December 13, 2007

ALL AGREEMENT STATES, MICHIGAN, NEW JERSEY, PENNSYLVANIA, VIRGINIA

ACTION: REVISION OF THE CHRONOLOGY OF NRC AMENDMENTS INCLUDING THE SUMMARY OF CHANGE DOCUMENT FOR NRC AMENDMENTS, REQUIREMENTS FOR EXPANDED DEFINITION OF BYPRODUCT MATERIAL. [RATS ID 2007-3] (FSME-07-111)

Purpose: To Provide the Agreement States with the Chronology of the U.S. Nuclear Regulatory Commission (NRC) Amendments including the addition, RATS ID 2007-3, Requirements for Expanded Definition of Byproduct Material (effective date November 30, 2007) and the Summary of Change Document.

Contents: -Chronology of NRC Amendments -Summary of Change Document

Background: The NRC is amending its regulations in multiple sections in the Code of Federal Regulations (CFR) to include jurisdiction over discrete sources of radium-226, accelerator produced radioactive materials, and discrete sources of radioactive material as required by the Energy Policy Act (2005). The final rules are posted in the Federal Register, 72 FR 55864 and can be accessed through this website: <u>http://www.gpoaccess.gov/fr/index.html</u>. The chronology is enclosed in its entirety and includes RATS ID: 2007-3, as maintained by the Office of Federal and State Materials and Environmental Management Programs (FSME). The chronology is for your use to plan rulemaking actions that are needed to satisfy the compatibility and health and safety category designations of the NRC regulations. This document will also be used by the Integrated Materials Performance Evaluation Program teams during upcoming program reviews. In addition, a summary of change document for the November 30, 2007 amendments has been enclosed with this letter. The summaries are for your use to identify the changes to the CFR text as well as the compatibility categories associated with these changes. These regulations are due for adoption by the Agreement States no later than November 30, 2010.

NRC Point of Contact: If you have any questions regarding this correspondence, please contact me or the individual named below.

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Enclosures: As stated <u>Distribution</u>: DMSSA r/f DCD (SP03)

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DATE	12/10/07	12/10/07	12/11/07	12/13/07	12/13/07

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Chronology of NRC Amendments

NRC Chronology Identification	FR Notice Number (State Implementation Due Date)	RATS ID
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2
Standards for Protection Against Radiation-Part 20	56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183; (1/1/94)	1991-3
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35	57 FR 45566; (none)	1992-2
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628; (10/25/96)	1993-1
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618; (none)	1994-1
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards - Part 40	59 FR 28220; (7/1/97)	1994-2
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3
Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use- Parts 30, 32, 35	59 FR 61767; 59 FR 65243; 60 FR 322; (1/1/98)	1995-1
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983; (3/1/98)	1995-3
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5

NRC Chronology Identification	FR Notice Number (State Implementation Due Date)	RATS ID
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28724; (4/1/99)	1996-1
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70	61 FR 1109; (none)	1996-2
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65120; (1/9/00)	1997-1
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150	62 FR 1662; (2/27/00)	1997-2
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28947; (6/27/00)	1997-5
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea-Part 30	62 FR 63634; (1/02/01)	1997-7
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773; (2/12/01)	1998-1
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20	63 FR 39477; 63 FR 45393; (10/26/01)	1998-5
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6

NRC Chronology Identification	FR Notice Number (State Implementation Due Date)	RATS ID
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269; (none)	1999-2
Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524; (2/2/03)	1999-3
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1
Revision of the Skin Dose Limit-Part 20	67 FR 16298; (4/5/05)	2002-1
Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; (10/24/05)	2002-2
Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327; (12/3/06)	2003-1
Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71.	69 FR 3697; (10/01/07)	2004-1
Security Requirements for Portable Gauges Containing Byproduct Material - Part 30	70 FR 2001; (7/11/08)	2005-1
Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35	70 FR 16336; 71 FR 1926 (4/29/08)	2005-2
Minor Amendments -Parts 20, 30,32, 35, 40, 70	71 FR 15005 (03/27/09)	2006-1
National Source Tracking System - Serialization Requirements Part 32 (with reference to Part 20 Appendix E)	71 FR 65685 (02/06/07)	2006-2
National Source Tracking System Part 20	71 FR 65685 (01/31/09 Cat I and Cat II)	2006-3
Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35	72 FR 45147, 54207 (10/29/10)	2007-1

