

Change to NRC Section	Title	State Section	Compat. Category	Summary of Change to CFR	Comments
§32.72	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.	105 CMR 120.128(J)	B		
§32.74	Manufacture and distribution of sources or devices containing byproduct material for medical use	120.128(L)	B		
§35.75(a)	Release of individuals containing unsealed byproduct material or implants containing byproduct material	120.540	C		
§35.92	Decay-in-storage	120.543	H&S		
§35.190	Training for uptake, dilution, and excretion studies.	120.546	B		
§35.290	Training for imaging and localization studies.	120.551	B		

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§20.1003	Definition: Accelerator-produced radioactive material	105 CMR 120.005 (existing)	H&S	In § 20.1003, the definition of <i>Accelerator-produced radioactive material</i> , is added to read as follows: <i>Accelerator-produced radioactive material</i> means any material made radioactive by a particle accelerator.	
§20.1003	Definition: Byproduct Material	120.005 (new)	[H&S]***	In § 20.1003, the definition of <i>Byproduct material</i> is revised	
§20.1003	Definition: Discrete Source	120.005 (new)	H&S	In § 20.1003, the definition of <i>Discrete source</i> is	
§20.1003	Definition: Particle Accelerator	120.005	H&S	In § 20.1003, the definition of <i>Particle accelerator</i> is added	
§20.1003	Definition: Waste	120.005 (new)	B	In § 20.1003, the definition of <i>Waste</i> is added	
§20.1009	List of OMB approved information collections		D	N/A	
§20.2001 (a)(4)	General requirements	120.251(A)(4)	C	In § 20.2001, paragraph (a)(4) is revised to read as follows: a) * * *	

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				(4) As authorized under §§20.2002, 20.2003, 20.2004, 20.2005, or 20.2008.	
§20.2006 (e)	Transfer for disposal and manifests	120.256(B)	B	In § 20.2006, paragraph (e) is added	
§20.2008	Disposal of 11e.(3) and 11e.(4) byproduct material	120.258 (new)	B	Section 20.2008 is added	
Part 20 Appendix B	Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage	120.296: Appendix B –List of Elements; Appendix B Tables.	A	In Appendix B to part 20, the List of Elements table is amended by adding Nitrogen and Oxygen in alphabetical order, and page 1 of Tables 1, 2, and 3 following the List of Elements is revised to read as follows: See tables at the end of the document.	
§30.3(a)	Activities requiring license	120.101(A)	C	Section 30.3(a) is revised to read as follows: (a) Except as provided in paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section and for persons exempt as provided in this part and part 150 of this	

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				chapter, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued in accordance with the regulations in this chapter.	
§30.3(b)(1), (2), & (3)	Activities requiring license		NRC	<p>Section 30.3(b)(1), (2), & (3) is revised to read as follows:</p> <p>(b)(1) The requirements, including provisions that are specific to licensees, in this part and parts 19, 20, 21, and 71 of this chapter, as well as the additional requirements for specific broad scope, industrial radiography, irradiator, or well logging uses in 10 CFR parts 33, 34, 36, or 39, respectively, shall apply to Government agencies or Federally recognized Indian Tribes on November 30, 2007, when conducting activities under the authority provided by paragraphs (b)(2) and (b)(3) of this section.</p> <p>(2) A specifically licensed Government agency or Federally recognized Indian Tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a license amendment is required to authorize the activities in paragraph (a) of this section, may continue to use these materials for</p>	

