

8. REGULATIONS AND ADVISORIES

International and national regulations and guidelines pertinent to human exposure to plutonium and to other radioactive substances are summarized in Table 8-1. Recommendations for radiation protection for people in the general population as a result of exposure to radiation in the environment are found in the International Commission on Radiological Protection (ICRP) Publication 60 (ICRP 1991). National guidelines for occupational radiation protection are found in the "Federal Radiation Protection Guidance for Occupational Exposure" (EPA 1987). The guidance presents general principles for the radiation protection of workers and specifies the numerical primary guides for limiting occupational exposure. These recommendations are consistent with the ICRP (ICRP 1991).

The basic philosophy of radiation protection is the concept of ALARA (As Low As Reasonably Achievable). ALARA requires that social and economic factors to be taken into consideration, and that further reductions in dose are not indicated where the costs of reducing exposure become disproportionate to the benefit achieved. As a rule, all exposure should be kept as low as reasonably achievable and the regulations and guidelines are meant to give an upper limit to exposure. Based on the primary guidelines (EPA 1987), guides for Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) have been calculated (USNRC 2007a). The ALI is defined as "the annual intake of a given radionuclide by Reference Man which would result in a committed effective dose equivalent of 5 rems (stochastic) or 50 rems to an organ or tissue (non-stochastic)" (USNRC 2007a). The DAC is defined as "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 of 1.2 m³ of air/hour), results in the intake of one ALI" (USNRC 2007e). The ALIs and DACs refer to occupational situations, but may be converted to apply to exposure of persons in the general population by application of conversion factors (Table 8-1).

No inhalation or oral MRLs were derived for plutonium or plutonium compounds.

The EPA IRIS database has withdrawn its cancer classification for radionuclides, but the EPA Office of Air and Radiation believes that all radionuclides, including the plutonium isotopes, should be considered to be known carcinogens, and has assigned them to Group A. Carcinogenic toxicity values for plutonium isotopes are listed in EPA's Radionuclide Table: Radionuclide Carcinogenicity – Slope Factors (Federal Guidance Report No. 13 Morbidity Risk Coefficients, in Units of Picocuries) (EPA 2001). Lifetime excess total cancer risk per unit intake is included for water ingestion, food ingestion, soil ingestion,

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inhalation, and external exposure. The risk values for selected plutonium isotopes are presented in Table 8-2. The EPA has not derived reference concentrations (RfCs) or reference doses (RfDs) for plutonium (IRIS 2007), but has derived a maximum contaminant level (MCL) of 15 pCi/L for total alpha-emitters (including plutonium), less uranium and radon (EPA 2003).

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Table 8-1. Regulations and Guidelines Applicable to Plutonium and Plutonium Compounds

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification ²³⁹ Pu and its decay products (may contain ²⁴⁰ Pu and other isotopes), as aerosols	Group 1 ^a	IARC 2006
ICRP	Occupational—whole body exposure Individual—short-term, to critical populations Individual—chronic exposure	5 rem/year 0.5 rem/year 0.1 rem/year	ICRP 1977
WHO	Air quality guidelines Drinking water quality guidelines	No data No data	WHO 2000 WHO 2004
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	Dose limits for exposure to ionizing radiation Effective dose In any single year Averaged over 5 years Annual equivalent dose to Lens of the eye Skin Hands and feet Embryo-fetus exposures once the pregnancy is known Monthly equivalent dose Dose to the surface of women's abdomen (lower trunk) Intake of radionuclide	 50 mSv 20 mSv per year 150 mSv 500 mSv 500 mSv 0.5 mSv 2 mSv for the remainder of the pregnancy 1/20 of ALI	ACGIH 2006
EPA	AEGL-1, -2, and -3 Occupational—the committed effective dose equivalent (internal) and annual effective dose equivalent (external) combined	No data 5 rem/year	EPA 2007b EPA 1987
FRC	Individual—whole body exposure Individual—operational guide for "suitable sample of population" when individual whole body doses are not known	5 rem/year 0.17 rem/year	FRC 1960

