

## 7. REGULATIONS

Because of the potential for ionizing radiation to cause deterministic (acute radiation syndrome, cataracts) and nondeterministic (cancer) health effects in exposed individuals, safe dose guidelines and regulations have been established for both external radiation exposure and radionuclides in air and water by a number of international and national agencies. International and national regulations and guidelines pertinent to human exposure to ionizing radiation are summarized in Table 7-1. Those that protect against deterministic effects are based on identified acute thresholds doses for those effects, with a reduction to protect sensitive populations and provide safety margins that account for uncertainties. Those that protect against nondeterministic effects use the observed frequencies with which those effects occur at high doses, account for uncertainties that may exist, and assume a linear dose-effect relationship to calculate the doses at which the effects would be presumed to occur at some acceptable frequency, such as the range of  $10^{-4}$  to  $10^{-6}$  which EPA often considers. This proportionality assumes a linear no threshold (LNT) dose effect curve. During the last decade, there have been reductions in LNT-based public radiation dose limits and site cleanup levels that have increased the scope and cost of medical, occupational, and environmental radiation protection efforts. Some recent studies found a reduction in health effects when the dose was delivered at lower dose rates, indicating a potential application to future protection guidelines and regulations.

An MRL of 0.004 mSv (0.4 rem) has been derived for acute-duration external exposure (14 days or less), based on the developmental studies of Schull et al. (1988) and the IQ studies of Burt (1966).

An MRL of 0.001 Sv/yr (0.1 rem/yr) above background has been derived for chronic-duration external exposure (365 days or more) to radiation based on information that identified radiation doses that have not been reported to have detrimental effects on humans (BEIR V 1990).

The health effects of radiation have been recognized since early in the twentieth century, and by 1928 the International X-Ray and Radium Protection Committee (now the International Commission on Radiological Protection [ICRP]) was established. In the United States, a year later, the Advisory Committee on X Ray and Radiation Protection, now called the National Council on Radiation Protection and Measurements (NCRP), was formed. The NCRP was chartered in 1964 by the U.S. Congress to: (1) disseminate information of public interest and recommend radiation levels to protect the public, (2) support cooperation among organizations concerned with radiation protection, (3) develop basic concepts

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about radiation protection, and (4) cooperate with the ICRP and the International Commission on Radiation Units and Measurements. Even though the NCRP is a nongovernmental organization, it provides recommendations that guide the establishment of federal radiation policies, agency requirements, and statutory laws. Through the governmental agencies that rely on NCRP recommendations, the work of this organization has a significant impact on the many activities in the United States involving the use of radiation and radioactive materials.

In the United States, the Environmental Protection Agency (EPA) sets radiation safety policy and basic safety standard. The execution of this policy is assigned to the various regulatory agencies, including the EPA itself, for application to the specific activities that they regulate. The U.S. Nuclear Regulatory Commission (USNRC), an independent government agency, regulates commercial nuclear power reactors; research/test/training reactors; fuel cycle facilities; and the transport, storage and disposal of nuclear materials and waste (USNRC 1997b). The EPA is responsible for protecting the public and the environment and for clean up of radioactively contaminated sites (EPA 1997). The Mine Safety and Health Administration (Department of Labor) is responsible for protecting miners from exposure to radon and its daughters and gamma rays in underground or surface mines (MSHA 1997). The Food and Drug Administration (FDA) develops standards for equipment that emits ionizing radiation, such as radiographic and fluoroscopic equipment (FDA 1997), radioactive material concentrations in food (FDA 1998), and medical devices used in radiation therapy (FDA 1997).

A mammogram device, for example, uses low-dose x rays to produce a radiographic image of breast tissue. Unfortunately, mammograms are among the most difficult radiographic images to read. To reduce the chance of false negative and false positive diagnoses, the image must be of high quality (FDA 1997). Senate hearings on breast cancer held in 1992 found a wide range of problems with mammography practices in the United States. In response to these issues and to the growing incidence of breast cancer and its associated mortality rate, the U.S. Congress enacted the Mammography Quality Standards Act (MQSA). The enactment of the MQSA in 1992 was a statutory means of certifying and inspecting mammography facilities. Regulations established by the FDA to implement the MQSA ensured that only facilities accredited by an approved accreditation body and certified by the Secretary of Health and Human Services would lawfully continue to operate after October 1, 1994. In order to meet the October deadline, however, the MQSA needed to be amended and the process for issuing standards for facilities and the standards to be met by the accrediting bodies needed to be shortened. The

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amendments gave the FDA the authority to issue interim regulations, which were published on December 21, 1993 (FDA 1997, 1999a, 1999b). Final regulations for the MQSA, published on October 28, 1997, mandated that facilities would incorporate new requirements into their programs by April 28, 1999, the effective date for most of the regulations. Regulations concerning equipment will become effective on October 28, 2002 (FDA 1999b). Except for the Department of Veterans Affairs, all mammography facilities that produce, process, or interpret mammograms must meet the requirements of the MQSA. In order to keep the basic safeguards in place beyond the year 2000, the Mammography Quality Standards Reauthorization Act of 1998 was passed by Congress on October 9, 1998 (U.S. Congress 1998). The FDA recently announced the availability of its guidance document, *Compliance Guidance: The Mammography Standards Act Final Regulations Document #1*, which is intended to assist mammography facilities in meeting the MQSA final regulations (FDA 1999a).

