

## 8. REGULATIONS AND ADVISORIES

The international, national, and state regulations and guidelines regarding americium in air, water, and other media are summarized in Table 8-1.

The USNRC maintains a database of information regarding licensees authorized to possess americium isotopes ( $^{241}\text{Am}$  through  $^{244}\text{Am}$ ) within the 18 non-Agreement States (states not committed to self-regulation). This database includes more than 2,000 records of licensees and site possession limits in the microcurie to curie range. The isotope,  $^{241}\text{Am}$ , accounts for most of the licenses. Such records for USNRC Agreement States are maintained by the individual state radioactive material regulatory organizations. The USNRC and EPA each have responsibilities for regulating the cleanup of radioactivity and decommissioning of USNRC licensed sites. USNRC and EPA reached an agreement in 2002, in response to Congressional mandate, to preclude double regulation of these efforts. The agreement provides that EPA will defer exercise of authority under CERCLA for the majority of facilities decommissioned under USNRC authority. It also contains provisions for joint consultation when certain EPA parameters are exceeded, including groundwater exceeding EPA-permitted levels, USNRC contemplation of restricted release or alternate release criteria, and residual soil radioactivity concentrations exceeding those in the agreement (USNRC 2002).

No inhalation or oral MRLs were derived for americium or americium 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The EPA IRIS database has withdrawn its cancer classification for radionuclides, but the EPA Office of Air and Radiation believes that all radionuclides, including the americium isotopes, should be considered to be known carcinogens, and has assigned them to Group A. Carcinogenic toxicity values for  $^{241}\text{Am}$  are listed in EPA's Federal Radiation Guidance Report No. 13 (EPA 2000a). Lifetime excess total cancer risk per unit intake are included for inhalation (Table 2.1), drinking water ingestion (Table 2.2), and submersion, ground plane exposure, and soil intake (Table 2.3). Media-specific usage rates (Table 3.1) provide a means of adjusting the values to be compatible with specific population groups (e.g., tap water intakes range from a low of 0.188 L/day for a newborn female to a high of 1.643 L/day for a 50-year-old male, with a societal average of 1.11 L/day). The EPA has not derived reference concentrations (RfCs) or reference doses (RfDs) for americium (IRIS 2002), but has derived a maximum contaminant level (MCL) of 15 pCi/L for total alpha-emitters (including americium), less uranium and radon (EPA 2000c).

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**Table 8-1. Regulations and Guidelines Applicable to Americium**

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC		No data	
<u>NATIONAL</u>			
Guidelines:			
a. Air			
ACGIH	Effective dose		ACGIH 2002
	Any single year	50 mSv	
	Averaged over 5 years	20 mSv	
	Annual equivalent dose to		
	Lens of the eye	150 mSv	
	Skin	500 mSv	
	Hands and feet	500 mSv	
	Embryo-fetus exposures once the pregnancy is known		
	Monthly equivalent dose	0.5 mSv	
	Dose to the surface of women's abdomen (lower trunk)	2 mSv for the remainder of the pregnancy	
	Intake of radionuclide	1/20 ALI	
NIOSH	REL (10-hour TWA)	No data	
<u>NATIONAL</u>			
Regulations:			
EPA	Concentration levels for environmental compliance		EPA 2001a 40CFR61, Appendix E
	<sup>241</sup> Am	$1.9 \times 10^{-15}$ Ci/m <sup>3</sup>	
	<sup>242</sup> Am	$1.5 \times 10^{-11}$ Ci/m <sup>3</sup>	
	<sup>243</sup> Am	$1.8 \times 10^{-15}$ Ci/m <sup>3</sup>	
OSHA	PEL (8-hour TWA)	No data	
USNRC	Occupational values— <u>inhalation</u>	<u>ALI(μCi)</u> <u>DAC(μCi/mL)</u>	USNRC 2001a 10CFR20, Appendix B
	<sup>241</sup> Am	$6 \times 10^{-3}$ $3 \times 10^{-12}$	
	<sup>242</sup> Am	$8 \times 10^1$ $4 \times 10^{-8}$	
	<sup>243</sup> Am	$6 \times 10^{-3}$ $3 \times 10^{-12}$	
	<u>Effluent concentrations—air</u>		USNRC 2001a 10CFR20, Appendix B
	<sup>241</sup> Am	$2 \times 10^{-14}$ μCi/mL	
	<sup>242</sup> Am	$1 \times 10^{-10}$ μCi/mL	
	<sup>243</sup> Am	$2 \times 10^{-14}$ μCi/mL	
b. Water			
USNRC	<u>Effluent concentrations—water</u>		USNRC 2001a 10CFR20, Appendix B
	<sup>241</sup> Am	$2 \times 10^{-8}$ μCi/mL	
	<sup>242</sup> Am	$5 \times 10^{-5}$ μCi/mL	
	<sup>243</sup> Am	$2 \times 10^{-8}$ μCi/mL	
EPA	Drinking water		EPA 2000c
	Gross alpha activity, less U, Rn	15 pCi/L	
c. Food			
FDA	Derived intervention level <sup>a</sup> (DIL; Bq/kg food) for <sup>241</sup> Am in accidentally-contaminated human food	2.0	FDA 1998