NRC Chronology Identification	FR Notice Number (State Implementation Due Date)	RATS ID
Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements – Parts 30. 31, 32, 150	72 FR 58473 (12/17/10)	2007-2
Requirements for Expanded Definition of Byproduct Material – Parts 20, 30, 31, 32, 33, 35, 61, 150	72 FR 55864 (11/30/10)	2007-3

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10												
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated						
§20.1003	Definition: Accelerator- produced radioactive material		H&S	In § 20.1003, the definition of Accelerator-produced radioactive material, is added to read as follows: Accelerator-produced radioactive material means any material made radioactive by a particle accelerator.									
§20.1003	Definition: Byproduct Material		[H&S]*** (***please note 10 CFR 20.1003 Definition of Byproduct Material was changed from a Compatibility Category A to a Compatibility Category H&S)	In § 20.1003, the definition of Byproduct material is revised to read as follows: Byproduct material means— (1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material; (2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material									

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10												
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated						
				 content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition; (3)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or (ii) Any material that— (A) Has been made radioactive by use of a particle accelerator; and (B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or (ii) Any material that— (A) Has been made radioactive by use of a particle accelerator; and (B) Is produced, extracted, or (A) Has been made radioactive by use for a commercial, medical, or (A) Has been made radioactive by use for a commercial, medical, or (A) Has been made radioactive by use for a commercial, medical, or (A) Hay discrete source of naturally occurring radioactive material, other than source material, that— 									

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10												
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated						
				 (i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and (ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity. 									
§20.1003	Definition: Discrete Source		H&S	In § 20.1003, the definition of <i>Discrete source</i> is added to read as follows:									
				<i>Discrete source</i> means a radionuclide that has been processed so that its									

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10											
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
				concentration within a material has been purposely increased for use for commercial, medical, or research activities.								
§20.1003	Definition: Particle Accelerator		H&S	In § 20.1003, the definition of Particle accelerator is added to read as follows: Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, "accelerator" is an equivalent term.								
§20.1003	Definition: Waste		В	In § 20.1003, the definition of Waste is added to read as follows: Waste means those low-level radioactive wastes containing source, special nuclear, or								

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10												
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated						
				byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in this section.									
§20.1009	List of OMB approved information collections		D	N/A	N/A								
§20.2001 (a)(4)	General requirements		С	In § 20.2001, paragraph (a)(4) is revised to read as follows: a) * * * (4) As authorized under §§20.2002, 20.2003, 20.2004, 20.2005, or 20.2008.									

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10												
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated						
§20.2006 (e)	Transfer for disposal and manifests		В	In § 20.2006, paragraph (e) is added to read as follows: (e) Any licensee shipping byproduct material as defined in paragraphs (3) and (4) of the definition of <i>Byproduct material</i> set forth in § 20.1003 intended for ultimate disposal at a land disposal facility licensed under part 61 of this chapter must document the information required on the NRC's Uniform Low- Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G to this part.									
§20.2008	Disposal of 11e.(3) and 11e.(4) byproduct material		В	Section 20.2008 is added to read as follows: (a) Licensed material as defined in paragraphs (3) and (4) of the definition of <i>Byproduct material</i> set forth in §20.1003 may be disposed									

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10												
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated						
				of in accordance with part 61 of this chapter, even though it is not defined as low level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under part 61 of this chapter, must meet the requirements of §20.2006. (b) A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of <i>Byproduct material</i> set forth in §20.1003, at a disposal facility authorized to dispose of such 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.									
Part 20 Appendix B	Annual Limits on Intake (ALIs) and Derived Air		A	In Appendix B to part 20, the List of Elements table is amended by adding Nitrogen									

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10											
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
	Concentration s (DACs) of Radionuclides for Occupational Exposure; Effluent Concentration s; Concentration s for Release to Sewerage			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		С	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 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.								