The FDA recently updated its guidance document that presents recommended action levels for radionuclides in foods, both domestic and imported (FDA 1998). These derived intervention levels (DILs) are estimated levels in food that could lead to individuals receiving a radiation equivalent dose equal to the FDA protection action guide (PAG) that is set as the more limiting of either 0.5 rem (5 mSv) for committed effective dose or 5 rem (50 mSv) committed dose equivalent to any individual tissue or organ. Table 7-4 presents the most restrictive food DILs.

Transport of radioactive materials is regulated by the Department of Transportation (DOT) in conjunction with the USNRC. Coordinating government emergency response to accidents involving radioactive materials is the responsibility of the Federal Emergency Management Administration (FEMA).

National regulations governing the occupational exposure to ionizing radiation include USNRC regulations (10CFR20), EPA standards for uranium and thorium mills (40 CFR 192), Occupational Safety and Health Administration (OSHA) standards for ionizing radiation (29 CFR 1910.1096), the Department of Energy (DOE) standards for occupational radiation protection (10 CFR 835), and MSHA's radon and gamma ray standards (60 FR 33719). National regulations concerning general population exposure to radiation have been developed by the EPA and USNRC based on the dose limit recommendations of the ICRP (ICRP 1997) and the NCRP (NCRP 1993).

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Currently there are 29 "NRC Agreement States." An agreement state is any state that has entered into an agreement with the USNRC under Section 274 of the Atomic Energy Act of 1954, as amended. The USNRC relinquishes to these states the majority of its regulatory authority over source, by-product, and special nuclear material in quantities not sufficient to form a critical mass. However, the regulation of nuclear reactors is under USNRC jurisdiction. In the remaining states, USNRC still handles all of the inspection, enforcement, and licensing responsibilities. States can regulate exposure to workers from electronic sources, as well as from naturally occurring and accelerator-produced radioactive materials. State regulations for  $^{226}\text{Ra}$  and strontium isotopes are listed in Tables 7-2 and 7-3, respectively.

The basic philosophy of radiation safety is to minimize unnecessary radiation exposure. The specific objectives of radiation safety guidance as stated by NCRP are (1) to prevent the occurrence of severe radiation-induced deterministic (nonstochastic) disease, and (2) to limit the risk of the nondeterministic (stochastic) effects (fatal cancer, and genetic effects) to a reasonable level compared with nonradiation risks and in relation to societal needs, benefits gained, and economic factors. In addition to regulations that set upper limits on radiation dose, the concept of ALARA (As Low As Reasonably Achievable) was introduced to ensure that work place endeavors resulting in exposures to radiation provide sufficient benefits which offset any potential detriment they cause (ACGIH 1998). The goal is not to eliminate all radiation exposure, which would not be possible, but instead to strive for an appropriate balance between protection of public health and reasonable costs (economic, social, etc.) while maintaining desirable dose limits. The American Conference of Governmental Industrial Hygienists (ACGIH) has adopted the occupational exposure guidance of the ICRP (ACGIH 1998). The values used by ACGIH as guidelines for exposure to radiation are given in Table 7-1.

The USNRC has set dose limits for individual members of the public of 0.1 rem/year, 5 rem/year for occupationally exposed workers, and 0.5 rem (0.005 Sv) during the gestation period to the fetus of a pregnant worker (USNRC 1996). More specific information on regulations pertaining to ionizing radiation exposure can be found in the references listed in Table 7-1 of this profile.

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**Table 7-1. Regulations and Guidelines Applicable to Ionizing Radiation**

Agency	Description	Information	References
<u>INTERNATIONAL</u>			
Guidelines:			
a. Occupational			
ICRP	Whole Body	10 rem/5 years <sup>a</sup> not to exceed 5 rem/year	ICRP 1991
	Equivalent Dose to Lens of Eye	15 rem/year	
	Equivalent Dose to Skin, Hands and Feet	50 rem/year	
	Annual Limits of Intake	$\frac{2 \text{ rem}}{E (50) \text{ Bq}^{-1}}$	
b. General Population			
ICRP	Effective dose limit and, if needed, higher values provided that the annual average over 5 years does not exceed this limit	0.1 rem/year	ICRP 1991
	Equivalent dose limit		
	lens of eye	1.5 rem/year	
	skin, hands and feet	5 rem/year	
	woman's abdomen	0.2 rem	
<u>NATIONAL</u>			
Regulations:			
a. Air			
DOE	Derived Air Concentrations	Yes	63 FR 59662 (10 CFR 835.209) DOE 1998
EPA	Hazardous Air Pollutant; radionuclides (including radon)	Yes	CAA Amendments, Title III, Section 112 (b) U.S. Congress 1990
	National Emissions Standards for Radon Emissions from Underground Uranium mines—effective dose equivalent for the public	10 mrem/year	40 CFR 61, Subpart B EPA 1989a
	National Emission Standards for Emissions of Radionuclides Other Than Radon from Department of Energy Facilities	Yes	40 CFR 61, Subpart H EPA 1989d
	National Emissions Standards for radionuclide Emissions from Facilities Licensed by the Nuclear Regulatory commission and Federal Facility not Covered by Subpart H	Yes	40 CFR 61, Subpart I EPA 1996a
	National Emission Standards for Radionuclide Emissions from Elemental Phosphorus Plants	2 Ci/year <sup>b</sup>	40 CFR 61, Subpart K EPA 1991
	National Emissions Standards for Radon Emissions from Phosphogypsum Stacks—inactive stacks	20 pCi/m <sup>2</sup>	40 CFR 61, Subpart R EPA 1992
	National Emission Standards for Radon Emissions from the Disposal of Uranium Mill Tailings—Radon-222 emissions to the ambient air from non-operational piles	20 pCi/m <sup>2</sup> -s of radon	40 CFR 61, Subpart T EPA 1994