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Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
c. Food			
	Sources of radiation used for inspection of food; sealed units producing radiation— <sup>241</sup> Am	10 Gy maximum allowed dose to food	FDA 2000 21CFR179.21
DOT	Activity values for radionuclides in transport <sup>241</sup> Am, <sup>242</sup> Am, and <sup>243</sup> Am		DOT 2001 40CFR173.435
	A <sub>1</sub>	5.41x10 <sup>1</sup> Ci	
	A <sub>2</sub>	5.41x10 <sup>-3</sup> Ci	
EPA	Annual possession quantities for environmental compliance <sup>241</sup> Am		EPA 2001a 40CFR61, Appendix E
	Gaseous form	2.3x10 <sup>-6</sup> Ci/year	
	Liquid/powder forms	2.3x10 <sup>-3</sup> Ci/year	
	Solid form	2.3x10 <sup>0</sup> Ci/year	
	<sup>242</sup> Am		
	Gaseous form	1.8x10 <sup>-2</sup> Ci/year	
	Liquid/powder forms	1.8x10 <sup>1</sup> Ci/year	
	Solid form	1.8x10 <sup>4</sup> Ci/year	
	<sup>243</sup> Am		
	Gaseous form	2.3x10 <sup>-6</sup> Ci/year	
	Liquid/powder forms	2.3x10 <sup>-3</sup> Ci/year	
	Solid form	2.3x10 <sup>0</sup> Ci/year	
	Radioactive waste—release limits for containment requirements <sup>b</sup> <sup>241</sup> Am or <sup>243</sup> Am	1x10 <sup>2</sup> Ci	EPA 2001b 40CFR191, Appendix A
	Reportable quantity <sup>241</sup> Am	1x10 <sup>-2</sup> Ci	EPA 2001c 40CFR302.4, Appendix B
	<sup>242</sup> Am	1x10 <sup>2</sup> Ci	
	<sup>243</sup> Am	1x10 <sup>-2</sup> Ci	
	Carcinogenicity—slope factors <sup>c</sup>		EPA 2002
	Ingestion—lifetime excess total cancer risk/pCi		
	Water		
	<sup>241</sup> Am	1.04x10 <sup>-10</sup>	
	<sup>243</sup> Am	1.03x10 <sup>-10</sup>	
	Food		
	<sup>241</sup> Am	1.34x10 <sup>-10</sup>	
	<sup>243</sup> Am	1.34x10 <sup>-10</sup>	
	Soil		
	<sup>241</sup> Am	2.17x10 <sup>-10</sup>	
	<sup>243</sup> Am	2.17x10 <sup>-10</sup>	
	Carcinogenicity—slope factors <sup>c</sup>		EPA 2002
	Inhalation—lifetime excess total cancer risk/pCi		
	<sup>241</sup> Am	2.81x10 <sup>-8</sup>	
	<sup>243</sup> Am	2.70x10 <sup>-8</sup>	
	External exposure—risk/year per pCi/g in soil		
	<sup>241</sup> Am	2.76x10 <sup>-8</sup>	
	<sup>243</sup> Am	9.47x10 <sup>-8</sup>	

