process or condition during which the x-ray tube produces x-ray radiation.

Field emission equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to action of an electric field.

Fluoroscopic air kerma display device means a device, subsystem, or component that provides the display of AKR and cumulative air kerma required by 1020.32(k). It includes radiation detectors, if any, electronic and computer components, associated software, and data displays.

Fluoroscopic imaging assembly means a subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptor(s), electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Fluoroscopic irradiation time means the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation.

Fluoroscopy means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term "radioscopy" in the standards of the International Electrotechnical Commission.

General purpose radiographic x-ray system means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

Half-value layer (HVL) means the thickness of specified material which attenuates the beam of radiation to an extent such that the AKR is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

Image intensifier means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image receptor means any device, such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image

by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

Image receptor support device means, for mammography x-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

Isocenter means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

Kerma means the quantity as defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dEtrby dm, where dEtris the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of material; thus K=dEtr/dm, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as "air kerma."

Last-image-hold (LIH) radiograph means an image obtained either by retaining one or more fluoroscopic images, which may be temporally integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

Lateral fluoroscope means the x-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral x-ray tube housing assembly and the lateral image receptor that are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table.

Leakage radiation means radiation emanating from the diagnostic source assembly except for:

(1) The useful beam; and

(2) Radiation produced when the exposure switch or timer is not activated.

Leakage technique factors means the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (or 10 mAs) or the minimum obtainable from the unit, whichever is larger;

(2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; and

(3) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Light field means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illuminance is one-fourth of the maximum in the intersection.

Line-voltage regulation means the difference between the no-load and the load line potentials expressed as a percent of the load line potential; that is,

Percent line-voltage regulation = 100(Vn- Vi)/Vi

where:

Vn= No-load line potential and

Vi= Load line potential.

Maximum line current means the root mean square current in the supply line of an x-ray machine operating at its maximum rating.

Mode of operation means, for fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog or digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting air kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

Movable tabletop means a tabletop which, when assembled for use, is capable of movement with respect to its supporting structure within the plane of the tabletop.

Non-image-intensified fluoroscopy means fluoroscopy using only a fluorescent screen.

Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Primary protective barrier means the material, excluding filters, placed in the useful beam to reduce the radiation exposure for protection purposes.

Pulsed mode means operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

Quick change x-ray tube means an x-ray tube designed for use in its associated tube housing such that:

(1) The tube cannot be inserted in its housing in a manner that would result in noncompliance of the system with the requirements of paragraphs (k) and (m) of this section;

(2) The focal spot position will not cause noncompliance with the provisions of this section or 1020.31 or 1020.32;

(3) The shielding within the tube housing cannot be displaced; and

(4) Any removal and subsequent replacement of a beam-limiting device during reloading of the tube in the tube housing will not result in noncompliance of the x-ray system with the applicable field limitation and alignment requirements of 1020.31 and 1020.32.

Radiation therapy simulation system means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiography means a technique for generating and recording an x-ray pattern for the purpose of providing the user with an image(s) after termination of the exposure.

Rated line voltage means the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate.

Rated output current means the maximum allowable load current of the x-ray high-voltage generator.

Rated output voltage means the allowable peak potential, in volts, at the output terminals of the x-ray high-voltage generator.

Rating means the operating limits specified by the manufacturer.

Recording means producing a retrievable form of an image resulting from x-ray photons.

Scan means the complete process of collecting x-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one or more tomograms.

Scan time means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

Solid state x-ray imaging device means an assembly, typically in a rectangular panel configuration, that intercepts x-ray photons and converts the photon energy into a modulated electronic signal representative of the x-ray intensity over the area of the imaging device. The electronic signal is then used to create an image for display and/or storage.

Source means the focal spot of the x-ray tube.

Source-image receptor distance (SID) means the distance from the source to the center of the input surface of the image receptor.

Source-skin distance (SSD) means the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient skin surface.

Spot-film device means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of the fluoroscopic image receptor for the purpose of producing a radiograph.

Stationary tabletop means a tabletop which, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop.

Technique factors means the following conditions of operation:

(1) For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliampere-seconds (mAs);

(2) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

(3) For CT equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of the tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(4) For CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

(5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

Tomogram means the depiction of the x-ray attenuation properties of a section through a body.

Tube means an x-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when they are contained within the tube housing.

Tube rating chart means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

Useful beam means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

Variable-aperture beam-limiting device means a beam-limiting device which has the capacity for stepless adjustment of the x-ray field size at a given SID.

Visible area means the portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

X-ray control means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

X-ray equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

(1)Mobile x-ray equipment means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;

(2)Portable x-ray equipment means x-ray equipment designed to be hand-carried; and

(3)Stationary x-ray equipment means x-ray equipment which is installed in a fixed location.

X-ray field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the AKR is one-fourth of the maximum in the intersection.

X-ray high-voltage generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

X-ray subsystem means any combination of two or more components of an x-ray system for which there are requirements specified in this section and 1020.31 and 1020.32.

X-ray system means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray table means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, fluoroscopic image receptor, or spot-film device beneath the tabletop.