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Table 8-1. Regulations and Guidelines Applicable to Plutonium and Plutonium Compounds

Agency	Description	Information	Reference
NATIONAL (cont.)			
EPA	National emission standards for emissions of radionuclides other than radon from Department of Energy facilities	10 mrem/year	EPA 2002 40 CFR Part 61
NIOSH OSHA	REL (10-hour TWA) Exposure limits of individuals to ionizing radiation in restricted areas (rems per calendar quarter)	No data	OSHA 2006 29 CFR 1910.1096
	Whole body: head and trunk; active blood-forming organs; lens of eyes; or gonads	1.25 rems	
	Hands and forearms; feet and ankles	18.75 rems	
	Skin of whole body	7.5 rems	
USNRC	Occupational values for oral ingestion ALI (μCi) of Class W		USNRC 2007a 10 CFR 20, Appendix B
	^{236}Pu	$2 \times 10^{+0}$	
	^{237}Pu	$1 \times 10^{+4}$	
	^{238}Pu	9×10^{-1} (bone surface)	
	^{239}Pu	8×10^{-1} (bone surface)	
	^{240}Pu	8×10^{-1} (bone surface)	
	^{241}Pu	$4 \times 10^{+1}$ (bone surface)	
	^{242}Pu	8×10^{-1} (bone surface)	
	^{243}Pu	$2 \times 10^{+4}$	
	^{244}Pu	8×10^{-1} (bone surface)	
	Occupational values for inhalation ALI (μCi) of Class W ^b		
	^{236}Pu	2×10^{-2}	
	^{237}Pu	$3 \times 10^{+3}$	
	^{238}Pu	7×10^{-3} (bone surface)	
	^{239}Pu	6×10^{-3} (bone surface)	
	^{240}Pu	6×10^{-3} (bone surface)	
	^{241}Pu	3×10^{-1} (bone surface)	
	^{242}Pu	7×10^{-3} (bone surface)	
	^{243}Pu	$4 \times 10^{+4}$	
	^{244}Pu	7×10^{-3} (bone surface)	
	Occupational values for inhalation ALI (μCi) of Class Y ^b		
	^{236}Pu	4×10^{-2}	
	^{237}Pu	$3 \times 10^{+3}$	
	^{238}Pu	2×10^{-2}	
	^{239}Pu	2×10^{-2} (bone surface)	
	^{240}Pu	2×10^{-2} (bone surface)	
	^{241}Pu	8×10^{-1} (bone surface)	
	^{242}Pu	2×10^{-2} (bone surface)	
	^{243}Pu	$4 \times 10^{+4}$	
	^{244}Pu	2×10^{-2} (bone surface)	

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Table 8-1. Regulations and Guidelines Applicable to Plutonium and Plutonium Compounds

Agency	Description	Information	Reference
NATIONAL (cont.)			
USNRC	Occupational values for inhalation DAC ($\mu\text{Ci/mL}$) of Class W ^b		USNRC 2007a 10 CFR 20, Appendix B
	²³⁶ Pu	8×10^{-12}	
	²³⁷ Pu	1×10^{-6}	
	²³⁸ Pu	3×10^{-12}	
	²³⁹ Pu	3×10^{-12}	
	²⁴⁰ Pu	3×10^{-12}	
	²⁴¹ Pu	1×10^{-10}	
	²⁴² Pu	3×10^{-12}	
	²⁴³ Pu	2×10^{-5}	
	²⁴⁴ Pu	3×10^{-12}	
	Occupational values for inhalation DAC ($\mu\text{Ci/mL}$) of Class Y ^b		
	²³⁶ Pu	2×10^{-11}	
	²³⁷ Pu	1×10^{-6}	
	²³⁸ Pu	8×10^{-12}	
	²³⁹ Pu	7×10^{-12}	
	²⁴⁰ Pu	7×10^{-12}	
	²⁴¹ Pu	3×10^{-10}	
	²⁴² Pu	7×10^{-12}	
²⁴³ Pu	2×10^{-5}		
²⁴⁴ Pu	7×10^{-12}		
b. Water	Drinking water standards and health advisories for gross alpha particle activity		EPA 2006
	10^{-4} Cancer risk	15 pCi/L	
	National primary drinking water standards for alpha particles		EPA 2003
	MCLG	Zero	
	MCL	15 pCi/L	
	Public health goal	Zero	
c. Food		No data	
	FDA	Guidance level for radionuclide in domestic and imported food	FDA 2004
	Derived intervention level	2 Bq/kg	
d. Other	ACGIH	Carcinogenicity classification	ACGIH 2006
	EPA	Carcinogenicity classification	EPA 2001
		Group A ^c	