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				<p>uses permitted under this part until the date of the NRC's final licensing determination, provided that the licensee submits an amendment application on or before June 2, 2008.</p> <p>(3) A Government agency or Federally recognized Indian Tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific license is required in paragraph (a) of this section, may continue to use such material for uses permitted under this part until the date of the NRC's final licensing determination provided that the agency or Indian Tribe submits an application for a license authorizing activities involving these materials on or before December 1, 2008.</p>	
§30.3(c) (1), (2), (3), & (d)	Activities requiring license		D	N/A	
§30.4	Definition: Accelerator produced radioactive material	120.005	H&S	In § 30.4, the definition of <i>Accelerator-produced radioactive material</i>, is added to read as follows:	
§30.4	Definition: Byproduct material	120.005	[H&S]*** H&S)	In § 30.4, the definition of <i>Byproduct material</i> is revised, to read as follows: <i>Byproduct material</i> means—	

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				(1) Any radioactive material (except	
§30.4	Definition: Consortium	120.005 (new)	C	In § 30.4, the definition of <i>Consortium</i>, is added to read as follows:	
§30.4	Definition: Cyclotron		D	N/A	
§30.4	Definition: Discrete Source	120.005 (new)	H&S	In § 30.4, the definition of <i>Discrete source</i>, is added to read as follows:	
§30.4	Definition: Particle accelerator	120.005 (see accelerator)	H&S	In § 30.4, the definition of <i>Particle accelerator</i> is	
§30.15 (a)(1)(viii)	Certain items containing byproduct material	120.104(C)(1)(a)8.	B	In § 30.15, paragraph (a)(1)(viii) is added to read as follows: (a) * * * (1) * * * (viii) 0.037 megabecquerel (1 microcurie) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.	
§30.18 (b)	Exempt quantities	120.104(B)	B	In § 30.18, paragraph (b) is revised to read as follows: (b) Any person, who possesses byproduct material received or acquired	

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				before September 25, 1971, under the general license then provided in § 31.4 of this chapter or similar general license of a State, is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 30 through 34, 36 and 39 of this chapter to the extent that this person possesses, uses, transfers, or owns byproduct material.	
§30.20(a)	Gas and aerosol detectors containing byproduct material	120.104(C)(3)	B	<p>In § 30.20, paragraph (a) is revised to read as follows:</p> <p>(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, and 30 through 36, and 39 of this chapter to the extent that the person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.26 of this chapter, which license authorizes the initial transfer of the product for use</p>	

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				under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a State under comparable provisions to § 32.26 of this chapter authorizing distribution to persons exempt from regulatory requirements.	
§30.32(g)	Application for specific licenses	120.124(G)	C	<p>In § 30.32, paragraphs (g)(1) and (g)(2) are revised and paragraphs (g)(3) are added to read as follows:</p> <p>(g) * * *</p> <p>(1) Identify the source or device by manufacturer and model number as registered with the Commission under § 32.210 of this chapter, with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to § 32.210 of this chapter; or</p> <p>(2) Contain the information identified in § 32.210(c) of this chapter; or</p> <p>(3) For sources or devices containing naturally occurring or accelerator produced radioactive material manufactured prior to November 30, 2007 that are not registered with the</p>	

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				Commission under § 32.210 of this chapter or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in §32.210(c) of this chapter, the applicant must provide: (i) All available information identified in § 32.210(c) of this chapter concerning the source, and, if applicable, the device; and (ii) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.	
§30.32(j)	Application for specific licenses	120.128(A) (new)	B	In § 30.32, paragraph (j) is added	
§30.34 (g)	Terms and conditions of licenses	120.131(H)	H&S*** (***)please note 10 CFR 30.34(g)	In § 30.34, paragraph (g) is revised to read as follows: (g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m	

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			Terms and Conditions of Licenses was changed from a Compatibility Category D to a Compatibility Category H&S)	generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with § 35.204 of this chapter. The licensee shall record the results of each test and retain each record for 3 years after the record is made.	
§30.34(j)	Terms and conditions of licenses	120.131(l) (new)	B	<p>In § 30.34, paragraph (j) is added to read as follows:</p> <p>(j)(1) Authorization under § 30.32(j) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.</p> <p>(2) Each licensee authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:</p> <p>(i) Satisfy the labeling requirements in § 32.72(a)(4) of this chapter for each PET radioactive drug transport radiation shield</p>	