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Agency	Description	Information	Reference
<u>NATIONAL</u> (cont.)			
USNRC	Activity values for radionuclides in transport <sup>241</sup> Am, <sup>242</sup> Am, and <sup>243</sup> Am		USNRC 2001b 10CFR71, Table A-1
	A <sub>1</sub>	5.41x10 <sup>1</sup> Ci	
	A <sub>2</sub>	5.41x10 <sup>-3</sup> Ci	
	Specific activity		
	<sup>241</sup> Am	3.4 Ci/g	
	<sup>242</sup> Am	1.0x10 <sup>1</sup> Ci/g	
	<sup>243</sup> Am	2.0x10 <sup>-1</sup> Ci/g	
	Byproduct material for <i>in vitro</i> clinical or laboratory testing— <sup>241</sup> Am	≤0.005 μCi	USNRC 2001c 10CFR31.11
	Calibration or reference sources; shall not possess at any one time, at any one location of storage or use of <sup>241</sup> Am	≤5 μCi	USNRC 2001d 10CFR31.8
	Exemption for low-level materials; contains only Americium in special form	Aggregate radioactivity ≤20 Ci	USNRC 2001e 10CFR71.10
	Export of byproduct material	≤1 Ci/shipment or ≤100 Ci/year	USNRC 2001f 10CFR110.23
	General applicability to domestic licensing of byproduct material; quantity of licensed material requiring labeling		USNRC 2001g 10CFR30, Appendix B
	<sup>241</sup> Am	1x10 <sup>-2</sup> μCi	
USNRC	Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of byproduct material; exempt quantities of <sup>241</sup> Am	0.05 μCi	USNRC 2001g 10CFR30.15(a)(9)
	Occupational values—oral ingestion (ALI)		USNRC 2001a 10CFR20, Appendix B
	<sup>241</sup> Am	8x10 <sup>-1</sup> μCi	
	<sup>242</sup> Am	4x10 <sup>3</sup> μCi	
	<sup>243</sup> Am	8x10 <sup>-1</sup> μCi	
	Quantity of radioactive material requiring need for an emergency plan for responding to a release— <sup>241</sup> Am, <sup>242</sup> Am, and <sup>243</sup> Am		USNRC 2001h 10CFR30.72, Schedule C
	Release fraction	0.001%	
	Quantity	2 Ci	
	Standards for protection against radiation—quantity of licensed material requiring labeling		USNRC 2001i 10CFR20, Appendix C
	<sup>241</sup> Am	1x10 <sup>-3</sup> μCi	
	<sup>242</sup> Am	1x10 <sup>1</sup> μCi	
	<sup>243</sup> Am	1x10 <sup>-3</sup> μCi	

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Agency	Description	Information	Reference
<u>STATE<sup>d</sup></u>			
a. Air			
Illinois	Concentrations in air above natural background		BNA 2001
	<sup>241</sup> Am	S 2x10 <sup>-13</sup> μCi/mL I 4x10 <sup>-12</sup> μCi/mL	
	<sup>242m</sup> Am	S 2x10 <sup>-13</sup> μCi/mL I 9x10 <sup>-12</sup> μCi/mL	
	<sup>242</sup> Am	S 1x10 <sup>-9</sup> μCi/mL I 2x10 <sup>-9</sup> μCi/mL	
	<sup>243</sup> Am	S 2x10 <sup>-13</sup> μCi/mL I 4x10 <sup>-12</sup> μCi/mL	
	<sup>244</sup> Am	S 1x10 <sup>-7</sup> μCi/mL I 8x10 <sup>-7</sup> μCi/mL	
New Jersey	Maximum permissible average concentrations in air Occupational (40-hour week)		BNA 2001
	<sup>241</sup> Am	S 6x10 <sup>-12</sup> μCi/mL I 1x10 <sup>-10</sup> μCi/mL	
	<sup>242m</sup> Am	S 6x10 <sup>-12</sup> μCi/mL I 3x10 <sup>-10</sup> μCi/mL	
	<sup>242</sup> Am	S 4x10 <sup>-8</sup> μCi/mL I 5x10 <sup>-8</sup> μCi/mL	
	<sup>243</sup> Am	S 6x10 <sup>-12</sup> μCi/mL I 1x10 <sup>-10</sup> μCi/mL	
	<sup>244</sup> Am	S 4x10 <sup>-6</sup> μCi/mL I 2x10 <sup>-5</sup> μCi/mL	
New Jersey	Maximum permissible average concentrations in air Non-occupational		BNA 2001
	<sup>241</sup> Am	S 2x10 <sup>-13</sup> μCi/mL I 4x10 <sup>-12</sup> μCi/mL	
	<sup>242m</sup> Am	S 2x10 <sup>-13</sup> μCi/mL I 9x10 <sup>-12</sup> μCi/mL	
	<sup>242</sup> Am	S 1x10 <sup>-9</sup> μCi/mL I 2x10 <sup>-9</sup> μCi/mL	
	<sup>243</sup> Am	S 2x10 <sup>-13</sup> μCi/mL I 4x10 <sup>-12</sup> μCi/mL	
	<sup>244</sup> Am	S 1x10 <sup>-7</sup> μCi/mL I 8x10 <sup>-7</sup> μCi/mL	
b. Water			
Colorado	Standards applicable to surface waters— <sup>241</sup> Am	15 pCi/L	BNA 2001
	Groundwater levels of radioactive materials shall not exceed this amount—Am	15 pCi/L	CO Dept of Public Health and Environ 1999