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Agency	Description	Information	Reference
NATIONAL (cont.)			
EPA	Superfund, emergency planning, and community right-to-know Designated CERCLA hazardous substance		EPA 2007c 40 CFR 302.4
	Reportable quantity (Ci)		
	²³⁶ Pu	0.1	
	²³⁷ Pu	1,000	
	²³⁸ Pu	0.01	
	²³⁹ Pu	0.01	
	²⁴⁰ Pu	0.01	
	²⁴¹ Pu	1	
	²⁴² Pu	0.01	
	²⁴³ Pu	1,000	
	²⁴⁴ Pu	0.01	
NTP	Carcinogenicity classification	Known to be human carcinogens	NTP 2005

^aGroup 1: carcinogenic to humans

^bThe ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1 µm and for three classes (D,W,Y) of radioactive material, which refer to their retention (approximately days, weeks, or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times of less than 10 days for D, for W from 10 to 100 days, and for Y greater than 100 days (USNRC 2007a).

^cGroup A: known human carcinogen

ACGIH = American Conference of Governmental Industrial Hygienists; AEGL = Acute Exposure Guideline Levels; ALI = Annual Limit on Intake; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CFR = Code of Federal Regulations; DAC = Derived Air Concentration; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; FRC = Federal Radiation Council; IARC = International Agency for Research on Cancer; ICRP = International Commission on Radiological Protection; MCL = maximum contaminant level; MCLG = maximum contaminant level goal; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; TWA = time-weighted average; USNRC = U.S. Nuclear Regulatory Commission; WHO = World Health Organization

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Table 8-2. Radionuclide Carcinogenicity—Slope Factors for Plutonium (Federal Guidance Report No. 13 Morbidity Risk Coefficients, in Units of Picocuries)^a