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				<p>and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.</p> <p>(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in § 32.72(c) of this chapter.</p> <p>(3) A licensee that is a pharmacy authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:</p> <p>(i) an authorized nuclear pharmacist that meets the requirements in § 32.72(b)(2) of this chapter, or</p> <p>(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in § 35.27 of this chapter.</p> <p>(4) A pharmacy, authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an</p>	

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				authorized nuclear pharmacist, shall meet the requirements of § 32.72(b)(5) of this chapter.	
§30.71	Schedule B	120.196:.APPENDIX B (existing)	B	<p>Section 30.71 is amended by adding Cesium 129 (Cs 129), Cobalt 57 (Co 57), Gallium 67 (Ga 67), Germanium 68 (Ge 68), Gold 195 (Au 195), Indium 111 (In 111), Iodine 123 (I 123), Iron 52n (Fe 52), Potassium 43 (K 43), Rubidium 81 (Rb 81), Sodium 22 (Na 22), Yttrium 87 (Y 87), and Yttrium 88 (Y 88) in alphabetical order by element as follows:</p> <p>See table at end of document.</p>	No change.
§30.72	Schedule C – Quantities of radioactive material requiring consideration of the need for an emergency plan for responding to a release	120.196.APPENDIX B--TableIII	H&S	<p>Section 30.72 is amended by adding radium-226 in alphabetical order to read as follows:</p> <p>See table at end of document.</p>	
§31.4	List of OMB approved Information collections		D	N/A	

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§31.5 (b)(1) & (c)(13)	Certain detecting, measuring, gauging, or controlling devices and/or an ionizing atmosphere	120.122(D)(2)(a)2.; .122(m)1.	B	<p>In § 31.5, paragraphs (b)(1)(i), (b)(1)(ii), and (c)(13)(i) are revised and paragraph (b)(1)(iii) is added to read as follows:</p> <p>(b)(1) * * *</p> <p>(i) A specific license issued under § 32.51 of this chapter; or</p> <p>(ii) An equivalent specific license issued by an Agreement State; or</p> <p>(iii) An equivalent specific license issued by a State with provisions comparable to § 32.51 of this chapter.</p> <p>* * * * *</p> <p>(c) * * *</p> <p>(13)(i) Shall register, in accordance with paragraphs (c)(13)(ii) and (iii) of this section, devices containing at least 370 megabecquerels (10 millicuries) of cesium-137, 3.7 megabecquerels (0.1 millicurie) of strontium-90, 37 megabecquerels (1 millicurie) of cobalt-60, 3.7 megabecquerels (0.1 millicurie) of radium-226, or 37 megabecquerels (1 millicurie) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under paragraph (c)(13)(iii)(D) of this section, represents a separate general licensee and requires</p>	

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				a separate registration and fee.	
§31.8	Americium-241 in the form of calibration and reference sources		D	N/A	
§31.11	General license for use of byproduct material for certain in vivo clinical and laboratory testing		D	N/A	
§31.12	General license for certain items and self-luminous products containing radium-226	120.122(E)	C	<p>Sections 31.12, 31.13, and 31.14 are redesignated as § 31.21, § 31.22, and § 31.23, respectively, §§31.13 through 31.20 are reserved, and a new § 31.12 is added to read as follows:</p> <p>(a) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of paragraphs (b), (c), and (d) of this section, radium-226 contained in the following products manufactured prior to November 30, 2007.</p> <p>(1) Antiquities originally intended for use by the general public. For the purposes of</p>	No change to Section 330.310.