X-ray tube means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) **Manufacturers' responsibility.** Manufacturers of products subject to 1020.30 through 1020.33 shall certify that each of their products meet all applicable requirements when installed into a diagnostic x-ray system according to instructions. This certification shall be made under the format specified in 1010.2 of this chapter. Manufacturers may certify a combination of two or more components if they obtain prior authorization in writing from the Director of the Office of Communication, Education, and Radiation Programs of the Center for Devices and Radiological Health. Manufacturers shall not be held responsible for noncompliance of their products if that noncompliance is due solely to the improper installation or assembly of that product by another person; however, manufacturers are responsible for providing assembly instructions adequate to assure compliance of their components with the applicable provisions of 1020.30 through 1020.33.

(d) **Assemblers' responsibility**. An assembler who installs one or more components certified as required by paragraph (c) of this section shall install certified components that are of the type required by 1020.31, 1020.32, or 1020.33 and shall assemble, install, adjust, and test the certified components according to the instructions of their respective manufacturers. Assemblers shall not be liable for noncompliance of a certified component if the assembly of that component was according to the component manufacturer's instruction.

(1) Reports of assembly. All assemblers who install certified components shall file a report of assembly, except as specified in paragraph (d)(2) of this section. The report will be construed as the assembler's certification and identification under 1010.2 and 1010.3 of this chapter. The assembler shall affirm in the report that the manufacturer's instructions were followed in the assembly or that the certified components as assembled into the system meet all applicable requirements of 1020.30 through 1020.33. All assembler reports must be on a form prescribed by the Director, CDRH. Completed reports must be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly.

(2) Exceptions to reporting requirements. Reports of assembly need not be submitted for any of the following:

(i) Reloaded or replacement tube housing assemblies that are reinstalled in or newly assembled into an existing x-ray system;

(ii) Certified accessory components that have been identified as such to CDRH in the report required under 1002.10 of this chapter;

(iii) Repaired components, whether or not removed from the system and reinstalled during the course of repair, provided the original installation into the system was reported; or

(iv)(A) Components installed temporarily in an x-ray system in place of components removed temporarily for repair, provided the temporarily installed component is identified by a tag or label bearing the following information:

Temporarily Installed Component

This certified component has been assembled, installed, adjusted, and tested by me according to the instructions provided by the manufacturer.

Signature

Company Name

Street Address, P.O. Box

City, State, Zip Code

Date of Installation

(B) The replacement of the temporarily installed component by a component other than the component originally removed for repair shall be reported as specified in paragraph (d)(1) of this section.

(e) **Identification of x-ray components**. In addition to the identification requirements specified in 1010.3 of this chapter, manufacturers of components subject to this section and 1020.31, 1020.32, and 1020.33, except high-voltage generators contained within tube housings and beam-limiting devices that are integral parts of tube housings, shall permanently inscribe or affix thereon the model number and serial number of the product so that they are legible and accessible to view. The word "model" or "type" shall appear as part of the manufacturer's required identification of certified x-ray components. Where the certification of a system or subsystem, consisting of two or more components, has been authorized under paragraph (c) of this section, a single inscription, tag, or label bearing the model number and serial number may be used to identify the product.

(1) Tube housing assemblies. In a similar manner, manufacturers of tube housing assemblies shall also inscribe or affix thereon the name of the manufacturer, model number, and serial number of the x-ray tube which the tube housing assembly incorporates.

(2) Replacement of tubes. Except as specified in paragraph (e)(3) of this section, the replacement of an x-ray tube in a previously manufactured tube housing assembly certified under paragraph (c) of this section constitutes manufacture of a new tube housing assembly, and the manufacturer is subject to the provisions of paragraph (e)(1) of this section. The manufacturer shall remove, cover, or deface any previously affixed inscriptions, tags, or labels that are no longer applicable.

(3) Quick-change x-ray tubes. The requirements of paragraph (e)(2) of this section shall not apply to tube housing assemblies designed and designated by their original manufacturer to contain quick change x-ray tubes. The manufacturer of quick-change x-ray tubes shall include with each replacement tube a label with the tube manufacturer's name, the model, and serial number of the x-ray tube. The manufacturer of the tube shall instruct the assembler who installs the new tube to attach the label to the tube housing assembly and to remove, cover, or deface the previously affixed inscriptions, tags, or labels that are described by the tube manufacturer as no longer applicable.

(g) **Information to be provided to assemblers.** Manufacturers of components listed in paragraph (a)(1) of this section shall provide to assemblers subject to paragraph (d) of this section and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for assembly, installation, adjustment, and testing of such components adequate to assure that the products will comply with applicable provisions of this section and 1020.31, 1020.32, and 1020.33, when assembled, installed, adjusted, and tested as directed. Such instructions shall include specifications of other components compatible with that to be installed when compliance of the system or subsystem depends on their compatibility. Such specifications may describe pertinent physical characteristics of the components and/or may list by manufacturer model number the components which are compatible. For x-ray controls and generators manufactured after May 3, 1994, manufacturers shall provide:

(1) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(2) A statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, the manufacturer shall provide information necessary to allow the assembler to determine the maximum line current for the particular tube housing assembly(ies);

(3) A statement of the technique factors that constitute the maximum line current condition described in paragraph (g)(2) of this section.