	Requireme	nts for Exp	(72 FR 55864)	of Byproduct Material 10 CFR Pa RATS ID # 2007-3 Effective date Due for State Adoption 11/30/10		31, 32, 33, 3	5, 61, and 150
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
§30.3(b) (1), (2), & (3)	Activities requiring license		NRC	 Section 30.3(b)(1), (2), & (3) is revised to read as follows: (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. (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, 			

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10										
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated				
				 may continue to use these materials for 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. (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. 							
§30.3(c)	Activities		D	N/A	N/A						
(1), (2),	requiring										

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10											
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
(3), & (d) §30.4	license Definition: Accelerator produced radioactive material		H&S	In § 30.4, the definition of Accelerator-produced radioactive material, is added to read as follows: Accelerator-produced radioactive material means any material made radioactive by a particle accelerator.								
§30.4	Definition: Byproduct material		[H&S]*** (***please note 10 CFR 30.4 Definition of Byproduct Material was changed from a Compatibility Category A to a Compatibility Category H&S)	In § 30.4, the definition of Byproduct material is revised, to read as follows: Byproduct material means— (1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material; (2)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after								

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10											
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
				August 8, 2005, for use for a commercial, medical, or research activity; or (ii) Any material that (A) Has been made radioactive by use of a particle accelerator; and (B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and (3) Any discrete source of naturally occurring radioactive material, other than source material, that— (i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and (ii) Before, on, or after August 8,								

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10											
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
				2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.								
§30.4	Definition: Consortium		С	In § 30.4, the definition of <i>Consortium</i> , is added to read as follows: <i>Consortium</i> means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.								

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10										
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated				
§30.4	Definition: Cyclotron		D	N/A	N/A						
§30.4	Definition: Discrete Source		H&S	In § 30.4, the definition of Discrete source, is added to read as follows: Discrete source means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.							
§30.4	Definition: Particle accelerator		H&S	In § 30.4, the definition of Particle accelerator is added to read as follows: Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at							

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10										
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated				
				energies usually in excess of 1 megaelectron volt. For purposes of this definition, accelerator is an equivalent term.							
§30.15 (a)(1)(viii)	Certain items containing byproduct material		В	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		В	In § 30.18, paragraph (b) is revised to read as follows: (b) Any person, who possesses byproduct material received or acquired 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							

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10											
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
				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		В	In § 30.20, paragraph (a) is revised to read as follows: (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,								

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10										
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated				
				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 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		С	In § 30.32, paragraphs (g)(1) and (g)(2) are revised and paragraphs (g)(3) are added to read as follows: (g) * * *							
				(1) Identify the source or device by manufacturer and model number as registered with the Commission under § 32.210 of this chapter,							

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				 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 (2) Contain the information identified in § 32.210(c) of this chapter; or (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 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, 								

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				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		В	 In § 30.32, paragraph (j) is added to read as follows: (j) An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium 								

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated			
				 authorized for medical use under part 35 of this chapter or equivalent Agreement State requirements shall include: (1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under part 30 of this chapter or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides. (2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in § 32.72(a)(2) of this chapter. (3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in § 32.72(b)(2) of this chapter. 						

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				(4) Information identified in § 32.72 (a)(3) of this chapter on the PET drugs to be noncommercially transferred to members of its consortium.							
§30.34 (g)	Terms and conditions of licenses		H&S*** (***please note 10 CFR 30.34(g) Terms and Conditions of Licenses was changed from a Compatibility Category D to a Compatibility Category H&S)	In § 30.34, paragraph (g) is revised to read as follows: (g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium- 99m 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							

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated			
				made.						
§30.34(j)	Terms and conditions of licenses		В	 In § 30.34, paragraph (j) is added to read as follows: (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. (2) Each licensee authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall: (i) Satisfy the labeling requirements in § 32.72(a)(4) of this chapter for each PET radioactive drug transport radiation 						

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				 shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium. (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. (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: (i) an authorized nuclear pharmacist that meets the requirements in § 32.72(b)(2) of 							

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated				
				 this chapter, or (ii) an individual under the supervision of an authorized nuclear pharmacist as specified in § 35.27 of this chapter. (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 authorized nuclear pharmacist, shall meet the requirements of § 32.72(b)(5) of this chapter. 							
§30.71	Schedule B		В	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							

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated				
				87), and Yttrium 88 (Y 88) in alphabetical order by element as follows: See table at end of document.							
§30.72	Schedule C – Quantities of radioactive material requiring consideration of the need for an emergency plan for responding to a release		H&S	Section 30.72 is amended by adding radium-226 in alphabetical order to read as follows: See table at end of document.							
§31.4	List of OMB approved Information collections		D	N/A	N/A						
§31.5 (b)(1) & (c)(13)	Certain detecting, measuring, gauging, or controlling devices		В	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: (b)(1) * * *							