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**Table 7-1. Regulations and Guidelines Applicable to Ionizing Radiation (continued)**

Agency	Description	Information	References
<b>NATIONAL (cont.)</b>			
	Test Methods		40 CFR 61, Appendix B
	Test method for measuring radionuclide emissions from stationary sources	Method 114	EPA 1996b
	Monitoring for radon-222 emissions	Method 115	
	Methods for Estimating Radionuclide Emissions	Yes	40 CFR 61, Appendix D EPA 1989c
	Compliance Procedures Methods for Determining compliance with [40 CFR 61], Subpart I	Yes	40 CFR 61, Appendix E EPA 1989b
OSHA	Toxic and Hazardous Substances—ionizing radiation	Yes	29 CFR 1910.1096 OSHA 1996a
	Safety and Health Regulations for Construction	Yes	29 CFR 1926.53 OSHA 1996b
b. Water:			
EPA	Maximum Contaminant Levels for Radium-226, Radium-228, and Gross Alpha Particle Radioactivity in Community Water Systems		40 CFR 141.15 EPA 1976a
	Combined radium-226, and radium-228	5 pCi/L	
	Gross alpha particle activity; including radium-226, but excluding radon and uranium	15 pCi/L	
	MCL for beta particles and photon activity	0.004 rem/year	40 CFR 141.16 EPA 1976b
	Average Annual Concentrations Assumed to Produce Total Body or Organ Dose of 4 mrem/yr		
	Tritium (total body)	20,000 pCi/L	
	Strontium-90 (bone marrow)	8 pCi/L	
	Monitoring frequency for radioactivity in community water systems	Yes	40 CFR 141.26 EPA 1976c
	National Primary Drinking Water Regulations; Analytical Methods for Radionuclides (final rule and proposed rule)	Yes	62 FR 10168 (40 CFR 141.25) EPA 1997
	Class V Injection Wells Underground Injection Control Regulations, revisions; proposed rule	Yes	63 FR 40586 (40 CFR 144, 145, and 146) EPA 1998b
c. Other: Occupational			
DOE	Exposure Limits for General Employees		63 FR 59662 DOE 1998 and
	Total effective dose	5 rem/year (0.05 Sv) <sup>c</sup>	10 CFR 835 DOE 1993
	Deep dose equivalent plus Committed dose to any organ or tissue other than lens of the eye	50 rem/year (0.5 Sv)	
	Eye lens dose equivalent	15 rem/year (0.15 Sv)	

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**Table 7-1. Regulations and Guidelines Applicable to Ionizing Radiation (continued)**

Agency	Description	Information	References
NATIONAL (cont.)	Shallow dose equivalent to skin or other extremity	50 rem/year	
	Planned Special Exposures	Yes	
	Limits for the embryo/fetus	0.5 rem (conception to birth)	
	Limit for minors (total effective dose equivalent)	0.1 rem (0.001 sievert) per year	
	Limit for members of the public in a controlled area (total effective dose equivalent)	0.01 rem per year	
	Requirements for Individual Monitoring	Yes	
DOT	General Requirements for Shipments and Packaging—Class 7 (Radioactive Material)		49 CFR 173, Subpart I DOT 1997
	Scope and definitions	Yes	
	Packaging design requirements	Yes	
	Table of activity limits	Yes	
	Requirements for determining A <sub>1</sub> and A <sub>2</sub> values for radionuclides and for the listing of radionuclides on shipping papers and labels	Yes <sup>d</sup>	
	Table of A <sub>1</sub> and A <sub>2</sub> values	Yes	
	Radiation level limitations external surface radiation level not to be exceeded under conditions normally incident to transportation -packages exceeding the radiation level limit	2 mSv/hour (200 mrem/hour) and the transport Index (TI) is less than 10	
	transport by exclusive use shipment	Yes	
	conditional maximum radiation level	10 mSv/hour (1000 mrem/hour)	
	Outer surfaces of vehicle including top and underside	2 mSv/hour (200 mrem/hour)	
	Any point 2 meters (6.6 feet) from the outer lateral surfaces, excluding top and underside	0.1 mSv/hour (10 mrem/hour)	
	Any normally occupied space except carriers operating under the provisions of a state or federally regulated radiation protection program and wearing radiation dosimetry devices	0.02 mSv/hour (2 mrem/hour)	63 FR 48568 (49 CFR 173) DOT 1998

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**Table 7-1. Regulations and Guidelines Applicable to Ionizing Radiation (continued)**