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				<p>this paragraph, antiques mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.</p> <p>(2) Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.</p> <p>(3) Luminous items installed in air, marine, or land vehicles.</p> <p>(4) All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.</p> <p>(5) Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of this paragraph, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC.</p> <p>(b) Persons who acquire, receive, possess, use, or transfer byproduct</p>	

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				<p>material under the general license issued in paragraph (a) of this section are exempt from the provisions of 10 CFR parts 19, 20, and 21, and § 30.50 and 30.51 of this chapter, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this chapter.</p> <p>(c) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in paragraph (a) of this section:</p> <p>(1) Shall notify the NRC should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director of the Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 within 30 days.</p> <p>(2) Shall not abandon products containing radium-226. The product, and any radioactive material from the product,</p>	

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				<p>may only be disposed of according to § 20.2008 of this chapter or by transfer to a person authorized by a specific license to receive the radium- 226 in the product or as otherwise approved by the NRC.</p> <p>(3) Shall not export products containing radium-226 except in accordance with part 110 of this chapter.</p> <p>(4) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under part 30 of this chapter, or equivalent regulations of an Agreement State, or as otherwise approved by the NRC.</p> <p>(5) Shall respond to written requests from the NRC to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director of the Office of Federal and State Materials and Environmental</p>	

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				<p>Management Programs, by an appropriate method listed in § 30.6(a) of this chapter, a written justification for the request.</p> <p>(d) The general license in paragraph (a) of this section does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.</p>	
§32.1 (c)(1)	Purpose and scope		NRC	<p>In § 32.1, paragraph (c) is added to read as follows:</p> <p>(c)(1) The requirements in this part, including provisions that are specific to licensees, shall apply to Government agencies and Federally recognized Indian Tribes with respect to accelerator-produced radioactive material or discrete sources of radium- 226 on November 30, 2007 except that the agency or tribe may continue to manufacture or initially transfer items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing requirements of part 30 of this chapter, and to persons generally licensed under part 31 of this chapter, and radioactive drugs and sources and devices to</p>	

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				medical use licensees, until the date of the NRC's final licensing determination, provided that the agency or tribe submits a new license application for these activities on or before December 1, 2008 or an amendment application for these activities on or before June 2, 2008.	
§32.1 (c)(2)	Purpose and scope		D	N/A	
§32.57	Calibration or reference sources containing americium-241: Requirements for license to manufacture or initially transfer	120.128(F)	B	<p>In § 32.57, the heading and the introductory text are revised to read as follows:</p> <p>An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium- 226, for distribution to persons generally licensed under § 31.8 of this chapter, will be approved if:</p>	
§32.58	Same: labeling of devices	120.128(F)	B	<p>Section 32.58 is revised to read as follows:</p> <p>Each person licensed under § 32.57 shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the</p>	

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				<p>information called for in the following statement:</p> <p>The receipt, possession, use, and transfer of this source, Model , Serial No., are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label. CAUTION-RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE</p> <p>_____ (Name of manufacturer or initial transferor)</p>	
§32.59	Same: Leak testing of each source	120.128(F)	B	<p>Section 32.59 is revised to read as follows:</p> <p>Each person licensed under § 32.57 shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under § 31.8 of this chapter. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the</p>	

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				application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If this test discloses more than 0.185 kilobecquerel (0.005 microcurie) of radioactive material, the source shall be deemed to be leaking or losing americium-241 or radium-226 and shall not be transferred to a general licensee under § 31.8 of this chapter or equivalent regulations of an Agreement State.	
§32.71 (b)(8) & (c)(1)	Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license	120.128(H)	B	<p>In § 32.71, paragraph (b)(8) is added, and paragraph (c)(1) is revised to read as follows:</p> <p>(b) * * *</p> <p>(8) Cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) each.</p> <p>(c) * * *</p> <p>(1) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 0.37 megabecquerel (10 microcuries) of iodine-131, iodine-125, selenium-75, or carbon-14; 1.85 megabecquerels (50 microcuries) of hydrogen-3 (tritium); or 0.74 megabecquerel (20 microcuries) of</p>	