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Agency	Description	Information	Reference	
<u>STATE (cont.)</u>				
New Jersey	Maximum permissible average concentrations in water		BNA 2001	
	Occupational (40-hour week)			
	<sup>241</sup> Am	S 1x10 <sup>-4</sup> μCi/mL I 8x10 <sup>-4</sup> μCi/mL		
	<sup>242m</sup> Am	S 1x10 <sup>-4</sup> μCi/mL I 3x10 <sup>-3</sup> μCi/mL		
	<sup>242</sup> Am	S 4x10 <sup>-3</sup> μCi/mL I 4x10 <sup>-3</sup> μCi/mL		
	<sup>243</sup> Am	S 1x10 <sup>-4</sup> μCi/mL I 8x10 <sup>-4</sup> μCi/mL		
	<sup>244</sup> Am	S 1x10 <sup>-1</sup> μCi/mL I 1x10 <sup>-1</sup> μCi/mL		
	Maximum permissible average concentrations in water			BNA 2001
	Non-occupational			
	<sup>241</sup> Am	S 4x10 <sup>-6</sup> μCi/mL I 2x10 <sup>-5</sup> μCi/mL		
	<sup>242m</sup> Am	S 4x10 <sup>-6</sup> μCi/mL I 9x10 <sup>-5</sup> μCi/mL		
	<sup>242</sup> Am	S 1x10 <sup>-4</sup> μCi/mL I 1x10 <sup>-4</sup> μCi/mL		
	<sup>243</sup> Am	S 4x10 <sup>-6</sup> μCi/mL I 3x10 <sup>-5</sup> μCi/mL		
	<sup>244</sup> Am	S 5x10 <sup>-3</sup> μCi/mL I 5x10 <sup>-3</sup> μCi/mL		
c. Food		No data		
d. Other				
Arkansas	Determination of A <sub>1</sub> and A <sub>2</sub> quantities for transportation		BNA 2001	
	<sup>241</sup> Am			
	A1	8 Ci		
	A2	0.008 Ci		
	Specific activity	3.2 Ci/g		
<sup>243</sup> Am			BNA 2001	
A1	8 Ci			
A2	0.008 Ci			
Specific activity	1.9x10 <sup>-1</sup> Ci/g			
Standards for protection against radiation— <sup>241</sup> Am	0.01 μCi			
California	Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more source of radioactive material; <sup>241</sup> Am is considered an exempt quantity	<0.05 μCi	BNA 2001	
Colorado	Determination of A <sub>1</sub> and A <sub>2</sub> for transportation		BNA 2001	
	<sup>241</sup> Am, <sup>242m</sup> Am, and <sup>243</sup> Am			
	A1	54.1 Ci		
A2	5.41x10 <sup>-3</sup> Ci			

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**Table 8-1. Regulations and Guidelines Applicable to Americium**

Agency	Description	Information	Reference
<u>STATE (cont.)</u>			
Florida	Quantity of radioactive material requiring need for an emergency plan for responding to a release of <sup>241</sup> Am, <sup>242</sup> Am, and <sup>243</sup> Am		BNA 2001
	Release fraction	0.001%	
	Quantity	2 Ci	
Georgia	Packages transported between locations within the U.S. which contain only Am or Pu in special form with an aggregate radioactivity	Not to exceed 20 Ci	BNA 2001
Mississippi	Packages transported between locations within the U.S. which contain only Am or Pu in special form with an aggregate radioactivity	Not to exceed 20 Ci	BNA 2001

<sup>a</sup>The FDA-recommended Derived Intervention Level (DIL) for radionuclides of <sup>241</sup>Am, is defined as the DIL for the most sensitive age group (3 months) that was calculated from the most limiting Protective Action Goal (PAG; 50 mSv committed dose equivalent to the bone).

<sup>b</sup>Release limit per 1,000 metric tons of heavy metal (MTHM) or other unit of waste.

<sup>c</sup>Radionuclide slope factors are calculated by EPA's Office of Radiation and Indoor Air (ORIA) to assist HEAST users with risk-related evaluations and decision-making at various stages of the remediation process. 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/picocurie (pCi). 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 distributed uniformly in a thick layer of soil, and are expressed as risk/year per pCi/gram of soil.

<sup>d</sup>The states included in this section are only those that were available from the BNA database.

ACGIH = American Conference of Governmental Industrial Hygienists; ALI = annual limits on intake; BNA = Bureau of National Affairs; CFR = Code of Federal Regulations; DAC = derived air concentration; DIL = Derived Intervention Level; DOE = Department of Energy; DOT = Department of Transportation; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; I = insoluble; IARC = International Agency for Research on Cancer; mSv = millisievert; NIOSH = National Institute for Occupational Safety and Health; OSHA = Occupational Safety and Health Administration; PAG = protective action goal; PEL = permissible exposure limit; S = soluble; REL = recommended exposure limit; TLV = threshold limit value; TWA = time-weighted average; USNRC = U.S. Nuclear Regulatory Commission