Agency	Description	Information	References	
<u>NATIONAL</u> (cont.)				
FDA	Radiation Protection Program Requirements		63 FR 48566 (49 CFR 172, et al.) DOT 1998	
	Hazardous materials table, special provisions, hazardous materials communications, emergency response information and training requirements (49 CFR 172, Subpart I)	Removed		
	Carriage by rail (49 CFR 174.705)	Removed		
	Carriage by aircraft (49 CFR 175.706)	Removed		
	Carriage by vessel (49 CFR 176.703)	Removed		
	Carriage by public highway (49 CFR 177.827)	Removed		
	Carriage by Public Highway Requirements for class 7 (radioactive material)	Yes	49 CFR 177.842 DOT 1995	
	Total transport index number	50		
	Irradiation in the Production, Processing and Handling of Animal Feed and Pet Food			
	Ionizing radiation for treatment of laboratory animal diets			21 CFR 579.22 FDA 1993a
	-energy source	Gamma rays from sealed units of the radionuclides cobalt-60 or cesium-137		
	-limit for electrons generated	Not to exceed 10 million electron volts		
	-single treatment for microbial disinfection of bagged complete diets for laboratory animals (mice, rats, hamsters, rabbits, and guinea pigs)	Absorbed dose not to exceed 50 kGy (5 Mrad)		
	Ionizing radiation for the treatment of poultry feed and poultry feed ingredients			21 CFR 579.40 FDA 1995
-energy source	Gamma rays from sealed units of cobalt-60			
-single treatment poultry feed or feed ingredients that do not contain drugs for rendering them salmonella negative	2.0 kGy (0.2 Mrad) minimum dose; 25 kGy (2.5 Mrad) maximum dose			

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**Table 7-1. Regulations and Guidelines Applicable to Ionizing Radiation (continued)**

Agency	Description	Information	References
<u>NATIONAL</u> (cont.)			
	Performance Standards For Ionizing Radiation Emitting Products		
	Cold-cathode gas discharge tubes	Yes	21 CFR 1020.20 FDA 1973b
	Diagnostic X-ray systems and their major components	Yes	21 CFR 1020.30 FDA 1994a
	Radiographic equipment	Yes	21 CFR 1020.31 FDA 1993b
	Fluoroscopic equipment	Yes	21 CFR 1020.32 FDA 1994b
	Computed tomography (CT) equipment	Yes	21 CFR 1020.33 FDA 1991
	Cabinet X-ray systems	Yes	21 CFR 1020.40 FDA 1974
MSHA	Radon daughters, Monitoring required 1/3 months Monitoring required 1/week Uranium Mines; monitoring monthly	>0.1 WL >0.3 WL 0.1 WL	MSHA 1997
	Gamma Radiation Dosimeters for All Employees and Records of Cumulative Individual Exposure	>0.002 roentgens/hr	
NRC	Limits for Adults		10 CFR 20, Subpart C USNRC 1991
	Total effective dose	5 rem/year	
	Effective deep dose equivalent plus committed dose to any organ or tissue other than lens of the eye	50 rem/year	
	Eye lens dose equivalent	15 rem/year	
	Skin or other extremity; shallow dose	50 rem/year	
	Dose Limit for Minors	10% of annual dose limit for adult workers	
	Dose Limit to an Embryo/fetus [of pregnant female]	0.5 rem	
	Annual Limits On Intake (ALIs) and Derived Air Concentration (DACs) of Radionuclide for Occupational Exposure	Yes	10 CFR 20, Appendix B USNRC 1993
	Quantities of Licensed Material Requiring Labeling	Yes	10 CFR 20, Appendix C USNRC 1995
	Physical Protection for Spent Nuclear Fuel and High-level Radioactive Material	Yes	63 FR 29655 USNRC 1998
d. Other : General Population			
EPA	Hazardous Waste Injection Restrictions Waste specific prohibitions, newly listed and identified waste -radioactive wastes mixed with newly identified D004-D011 waste	Effective May 26, 2000	63 FR 28556 (40 CFR 148.18) EPA 1998a

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**Table 7-1. Regulations and Guidelines Applicable to Ionizing Radiation (continued)**

Agency	Description	Information	References
<u>NATIONAL</u> (cont.)	Environmental Standards for Uranium Fuel Cycle: Standards for Normal Operation	Annual dose not to exceed: -whole body ≤ 25 mrem -thyroid ≤ 75 mrem -any other organ ≤ 25 mrem	40 CFR 190, Subpart B EPA 1977
	Total quantity of radioactive materials entering the general environment -krypton-85 -iodine-129 50,000 Ci -plutonium-239 combined with other alpha-emitting transuranic radionuclides with half-lives greater than one year 5 mCi 0.5 mCi		
	Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-level and Transuranic Radioactive Wastes	Yes	40 CFR 191 EPA 1993a
	Environmental standards for management and storage— applicability and definitions -whole body 25 mrem -thyroid 75 mrem -other critical organs 25 mrem		
	Environmental standards for disposal— applicability, definitions, containment and individual protection requirements	Yes	
	-release limits for containment requirements Americium-241 or -243 100 Carbon-14 100 Cesium-135 or -137 1,000 Iodine-129 100 Neptunium-237 100 Plutonium-239, -240, or -242 100 Radium-226 100 Strontium-90 1,000 Technetium-99 10,000 Thorium-230 or -232 10 Tin-126 1,000 Uranium-233, -234, -235, -236, or -238 100	<u>Per 1000 MTHM<sup>a</sup></u>	
	Any other alpha-emitting radionuclide with a half-life greater than 20 years	100	
	Any other radionuclide with a half-life greater than 20 years that does not emit alpha particles	1,000	