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				iron-59; or Mock Iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 0.185 kilobecquerel (0.005 microcurie) of americium-241 each; or cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries); and	
§32.72 (a)(2)(i), (iii), (iv), (v), & (b)	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs, containing byproduct material for certain in vitro clinical or laboratory testing under general license	120.128(J)	B	<p>In § 32.72, paragraphs (a)(2)(i), (a)(2)(iii), (a)(2)(iv), (b)(2)(ii), (b)(4), and (b)(5) are revised, and a new paragraph (a)(2)(v) is added to read as follows:</p> <p>(a) * * *</p> <p>(2) * * *</p> <p>(i) Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);</p> <p>* * * * *</p> <p>(iii) Licensed as a pharmacy by a State Board of Pharmacy;</p> <p>(iv) Operating as a nuclear pharmacy within a Federal medical institution; or</p> <p>(v) A Positron Emission Tomography (PET) drug production facility registered with a State agency.</p> <p>* * * * *</p> <p>(b) * * *</p>	

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				<p>(2) * * *</p> <p>(ii) This individual meets the requirements specified in § 35.55(b) and 35.59 of this chapter, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or</p> <p>* * * * *</p> <p>(4) May designate a pharmacist (as defined in § 35.2 of this chapter) as an authorized nuclear pharmacist if:</p> <p>(i) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and</p> <p>(ii) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.</p> <p>(5) Shall provide to the Commission:</p> <p>(i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in § 35.55(a) of this chapter with the written attestation signed by a preceptor as required by § 35.55(b)(2) of this chapter; or</p> <p>(ii) The Commission or Agreement State license, or</p>	

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				<p>(iii) Commission master materials licensee permit, or</p> <p>(iv) The permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or</p> <p>(v) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and</p> <p>(vi) A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to work as an authorized nuclear pharmacist.</p>	
§32.102	Schedule-C prototype tests for calibration or reference sources containing americium-241	120.128(F)	B	<p>In § 32.102, the heading and the introductory paragraph are revised to read as follows:</p> <p>An applicant for a license under § 32.57 shall, for any type of source which is designed to contain more than 0.185 kilobecquerel (0.005 microcurie)</p>	

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				of americium-241 or radium-226, conduct prototype tests, in the order listed, on each of five prototypes of the source, which contains more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, as follows:	
§33.100	Schedule A		D	N/A	
§35.2	Definition: Cyclotron		D	N/A	
§35.2	Definition: Positron Emission Tomography (PET) radionuclide production facility	120.005 (new)	H&S	<p>In § 35.2, new definition for <i>Positron Emission Tomography (PET) radionuclide production facility</i> is added to read as follows:</p> <p><i>Positron Emission Tomography (PET) radionuclide production facility</i> is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.</p>	
§35.10(a) & (g)	Implementation		D	N/A	
§35.11(a)	License required	120.506(A)	C	<p>In § 35.11, paragraph (a) is revised to read as follows:</p> <p>(a) A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in</p>	

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				accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) or (c) of this section.	
§35.11 (c)(1)	License required		NRC	<p>In § 35.11 paragraph (c) is added to read as follows:</p> <p>(c)(1) A Government agency or a Federally recognized Indian Tribe, that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required in paragraph (a) of this section, may continue to use such materials for medical uses until the date of the NRC's final licensing determination, provided that the person submits a medical use license application on or before December 1, 2008.</p>	
§35.11 (c)(2)	License required		D	N/A	
§35.13 (a)(1)	License amendments		NRC	<p>In § 35.13, paragraphs (a)(1) is revised to read as follows:</p> <p>(a) Before it receives, prepares, or uses byproduct material for a type of use that is permitted under this part, but is not authorized on the licensee's current</p>	