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	and/or an ionizing atmosphere			 (i) A specific license issued under § 32.51 of this chapter; or (ii) An equivalent specific license issued by an Agreement State; or (iii) An equivalent specific license issued by a State with provisions comparable to § 32.51 of this chapter. 							
				(c) * * * (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							

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				paragraph (c)(13)(iii)(D) of this section, represents a separate general licensee and requires a separate registration and fee.							
§31.8	Americium- 241 in the form of calibration and reference sources		D	N/A	N/A						
§31.11	General license for use of byproduct material for certain in vivo clinical and laboratory testing		D	N/A	N/A						
§31.12	General license for certain items and self- luminous		С	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							

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated				
	products containing radium-226			 added to read as follows: (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. (1) Antiquities originally intended for use by the general public. For the purposes of this paragraph, antiquities 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. (2) Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in 							

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NRC Section	THE	Section	Category	Summary of Shange to Sh K	Yes/No	Yes/No	Not Was a Comment Generated				
				 timepieces. (3) Luminous items installed in air, marine, or land vehicles. (4) All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time. (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. (b) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in paragraph (a) of this section 							

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated			
				 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. (c) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in paragraph (a) of this section: (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 						

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
				 and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 within 30 days. (2) Shall not abandon products containing radium-226. The product, and any radioactive material from the product, 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. (3) Shall not export products containing radium-226 except in accordance with part 110 of this chapter. (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 								

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				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. (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 Management Programs, by an appropriate method listed in § 30.6(a) of this chapter, a written justification for the request.								

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
				(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.								
§32.1 (c)(1)	Purpose and scope		NRC	In § 32.1, paragraph (c) is added to read as follows: (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								

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
				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 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	N/A							
§32.57	Calibration or reference sources containing americium- 241: Poquiromonto		В	In § 32.57, the heading and the introductory text are revised to read as follows: An application for a specific license to manufacture or initially								
	Requirements for license to manufacture			transfer calibration or reference sources containing americium-241 or radium- 226, for distribution to								

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	or initially transfer			persons generally licensed under § 31.8 of this chapter, will be approved if:								
§32.58	Same: labeling of devices		В	Section 32.58 is revised to read as follows: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 information called for in the following statement: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								

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
				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 (Name of manufacturer or initial transferor)								
§32.59	Same: Leak testing of each source		В	Section 32.59 is revised to read as follows: 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 application of moderate finger								

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				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		В	In § 32.71, paragraph (b)(8) is added, and paragraph (c)(1) is revised to read as follows: (b) * * * (8) Cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) each. (c) * * *								

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
				(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 iron-59; or Mock lodine-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		В	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: (a) * * *								

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	byproduct material for certain in vitro clinical or laboratory testing under general license			 (2) * * * (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); ***** (iii) Licensed as a pharmacy by a State Board of Pharmacy; (iv) Operating as a nuclear pharmacy within a Federal medical institution; or (v) A Positron Emission Tomography (PET) drug production facility registered with a State agency. ***** (b) *** (2) *** (ii) This individual meets the requirements specified in § 35.55(b) and 35.59 of this chapter, 								

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
				identifying this individual as an authorized nuclear pharmacist; or								
				 (4) May designate a pharmacist (as defined in § 35.2 of this chapter) as an authorized nuclear pharmacist if: (i) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and (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. (5) Shall provide to the Commission: (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 								

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
				this chapter with the written attestation signed by a preceptor as required by § 35.55(b)(2) of this chapter; or (ii) The Commission or Agreement State license, or (iii) Commission master materials licensee permit, or (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 (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 (vi) A copy of the State pharmacy licensure or registration, no later than 30 days after the date that								

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated			
				the licensee allows, under paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to work as an authorized nuclear pharmacist.						
§32.102	Schedule-C prototype tests for calibration or reference sources containing americium- 241		В	In § 32.102, the heading and the introductory paragraph are revised to read as follows: 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) 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	N/A					
§35.2	Definition:		D	N/A	N/A					

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated				
	Cyclotron										
§35.2	Definition: Positron Emission Tomography (PET) radionuclide production facility		H&S	In § 35.2, new definition for Positron Emission Tomography (PET) radionuclide production facility is added to read as follows: Positron Emission Tomography (PET) radionuclide production facility is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.							
§35.10(a) & (g)	Implementatio n		D	N/A	N/A						
§35.11(a)	License required		С	In § 35.11, paragraph (a) is revised to read as follows: (a) A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the Commission							