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**Table 7-1. Regulations and Guidelines Applicable to Ionizing Radiation (continued)**

Agency	Description	Information	References
<p><u>NATIONAL</u> (cont.)</p>	<p>Environmental Standards for Ground-water Protection -applicability and definitions</p>	<p>Yes</p>	
	<p>-disposal standards; levels of radioactivity in any underground drinking water source</p>	<p>Not to exceed limits specified in 40 CFR 141</p>	
	<p>Land Disposal Restrictions, Effective dates of surface disposed wastes —mixed radioactive/newly identified waste codes D003-D011</p>	<p>May 26, 2000</p>	<p>63 FR 28556 (40 CFR 268, App. VII) EPA 1998a</p>
	<p>F035; mixed with radioactive waste</p>	<p>May 12, 1999</p>	
	<p>Treatment Standards; radioactive high level wastes (nonwastewaters) generated during the reprocessing of fuel rods—Hazardous waste codes D002, D004-D011</p>	<p>HLVIT'</p>	
	<p>Standards for Control of Residual Radioactive Material from Inactive Uranium Processing Sites</p>	<p>Yes</p>	<p>40 CFR 192, Subpart A EPA 1995a</p>
	<p>Definitions</p>	<p>Yes</p>	
	<p>Standards (for control of residual radioactive materials and their listed constituents)</p>	<p>Yes</p>	
	<p>Maximum concentration of constituents for ground-water protection</p>	<p>30 pCi/L</p>	
	<p>Standards for Cleanup of Land and building Contaminated with Residual Radioactive Materials from Inactive Uranium Processing Sites</p>	<p>Yes</p>	<p>40 CFR 192, Subpart B EPA 1995b</p>
	<p>Guidance for Implementation</p>	<p>Yes</p>	<p>40 CFR 192, Subpart C EPA 1995c</p>
	<p>Additional Listed Constituents (replacement list of constituents for screening purposes )</p>	<p>Combined <sup>234</sup>U and <sup>238</sup>U</p>	
	<p>Standards for Management of Uranium Byproduct Materials Pursuant to Section 84 of the Atomic Energy Act of 1954, as Amended</p>	<p>Yes</p>	<p>40 CFR 192, Subpart D EPA 1993b</p>
	<p>Standards (for application during processing operations and prior to the endo of the closure period— concentration limits</p>	<p>5 pCi/L</p>	

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**Table 7-1. Regulations and Guidelines Applicable to Ionizing Radiation (continued)**

Agency	Description	Information	References
<u>NATIONAL</u> (cont.)			
FDA	Standards for Management of Thorium Byproduct Materials Pursuant to Section 84 of the Atomic Energy Act of 1954, as Amended	Yes	40 CFR 192, Subpart E EPA 1993c
	Irradiation in the Production, Processing and Handling of Food		
	Sources of radiation used for inspection of food, inspection of packaged food and for controlling food processing	Yes	21 CFR 179.21 FDA 1996a
	General provisions for food irradiation		21 CFR 179.25 FDA 1986
	Ionizing radiation for the treatment of food		21 CFR 179.26 FDA 1997
	-energy source	gamma rays from sealed units of radionuclides <sup>60</sup> Co or <sup>137</sup> Cs	
	-limit for electrons generated	10 million electron volts	
	-limit for X-rays	5 million electron volts	
	-control of <i>Trichinella spiralis</i> in pork carcasses of fresh	0.3 kGy to 1 kGy (30 to 100 krad)	
	-growth and maturation inhibition of fresh food	Not to exceed 1 kGy (100 krad)	
	-disinfestation of arthropod pests in food	Not to exceed 1 kGy (100 krad)	
	-microbial disinfection of dry or dehydrated enzyme preparations (including immobilized enzymes)	Not to exceed 10 kGy (1 Mrad)	
	-microbial disinfection of selected dry or dehydrated aromatic vegetables substances when used as ingredients in small amounts solely for flavoring or aroma	Not to exceed 30 kGy (3 Mrad)	
-control of food-borne pathogens in fresh or frozen, uncooked poultry products	Not to exceed 30 kGy (3 Mrad); packaging shall not exclude oxygen		
-sterilization of frozen, packaged meats used solely in the National Aeronautics and Space Administration space flight program	Minimum dose 44 kGy (4.4 Mrad)		

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**Table 7-1. Regulations and Guidelines Applicable to Ionizing Radiation (continued)**