Change to NRC Section	Title	State Section	Compat. Category	Summary of Change to CFR	Comments
				license issued under this part; except that— (1) A Government agency or a Federally recognized Indian Tribe licensee who possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 may continue to use such material for medical uses permitted under this part until the date of the NRC's final licensing determination, provided that the licensee submits an amendment application on or before June 2, 2008.	
§35.13 (a)(2), (b)(5), (e),	License amendments		D	N/A	
§35.14 (a) & (b)(5)	Notifications		D	N/A	
§35.15 (f)	Exemptions regarding Type A specific licenses of broad scope		D	N/A	
§35.57 (a)(3) & (b)(3)	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user,		D	N/A	

Change to NRC Section	Title	State Section	Compat. Category	Summary of Change to CFR	Comments
	and nuclear pharmacist				
§35.63 (b)(2)(ii), (b)(2)(iii), & (c)(3)	Determination of dosages of unsealed byproduct material for medical use	120.534	H&S	<p>In § 35.63, paragraphs (b)(2)(ii) and (c)(3) are revised, and paragraph (b)(2)(iii) is added to read as follows:</p> <p>(b) * * *</p> <p>(2) * * *</p> <p>(ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or</p> <p>(iii) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements.</p> <p>(c) * * *</p> <p>(3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by:</p> <p>(i) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or</p> <p>(ii) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements.</p>	

Change to NRC Section	Title	State Section	Compat. Category	Summary of Change to CFR	Comments
§35.100 (a) & (b)	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required	120.544	H&S	<p>In § 35.100, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows:</p> <p>(a) Obtained from: (1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or (2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or</p> <p>(b) Excluding production of PET radionuclides, prepared by:</p>	
§35.200 (a) & (b)	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.	120.547	H&S	<p>In § 35.200, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows:</p> <p>(a) Obtained from: (1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or (2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or</p> <p>(b) Excluding production of PET radionuclides, prepared by:</p>	

Change to NRC Section	Title	State Section	Compat. Category	Summary of Change to CFR	Comments
§35.204 (a)	Permissible molybdenum-99 concentrations	120.548	H&S	<p>In § 35.204, the heading and paragraph (a) are revised to read as follows:</p> <p>(a) A licensee may not administer to humans a radiopharmaceutical that contains:</p> <p>(1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or</p> <p>(2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).</p>	
§35.204 (c) & (d)	Permissible molybdenum-99 concentrations		D	N/A	
§ 35.300 (a) & (b)	Use of unsealed byproduct material for which a written directive is	120.552	H&S	<p>In § 35.300, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows:</p> <p>(a) Obtained from:</p> <p>(1) A manufacturer or preparer</p>	

Change to NRC Section	Title	State Section	Compat. Category	Summary of Change to CFR	Comments
	required			<p>licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or</p> <p>(2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or</p> <p>(b) Excluding production of PET radionuclides, prepared by:</p>	
§35.2204	Records of molybdenum-99 concentrations		D	N/A	
§50.2	Definition: Byproduct Material		NRC	<p>In § 50.2, the definition of <i>Byproduct material</i> is revised to read as follows:</p> <p><i>Byproduct material</i> means—</p> <p>(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;</p> <p>(2)(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</p> <p>(ii) Any material that—</p>	

Change to NRC Section	Title	State Section	Compat. Category	Summary of Change to CFR	Comments
				<p>(A) Has been made radioactive by use of a particle accelerator; and</p> <p>(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</p> <p>(3) Any discrete source of naturally occurring radioactive material, other than source material, that—</p> <p>(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</p> <p>(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.</p>	
§61.2	Definition: Waste	120.005 (new)	B	<p>In § 61.2, the definition for <i>Waste</i> is revised to read as follows:</p> <p><i>Waste</i> means those low-level radioactive wastes containing source, special nuclear, or byproduct material that</p>	