(h) **Information to be provided to users**. Manufacturers of x-ray equipment shall provide to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, manuals or instruction sheets which shall include the following technical and safety information:

(1) All x-ray equipment . For x-ray equipment to which this section and 1020.31, 1020.32, and 1020.33 are applicable, there shall be provided:

(i) Adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the equipment; and

(ii) A schedule of the maintenance necessary to keep the equipment in compliance with this section and 1020.31, 1020.32, and 1020.33.

(2) Tube housing assemblies . For each tube housing assembly, there shall be provided:

(i) Statements of the leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the tube housing assembly manufacturer states compatibility, the minimum filtration permanently in the useful beam expressed as millimeters (mm) of aluminum equivalent, and the peak tube potential at which the aluminum equivalent was obtained;

(ii) Cooling curves for the anode and tube housing; and

(iii) Tube rating charts. If the tube is designed to operate from different types of x-ray high-voltage generators (such as single-phase self rectified, single-phase half-wave rectified, single-phase full-wave rectified, 3-phase 6-pulse, 3-phase 12-pulse, constant potential, capacitor energy storage) or under modes of operation such as alternate focal spot sizes or speeds of anode rotation which affect its rating, specific identification of the difference in ratings shall be noted.

(3) X-ray controls and generators . For the x-ray control and associated x-ray high-voltage generator, there shall be provided:

(i) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(ii) A statement of the maximum line current of the x-ray system based on the maximum input voltage and output current characteristics of the tube housing assembly compatible with rated output voltage and rated current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the

manufacturer of the x-ray control and associated high-voltage generator, the manufacturer shall provide necessary information to allow the purchaser to determine the maximum line current for his particular tube housing assembly(ies);

(iii) A statement of the technique factors that constitute the maximum line current condition described in paragraph (h)(3)(ii) of this section;

(iv) In the case of battery-powered generators, a specification of the minimum state of charge necessary for proper operation;

(v) Generator rating and duty cycle;

(vi) A statement of the maximum deviation from the preindication given by labeled technique factor control settings or indicators during any radiographic or CT exposure where the equipment is connected to a power supply as described in accordance with this paragraph. In the case of fixed technique factors, the maximum deviation from the nominal fixed value of each factor shall be stated;

(vii) A statement of the maximum deviation from the continuous indication of x-ray tube potential and current during any fluoroscopic exposure when the equipment is connected to a power supply as described in accordance with this paragraph; and

(viii) A statement describing the measurement criteria for all technique factors used in paragraphs (h)(3)(iii), (h)(3)(vi), and (h)(3)(vii) of this section; for example, the beginning and endpoints of exposure time measured with respect to a certain percentage of the voltage waveform.

(4) Beam-limiting device. For each variable-aperture beam-limiting device, there shall be provided;

(ii) A statement including the minimum aluminum equivalent of that part of the device through which the useful beam passes and including the x-ray tube potential at which the aluminum equivalent was obtained. When two or more filters are provided as part of the device, the statement shall include the aluminum equivalent of each filter.

(5) Imaging system information. For x-ray systems manufactured on or after June 10, 2006, that produce images using the fluoroscopic image receptor, the following information shall be provided in a separate, single section of the user's instruction manual or in a separate manual devoted to this information:

(i) For each mode of operation, a description of the mode and detailed instructions on how the mode is engaged and disengaged. The description of the mode shall identify those technique factors and system controls that are fixed or automatically adjusted by selection of the mode of operation, including the

manner in which the automatic adjustment is controlled. This information shall include how the operator can recognize which mode of operation has been selected prior to initiation of x-ray production.

(ii) For each mode of operation, a descriptive example(s) of any specific clinical procedure(s) or imaging task(s) for which the mode is recommended or designed and how each mode should be used. Such recommendations do not preclude other clinical uses.

(6) Displays of values of AKR and cumulative air kerma. For fluoroscopic x-ray systems manufactured on or after June 10, 2006, the following shall be provided:

(i) A schedule of maintenance for any system instrumentation associated with the display of air kerma information necessary to maintain the displays of AKR and cumulative air kerma within the limits of allowed uncertainty specified by 1020.32(k)(6) and, if the capability for user calibration of the display is provided, adequate instructions for such calibration;

(ii) Identification of the distances along the beam axis:

(A) From the focal spot to the isocenter, and

(B) From the focal spot to the reference location to which displayed values of AKR and cumulative air kerma refer according to 1020.32(k)(4);

(iii) A rationale for specification of a reference irradiation location alternative to 15 cm from the isocenter toward the x-ray source along the beam axis when such alternative specification is made according to 1020.32(k)(4)(ii).

(j) **Warning label.** The control panel containing the main power switch shall bear the warning statement, legible and accessible to view:

"Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed."

Adopted this 25th day of February, 2013.

JAMES W. GILLAN
Director of Public Health & Social Services

Office of the Legislative Secretary
Senator Tina Rose Muña Barnes
Date 2-25-13
Time 11:30
Received by