Agency	Description	Information	References
<u>NATIONAL</u> (cont.)			
	-control of food-borne pathogens in and for extension of shelf-life of refrigerated or frozen, uncooked meat, meat byproducts or meat food products	Not to exceed 4.5 kGy (450 krad) maximum for refrigerated products; not to exceed 7.0 kGy (700 krad) maximum for frozen products	
	Radio-frequency radiation for the heating of food, including microwave frequencies	Yes	21 CFR 179.30 FDA 1977a
	Ultraviolet radiation for the processing and treatment of food	Yes	21 CFR 179.39 FDA 1977b
	Pulsed light for the treatment of food -radiation sources	xenon flashlamps; emitting broad band radiation of 200 to 1,000 nanometers	21 CFR 179.41 FDA 1996b
	-pulse duration	2 milliseconds	
	-total cumulative treatment for control surface microorganisms	12 Joules/cm <sup>2</sup>	
	Packaging materials for use during the irradiation of prepackaged foods	Yes	21 CFR 179.45 FDA 1996c
	Performance Standards for Ionizing Radiation Emitting Products Television receivers	Yes	21 CFR 1020.10 FDA 1973a
NRC	Radiation Dose Limits For Individual Members of the Public Total effective dose equivalent to individual	0.1 rem/year	10 CFR 20.1301 USNRC 1997b
	Dose from external sources	0.002 rem/hour	
	Effluent Concentrations and Concentrations for Releases to Sewerage	Yes	10 CFR 20, Appendix B USNRC 1993
USDA	Hawaiian Fruits and Vegetables	Yes	7 CFR 318.13 to .13-4f USDA 1997
Guidelines: a, Water	MCLG for beta particles and photon activity	none	EPA 1998c
	MCLG for gross alpha particle activity	none	
	MCLG for <sup>226</sup> Rn and <sup>228</sup> Rn combined	none	
ACGIH	Effective Dose Any single year Averaged over 5 years; per year	50 mSv (5 rem) 20 mSv (2 rem)	

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**Table 7-1. Regulations and Guidelines Applicable to Ionizing Radiation (continued)**

Agency	Description	Information	References
<b>NATIONAL (cont.)</b>			
<b>b. Other: Occupational</b>			
	Annual Equivalent Dose		ACGIH 1998
	Lens of the eye	150 mSv (15 rem)	
	Skin	500 mSv (50 rem)	
	Hands and feet	500 mSv (50 rem)	
	Embryo-Fetus exposures once pregnancy is known		
	Monthly equivalent dose <sup>a</sup>	0.5 mSv (0.05 rem)	
	Dose to surface of women's abdomen (lower trunk); for the remainder of the pregnancy	2 mSv (0.2 rem)	
	Intake of radionuclide	1/20 of annual limit on	
	Radon Daughters	intake (ALI) 4 working level months (WLM)	
DOT	General public	2 mrem/hr	DOT 1996
	Cumulative dose, individual	100 mrem/week 500 mrem/year	
EPA <sup>b</sup>	Effective dose equivalent		EPA 1987 Fed Reg Part II
	Adult	5 rem/year	
	Lens of the eye	15 rem/year	
	All other organs	50 rem/year	
	Juvenile workers (<18 years old)	0.5 rem/year	
	Pregnant workers	0.5 rem/gestation period	
	Effective dose equivalent limit (stochastic limits)	5 rem/year not to exceed 1 rem x age of individual	NCRP 1993
	Equivalent dose limit (nonstochastic limits)	5 rem/year	
	Skin, hands, and feet	15 rem/year	
	Lens of the eyes	50 rem/year	
	All other organs		
	Guidance: Cumulative exposure	1 rem x age in years	
	Annual Reference Levels of Intake (ARLI)	2 rem /yr (20 mSv/yr) <sup>i</sup>	
<b>c. Other: General Population</b>			
FDA	Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies	Yes	FDA 1998
	Protective action guides for tissue or organ; ingestion pathway		
	Committed effective dose equivalent	5 mSv (0.5 rem)	
	Committed dose equivalent	50 mSv (5 rem)	

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**Table 7-1. Regulations and Guidelines Applicable to Ionizing Radiation (continued)**

Agency	Description	Information	References
<b>NATIONAL (cont.)</b>			
NCRP <sup>b</sup>	Effective dose equivalent limit		NCRP 1993
	Continuous or frequent exposure	0.1 rem/year	
	Infrequent exposure	0.5 rem/year	
	Lens of the eye, skin, and extremities	5 rem/year	
	Embryo-fetus	0.05 rem/month	
	Remedial action recommended		NCRP 1987
	Effective dose equivalent <sup>l</sup>	>0.5 rem/year	
	Exposure to radon and its decay products	>2 WLM/year	
	Education and Training Exposures		
	Effective dose equivalent limit	0.1 rem/year	
Dose equivalent limit in a month	0.05 rem		
Negligible Individual Risk Level			
Effective dose equivalent per source or practice	0.01 rem/year		
<b>STATE</b>			
Regulations and Guidelines: Public Protection			
a. Virginia	Acceptable ambient air concentrations Radionuclides	8.00 µg/m <sup>3</sup> (24 hours)	NATICH 1992

<sup>a</sup> Rem means the unit of dose equivalent from ionizing radiation to the total body or any internal organ or organ system. A "millirem (mrem)" is 1/1000 of a rem.

<sup>b</sup> Curie (Ci) means the quantity of radioactive material producing 37 billion nuclear transformations per second; 1 millicurie [mCi] = 0.001 Ci, 1 picocurie [pCi] = 10<sup>-12</sup> Ci).