Change to NRC Section	Title	State Section	Compat. Category	Summary of Change to CFR	Comments
				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 <i>Byproduct material</i> set forth in § 20.1003 of this chapter.	
§ 62.2	Definition: Low-Level radioactive waste		NRC	<p>In § 62.2, the definition for <i>Low-level radioactive waste (LLW)</i> is revised to read as follows:</p> <p><i>Low-level radioactive waste (LLW)</i> means radioactive material that—</p> <p>(1) Is not high-level radioactive waste, spent nuclear fuel, or byproduct material (as defined in paragraphs (2), (3), and (4) of the definition of <i>Byproduct Material</i> set forth in § 20.1003 of this chapter); and</p> <p>(2) The NRC, consistent with existing law and in accordance with paragraph (1) of this definition, classifies as low level radioactive waste.</p>	
§ 72.3	Definition: Byproduct Material		NRC	<p>In § 72.3, the definition for <i>Byproduct material</i> is revised to read as follows:</p> <p><i>Byproduct material</i> means—</p> <p>(1) Any radioactive material (except special nuclear material) yielded in, or</p>	

Change to NRC Section	Title	State Section	Compat. Category	Summary of Change to CFR	Comments
				<p>made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;</p> <p>(2)(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</p> <p>(ii) Any material that—</p> <p>(A) Has been made radioactive by use of a particle accelerator; and</p> <p>(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</p> <p>(3) Any discrete source of naturally occurring radioactive material, other than source material, that—</p> <p>(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</p> <p>(ii) Before, on, or after August 8, 2005, is</p>	

Change to NRC Section	Title	State Section	Compat. Category	Summary of Change to CFR	Comments
				extracted or converted after extraction for use in a commercial, medical, or research activity.	
§110.2	Definition: Accelerator produced radioactive material		NRC	<p>In § 110.2, definition of <i>Accelerator-produced radioactive material</i> is added to read as follows:</p> <p><i>Accelerator-produced radioactive material</i> means any material made radioactive by a particle accelerator.</p>	
§110.2	Definition: Discrete Source		NRC	<p>In § 110.2, definition of <i>Discrete source</i> is added to read as follows:</p> <p><i>Discrete source</i> 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.</p>	
§110.2	Definition: Particle accelerator		NRC	<p>In § 110.2, definition of <i>Particle accelerator</i> is added to read as follows:</p> <p><i>Particle accelerator</i> 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</p>	

Change to NRC Section	Title	State Section	Compat. Category	Summary of Change to CFR	Comments
				definition, "accelerator" is an equivalent term.	
§150.3	Definition: Byproduct material	120.005 (new)	H&S*** (***)please note 10 CFR 150.3 Definition of Byproduct Material was changed from a Compatibility Category A to a Compatibility Category H&S)	<p>In § 150.3, the definition of <i>Byproduct material</i> is revised to read as follows:</p> <p><i>Byproduct material</i> means—</p> <p>(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;</p> <p>(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;</p> <p>(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</p>	

Change to NRC Section	Title	State Section	Compat. Category	Summary of Change to CFR	Comments
				<p>(ii) Any material that—</p> <p>(A) Has been made radioactive by use of a particle accelerator; and</p> <p>(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</p> <p>(4) Any discrete source of naturally occurring radioactive material, other than source material, that—</p> <p>(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</p> <p>(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.</p>	
§150.3	Definition: Discrete source	120.005 (new)	H&S	<p>In § 150.3, the definition of <i>Discrete source</i> is added to read as follows:</p> <p><i>Discrete source</i> means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for</p>	

RATS 2007-3

Roadmap

2007-3-02

Change to NRC Section	Title	State Section	Compat. Category	Summary of Change to CFR	Comments
				commercial, medical, or research activities.	