Isotope ^b	Slope factor (morbidity risk coefficient) lifetime excess total cancer risk per unit intake or exposure					
	Gastro-intestinal absorption Fraction ^c	Water ingestion (risk/pCi)	Food ingestion (risk/pCi)	Soil ingestion (risk/pCi)	Inhalation (risk/pCi)	External exposure (risk/year per pCi/g)
Pu-234	5.00x10 ⁻⁴	8.58x10 ⁻¹³	1.25x10 ⁻¹²	2.39x10 ⁻¹²	6.85x10 ⁻¹¹	1.61x10 ⁻⁷
Pu-235	5.00x10 ⁻⁴	4.37x10 ⁻¹⁵	6.03x10 ⁻¹⁵	9.73x10 ⁻¹⁵	2.39x10 ⁻¹⁵	2.37x10 ⁻⁷
Pu-236	5.00x10 ⁻⁴	7.47x10 ⁻¹¹	9.92x10 ⁻¹¹	1.74x10 ⁻¹⁰	2.28x10 ⁻⁸	1.19x10 ⁻¹⁰
Pu-237	5.00x10 ⁻⁴	5.77x10 ⁻¹³	8.40x10 ⁻¹³	1.62x10 ⁻¹²	1.27x10 ⁻¹²	1.12x10 ⁻⁷
Pu-238	5.00x10 ⁻⁴	1.31x10 ⁻¹⁰	1.69x10 ⁻¹⁰	2.72x10 ⁻¹⁰	3.36x10 ⁻⁸	7.22x10 ⁻¹¹
Pu-239	5.00x10 ⁻⁴	1.35x10 ⁻¹⁰	1.74x10 ⁻¹⁰	2.76x10 ⁻¹⁰	3.33x10 ⁻⁸	2.00x10 ⁻¹⁰
Pu-240	5.00x10 ⁻⁴	1.35x10 ⁻¹⁰	1.74x10 ⁻¹⁰	2.77x10 ⁻¹⁰	3.33x10 ⁻⁸	6.98x10 ⁻¹¹
Pu-241	5.00x10 ⁻⁴	1.76x10 ⁻¹²	2.28x10 ⁻¹²	3.29x10 ⁻¹²	3.34x10 ⁻¹⁰	4.11x10 ⁻¹²
Pu-242	5.00x10 ⁻⁴	1.28x10 ⁻¹⁰	1.65x10 ⁻¹⁰	2.63x10 ⁻¹⁰	3.13x10 ⁻⁸	6.25x10 ⁻¹¹
Pu-243	5.00x10 ⁻⁴	4.74x10 ⁻¹³	6.92x10 ⁻¹³	1.34x10 ⁻¹²	2.94x10 ⁻¹³	5.50x10 ⁻⁸
Pu-244	5.00x10 ⁻⁴	1.37x10 ⁻¹⁰	1.80x10 ⁻¹⁰	2.94x10 ⁻¹⁰	2.93x10 ⁻⁸	3.01x10 ⁻¹¹
Pu-245	5.00x10 ⁻⁴	4.48x10 ⁻¹²	6.55x10 ⁻¹²	1.28x10 ⁻¹¹	2.07x10 ⁻¹²	1.77x10 ⁻⁶
Pu-246	5.00x10 ⁻⁴	1.73x10 ⁻¹¹	2.53x10 ⁻¹¹	4.92x10 ⁻¹¹	1.73x10 ⁻¹¹	4.04x10 ⁻⁷

^aEPA classifies all radionuclides as Group A (known human) carcinogens. Radionuclide risk coefficients, or slope factors, are calculated by EPA's ORIA to assist HEAST users with risk-related evaluations and decision-making at various stages of the remediation process. Most values presented are taken from EPA (1999, 2000); risk estimates for the soil ingestion pathway are not addressed, but have been computed using similar methods. Ingestion and inhalation slope factors are central estimates in a linear model of the age-averaged, lifetime attributable radiation cancer incidence (fatal and nonfatal cancer) risk per unit of activity inhaled or ingested, expressed as risk/pCi. Slope factors can be converted into the SI units of becquerels (1 Bq=1 nuclear transformation per second) by dividing each inhalation, ingestion, or external exposure value by 0.037. Ci, the customary unit of activity is equal to 3.7x1,010 nuclear transformations per second (1 pCi=10⁻¹² Ci). Inhalation values for particulates represent the indicated ICRP lung absorption type (medium, particulate). External exposure slope factors are central estimates of the lifetime attributable radiation cancer incidence risk for each year of exposure to external radiation from photon-emitting radionuclides uniformly distributed in a thick layer of soil (expressed as risk/year per pCi/g of soil).

^bFor each radionuclide listed, slope factors correspond to the risks per unit intake or exposure for that radionuclide only.

^cGastrointestinal absorption fractions are the fractional amounts of each radionuclide absorbed across the gastrointestinal tract into the bloodstream.

Bq = Becquerel; Ci = curie; EPA = Environmental Protection Agency; HEAST = Health Effects Assessment Summary Table; ICRP = International Commission on Radiological Protection; ORIA = Office of Radiation and Indoor Air; pCi = picocurie; SI = International System

Source: EPA 2001