<sup>c</sup> Unless otherwise specified, the radiological unit Sievert (Sv) is provided in the DOE regulations parenthetically and is not authorized for use in the documents required for record keeping. The quantities used in the records must be clearly indicated in special units of curie, rad, or rem, including multiples and subdivisions of these units. 10 mSv = 1 rem.

<sup>d</sup> A<sub>1</sub> means the maximum activity of special form Class 7 (radioactive) material permitted in a Type A package. A<sub>2</sub> means the maximum activity of class 7 material, other than special form, low specific activity material or surface contaminated objects permitted in a Type A package. See 49 CFR 173.403 for more detailed definitions.

<sup>e</sup> Values represent cumulative releases to the accessible environment for 10,000 years after disposal.

<sup>f</sup> HLWIT means vitrification of high level mixed radioactive wastes in units in compliance with all applicable radioactive protection.

<sup>g</sup> Sum of internal and external exposure but excluding doses from natural sources as recommended by the NCRP.

<sup>h</sup> Sum of external and internal exposures.

<sup>i</sup> The ARLI is the occupational, annual intake of radionuclides in Bq, averaged over 5 years, that equal a 50-year committed effective dose equivalent of 20 mSv.

<sup>j</sup> Including background but excluding internal exposures.

ACGIH = American Conference of Governmental Industrial Hygienists; CAA = Clean Air Act; DOE = Department of Energy; DOT = Department of Transportation; EPA = Environmental Protection Agency; ICRP = International Commission on Radiological Protection; kGy = KiloGray; krad = Kilorad; MCL = maximum contaminant level; MCLG = maximum contaminant level goal; MSHA = Mine Safety Health Administration; Mrad = Megarad; mSv = Millisievert; MTHM = Metric Tons of Heavy Metal; NATICH = National Air Toxics Information Clearing House; NCRP = National Council on Radiation Protection; NRC = Nuclear Regulatory Commission (USNRC); OSHA = Occupational Safety and Health Administration; WL = working level; WLM = working level month

7. REGULATIONS

**Table 7-2. Regulations and Guidelines Applicable to <sup>226</sup>Ra**

Agency	Description	Information	References
<u>STATE</u>			
a. Regulations:			
	Water Quality Criteria: Human Health		CELDs 1994
AK	Drinking water	5 pCi/L	
AL	Drinking water	5 pCi/L	
AZ	Drinking water	5 pCi/L	
CA	Drinking water	5 pCi/L	
CO	Drinking water	5 pCi/L combined	
CT	Drinking water	5 pCi/L	
DE	Drinking water	5 pCi/L	
FL	Drinking water	5 pCi/L combined	
GA	Drinking water	5 pCi/L	
HI	Drinking water	5 pCi/L	
IA	Drinking water	5 pCi/L	
IN	Drinking water	5 pCi/L	
KY	Drinking water/waste management	5 pCi/L	
MD	Drinking water	5 pCi/L	
ME	Drinking water	5 pCi/L	
MT	Drinking water	5 pCi/L	
NC	Drinking water	5 pCi/L	
ND	Drinking water	5 pCi/L	
NE	Drinking water	5 pCi/L	
NH	Drinking water	5 pCi/L combined	
NM	Drinking water	5 pCi/L	
NY	Drinking water	3 pCi/L	
PR	Drinking water	3 pCi/L	
OH	Drinking water	5 pCi/L	
OK	Drinking water	5 pCi/L	
RI	Drinking water	5 pCi/L	
SC	Drinking water	5 pCi/L	
SD	Drinking water	5 pCi/L	
TN	Drinking water	5 pCi/L	
TX	Drinking water	5 pCi/L	
VA	Drinking water	5 pCi/L	
UT	Drinking water	5 pCi/L	

## 7. REGULATIONS

**Table 7-2. Regulations and Guidelines Applicable to <sup>226</sup>Ra (continued)**

Agency	Description	Information	References
<u>STATE (cont.)</u>			
WA	Drinking water	3 pCi/L	
WV	Drinking water	5 pCi/L	
WY	Drinking water	3 pCi/L combined	
	Water Quality Criteria: Aquatic Life		CELDs 1994
IA	Raw water sources for potable water	5 pCi/L	
MT		None	
NC		5 pCi/L	
ND		5 pCi/L	
NH		5 pCi/L	
PR		3 pCi/L	
WV		5 pCi/L	
WY		5 pCi/L	
	Water Quality Criteria: Agriculture		CELDs 1994
AZ	Private Agriculture	5 pCi/L	
ND	Irrigation	5 pCi/L	
WY	Not specified	5 pCi/L	
	Water Quality Criteria: Recreational		CELDs 1994
ND	Recreational (boating, fishing)	5 pCi/L	
NH	Recreational	3 pCi/L	
WY	Not specified	5 pCi/L	
	Water Quality - Monitoring		CELDs 1994
CA	Drinking water	5 pCi/L	
FL	Drinking water	5 pCi/L	
IA	Drinking water	1 pCi/L	
ID	Drinking water	5 pCi/L	
IL	Drinking water	5 pCi/L	
IN	Drinking water	3 pCi/L	
MA	Drinking water	5 pCi/L	
MD	Drinking water	1 pCi/L	
MI	Drinking water	3 pCi/L	
MO	Drinking water	5 pCi/L	
MT	Drinking water	Yes	
NC	Drinking water	5 pCi/L	
ND	Drinking water	5 pCi/L	