Appendix B

List of Elements

Name	Atomic	
	Symbol	No.
*****	**	**
Nitrogen	N	7
*****	**	**
Oxygen	O	8
*****	**	**

Atomic No.	Radionuclide	Class	Table 1 Occupational Values			Table 2 Effluent Concentration		Table 3 Releases to Sewers
			Col 1	Col 2	Col 3	Col 1	Col. 2	Monthly Average Concentration (μCi/ml)
			Oral Ingestion	Inhalation		Air (μCi/ml)	Water (μCi/ml)	
				ALI (μCi)	ALI (μCi/ml)			
1	Hydrogen-3	Water, DAC includes skin absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
		Gas (HT or T ₂) Submersion ¹ Use above values as HT and T ₂ oxidize in air and in the body to HTO						
4	Beryllium-7	W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
		Y, oxides, halides, and nitrates	-	2E+4	8E-6	3E-8	-	-
4	Beryllium-10	W, see ⁷ Be	1E+3 LLI wall	2E+2	6E-8	2E-10	-	-
			(1E+3)	-	-	-	2E-5	2E-4
		Y, see ⁷ Be	-	1E+1	6E-9	2E-11	-	-
6	Carbon-11 ²	Monoxide	-	1E+6	5E-4	2E-6	-	-
		Dioxide	-	6E+5	3E-4	9E-7	-	-
		Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
6	Carbon-14	Monoxide	-	2E+6	7E-4	2E-6	-	-
		Dioxide	-	2E+5	9E-5	3E-7	-	-
		Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
7	Nitrogen-13 ²	Submersion ¹	-	-	4E-6	2E-8	-	-
8	Oxygen-15 ²	Submersion ¹	-	-	4E-6	2E-8	-	-
9	Fluorine-18 ²	D, fluorides of H, Li, Na, K, Rb, Cs, and Fr	5e+4 St wall	7E+4	3E-5	1E-7	-	-
			(5E+4)	-	-	-	7E-4	7E3
		W, fluondes of Be, Mg Ca, Sr, Ba, Ra, Al, Ga, In, Ti, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Nm, Tc, and Re	-	9e+4	4e-5	1e-7	-	-
		y, LANTHANUM FLUORIDE	-	8e+4	3e-5	1e-7	-	-
11	Sodium-22	D, all compounds	4E+2	6E+2	3E-7	9E-10	6E-6	6E-5
11	Sodium-24	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
12	Magnesium-28	D, all compounds except those given for W	7E+2	2E+3	7E-7	2E-9	9E-6	9E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	1E+3	5E-7	2E-9	-	-
13	Aluminum-26	D, all compounds except those given for W	4E+2	6E+1	3E-8	9E-11	6E-6	6E-5

1 “Submersion” means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.

2 These radionuclides have radiological half-lives of less than 2 hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class “Submersion,” are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do not include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute $1\text{E}-7 \mu\text{Ci/ml}$ for the listed DAC to account for the submersion dose prospectively, but should use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits. (See § 20.1203.)

* * * * *

30.71 Schedule B

Byproduct material	Microcuries

Cesium 129 (Cs 129)	100

Cobalt 57 (Co 57)	100

Gallium 67 (Ga 67)	100

Germanium 68 (Ge 68)	10

Gold 195 (Au 195)	10

Indium 111 (In 111)	100

Iodine 123 (I 123)	100

Iron 52 (Fe 52)	10

Potassium 43 (K 43)	10

Rubidium 81 (Rb 81)	10

Sodium 22 (Na 22)	10

Yttrium 87 (Y 87)	10
Yttrium 88 (Y 88)	10

30.72 Schedule C

Radioactive material 1 (curies)	Release fraction	Quantity
*	*	*
Radium-226	0.001	100
*	*	*

Change to NRC Section	Title	State Section	Compat. Category	Summary of Change to CFR	Comments
§35.50	Training for Radiation Safety Officer	120.524	B		
§35.51	Training for an authorized medical physicist	120.525	B		
§35.57	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.	120.528	B		
§35.190	Training for uptake, dilution, and excretion studies.	120.546	B		
§35.290	Training for imaging and localization studies.	120.551	B		
§35.390	Training for use of unsealed byproduct material for which a written directive is required	120.556	B		
§35.392	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).	120.557	B		

30.72 Schedule C