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated				
				or an Agreement State, or as allowed in paragraph (b) or (c) of this section.							
§35.11 (c)(1)	License required		NRC	In § 35.11 paragraph (c) is added to read as follows: (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.							
§35.11 (c)(2)	License required		D	N/A	N/A						
§35.13	License		NRC	In § 35.13, paragraphs (a)(1) is							

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
(a)(1)	amendments			revised to read as follows:								
				 (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 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	N/A							
§35.14 (a) & (b)(5)	Notifications		D	N/A	N/A							
§35.15 (f)	Exemptions		D	N/A	N/A							

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated				
	regarding Type A specific licenses of broad scope										
§35.57 (a)(3) & (b)(3)	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist		D	N/A	N/A						
§35.63 (b)(2)(ii), (b)(2)(iii), & (c)(3)	Determination of dosages of unsealed byproduct material for medical use		H&S	In § 35.63, paragraphs (b)(2)(ii) and (c)(3) are revised, and paragraph (b)(2)(iii) is added to read as follows: (b) * * * (2) * * * (ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-							

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10											
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
				approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or (iii) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements. (c) * * * (3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by: (i) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or (ii) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements.								
§35.100 (a) & (b)	Use of unsealed byproduct material for uptake, dilution, and		H&S	In § 35.100, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows:								

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
	excretion studies for which a written directive is not required			 (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 (b) Excluding production of PET radionuclides, prepared by: 								
§35.200 (a) & (b)	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.		H&S	In § 35.200, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows: (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								

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
				(b) Excluding production of PET radionuclides, prepared by:								
§35.204 (a)	Permissible molybdenum- 99 concentration s		H&S	In § 35.204, the heading and paragraph (a) are revised to read as follows: (a) A licensee may not administer to humans a radiopharmaceutical that contains: (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 (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-85 per megabecquerel of rubidium-85 per megabecquerel of rubidium-85 per megabecquerel of rubidium-85 per megabecquerel								

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10										
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated				
				millicurie of rubidium-82).							
§35.204 (c) & (d)	Permissible molybdenum- 99 concentration s		D	N/A	N/A						
§ 35.300 (a) & (b)	Use of unsealed byproduct material for which a written directive is required		H&S	In § 35.300, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows: (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 (b) Excluding production of PET radionuclides, prepared by:							
§35.2204	Records of molybdenum-		D	N/A	N/A						

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10										
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated				
	99 concentration s										
§61.2	Definition: Waste		В	In § 61.2, the definition for <i>Wast</i> e is revised to read as follows:							
				<i>Waste</i> means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are							
				acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means							
				radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as							
				defined in paragraphs (2), (3), and (4) of the definition of <i>Byproduct</i> <i>material</i> set forth in § 20.1003 of this chapter.							
§150.3	Definition: Byproduct material		H&S*** (***please note 10 CFR 150.3	In § 150.3, the definition of <i>Byproduct material</i> is revised to read as follows:							

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
			Definition of Byproduct Material was changed from a Compatibility Category A to a Compatibility Category H&S)	 Byproduct material means— (1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material; (2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition; (3)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research 								

	Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) RATS ID # 2007-3 Effective date 11/30/07 Date Due for State Adoption 11/30/10											
Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated					
				activity; or (ii) Any material that— (A) Has been made radioactive by use of a particle accelerator; and (B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and (4) Any discrete source of naturally occurring radioactive material, other than source material, that— (i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and (ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a								

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated				
				commercial, medical, or research activity.							
§150.3	Definition: Discrete source		H&S	In § 150.3, the definition of <i>Discrete source</i> is added to read as follows:							
				Discrete source means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.							

<u>Appendix B</u>

List of Elements

Name	Atomic			
	Symbol	No.		
****	**	**		
Nitrogen	N	7		
****	**	**		
Oxygen	0	8		
****	**	**		

			Occup		Values	Table 2 Effluent Concentration		Table 3 Releases to Sewers	
			Col 1	Col 2	Col 3	Col 1	Col. 2		
			Oral Ingestion		halation			Monthly Average	
Atomic No.	Radionuclide	Class	ALI (µCı)	ALI (µCı/ml)	DAC (µCı/mł)	Aır (µCi/ml)	Water (µCi/ml)	Concentration (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, fluorides 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	

Footnotes

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 $1E-7 \ \mu Ci/ml$ 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
lodine 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) Yttrium 88 (Y 88)	

30.72 Schedule C

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