## 7. REGULATIONS

**Table 7-2. Regulations and Guidelines Applicable to <sup>226</sup>Ra (continued)**

Agency	Description	Information	References
<u>STATE (cont.)</u>			
NM	Drinking water	1 pCi/L	
NY	Drinking water	5 pCi/L	
OH	Drinking water	5 pCi/L	
PR	Drinking water	5 pCi/L	
RI	Drinking water	5 pCi/L	
SC	Drinking water	5 pCi/L	
SD	Drinking water	5 pCi/L	
TN	Drinking water	1 pCi/L	
TX	Drinking water	5 pCi/L	
VA	Drinking water	5 pCi/L	
UT	Drinking water	5 pCi/L	
WA	Drinking water	5 pCi/L	
WI	Drinking water	5 pCi/L	
WV	Drinking water	5 pCi/L	
	Groundwater Quality Standards		CELDs 1994
NE	Groundwater	5 pCi/L	
NC	Drinking, potable mineral water	5 pCi/L	
NY	Not specified	3 pCi/L	
PR	Not specified	3 pCi/L	
TN	Not specified	5 pCi/L	
VA	Not specified	5 pCi/L	
WY	Not specified	5 pCi/L	
	Groundwater Monitoring Parameters		CELDs 1994
CA	Hazardous waste facilities	Yes	
CO	Hazardous waste facilities	5 pCi/L	
IN	Public supply	3 pCi/L	
NC	Public supply	5 pCi/L	
NJ	Hazardous waste facilities	5 pCi/L	
NM	Public supply	1 pCi/L	
NY	Hazardous facility	5 pCi/L	
SC	Hazardous waste	5 pCi/L	
TN	Not specified	5 pCi/L	
WI	Hazardous waste	5 pCi/L	

CELDs = Comprehensive Environmental Legislative Database

## 7. REGULATIONS

**Table 7-3. Regulations and Guidelines Applicable to Strontium Isotopes**

Agency	Description	Information	References
<b>STATE</b>			
a. Regulations:			
	Water Quality Criteria - Human Health		CELDs 1994
AZ	Agricultural, public, aquatic	8 pCi/L	
AL	Drinking water	8 pCi/L	
CA	Drinking water	8 pCi/L	
CO	Drinking water	2 pCi/L	
CT	Drinking water - standard	8 pCi/L	
DE	Drinking water - standard and monitoring	8 pCi/L	
FL	Drinking water	8 pCi/L	
GA	Drinking water	Yes	
HI	Drinking water	8 pCi/L	
IA	Drinking water	8 pCi/L	
ID	Drinking water	8 pCi/L	
IL	Drinking water	8 pCi/L	
IN	Drinking water	8 pCi/L	
	Surface Water Quality Standards		CELDs 1994
CO		8 pCi/L	
	Water Quality Monitoring		CELDs 1994
AL	Drinking water	Yes	
AZ	Drinking water	Yes	
CA	Drinking water	8 pCi/L	
CO	Drinking water	2 pCi/L	
DE	Drinking water	8 pCi/L	
GA	Drinking water	Yes	
HI	Drinking water	Yes	
IA	Drinking water	Yes	
ID	Drinking water	Yes	
IL	Drinking water	8 pCi/L	
IN	Drinking water	Yes	
	Groundwater Quality Standards		CELDs 1994
CO	Groundwater - Public	8 pCi/L	
IN	Groundwater - Drinking	10 pCi/L	

CELDs = Comprehensive Environmental Legislative Database

## 7. REGULATIONS

**Table 7-4. FDA Derived Intervention Levels<sup>a</sup> (Bq/kg)**

Radionuclide	Age of individual at time of ingestion					
	3 months	1 year	5 years	10 years	15 years	Adult
<sup>90</sup> Sr	308	362	616	389	160	465
<sup>131</sup> I	196	167	722	1200	1690	2420
<sup>134</sup> Cs	1600	2190	1940	1530	958	930
<sup>137</sup> Cs	2000	2990	2810	2180	1370	1360
Cs group <sup>b</sup>	1800	2590	2380	1880	1160	1150
<sup>103</sup> Ru	6770	8410	12200	16400	25000	28400
<sup>106</sup> Ru	449	621	935	1340	2080	2360
<sup>238</sup> Pu	2.5	21	17	14	12	10
<sup>239</sup> Pu	2.2	18	14	13	10	9.8
<sup>241</sup> Am	2.0	17	13	11	9.1	8.8
Pu+Am group <sup>c</sup>	2.2	19	15	13	9.6	9.3

<sup>a</sup> Derived Intervention Levels (DIL) presented are food concentrations whose consumption would deliver a committed effective dose equivalent equal to the most limiting of the protective action guides (PAGs) developed by FDA

<sup>b</sup> Computed as: (DIL for <sup>134</sup>Cs + DIL for <sup>137</sup>Cs)/2

<sup>c</sup> Computed as: (DIL for <sup>238</sup>Pu + DIL for <sup>239</sup>Pu + DIL for <sup>241</sup>Am)/3

Source: FDA 1998