September 22, 2008

ALL AGREEMENT STATES, MICHIGAN, NEW JERSEY, VIRGINIA

ACTION: ADMINISTRATIVE CHANGES ISSUED FOR RATS ID 2007-3, REQUIREMENTS FOR EXPANDED DEFINITION OF BYPRODUCT MATERIAL AND REVISION OF THE CHRONOLOGY OF NRC AMENDMENTS INCLUDING THE SUMMARY OF CHANGE DOCUMENT (FSME-08-074)

Purpose: To provide the Agreement States with the revised Summary of Change Document for RATs ID 2007-3, Requirements for Expanded Definition of Byproduct Material (effective date November 30, 2007) and the revisions to the chronology of the U.S. Nuclear Regulatory Commission (NRC) Amendments and the Summary of Change Documents.

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

Background: These Administrative Changes were published on July 23, 2008. The NRC amended its regulations to correct miscellaneous errors contained in several final rules including the final rule, Requirements for Expanded Definition of Byproduct Material, published on October 1, 2007 (*Federal Register*, 72 FR 55864), RATs ID 2007-3. The revision to RATs ID 2007-3 is in 10 CFR 32.57. Initially the terms, “or radium-226", were added only to the introductory text of §32.57. This revision explains that the terms “or radium-226” should have been added to §32.57(b) (1), (b) (3), (b) (4), (c), (d), and (d) (1) after the term “americium-241”. This was an omission in the October 1, 2007 rulemaking. No other requirements related to the Requirements for Expanded Definition of Byproduct Material are being revised by this rule. The final rules are posted in the *Federal Register*, 73 FR 426710 and can be accessed through this website: http://www.gpoaccess.gov/fr/index.html.

The chronology is enclosed in its entirety, as maintained by the Office of Federal and State Materials and Environmental Management Programs. 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 revision of change document for RATs ID 2007-3 has been enclosed with this letter. This summary is for your use to identify the changes to the Code of Federal Regulations (CFR) text, as well as the compatibility categories associated with the changes. These regulations are due for adoption by the Agreement States no later than November 30, 2010.

FSME-08-074

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

POINT OF CONTACT: Kathleen Schneider
TELEPHONE: (301) 415-2320
INTERNET: kathleen.schneider@nrc.gov
FAX: (301) 415-3502

/RA/

Robert J. Lewis, Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Enclosures:
1. Chronology of NRC Amendments
2. Revised Summary of Change Document

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OFFICE	FSME/DMSSA	FSME/DMSSA	FSME/DMSSA
NAME	KSchneider: sxg6	DWhite	TReis (acting Director)
DATE	09/ 18 /08	09/ 18 /08	09/ 22 /08

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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

NRC Chronology Identification	FR Notice Number (State Implementation Due Date)	RATS ID
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
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

NRC Chronology Identification	FR Notice Number (State Implementation Due Date)	RATS ID
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
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

NRC Chronology Identification	FR Notice Number (State Implementation Due Date)	RATS ID
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
Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements Parts 30, 31, 32, and 150	72 FR 58473 (12/17/10)	2007-2
Requirements for Expanded Definition of Byproduct Material Parts - 20, 30, 31, 32, 33, 35,61, and 150	72 FR 55864, 73 FR 42672 (11/30/10)	2007-3
Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material (Order EA-07-305)	72 FR 70901 (06/05/08)	2007-4
Occupational Dose Records, Labeling Containers, and the Total Effective Dose Equivalent Parts – 19 and 20	72 FR 68043, 72233 (02/15/11)	2008-1

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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			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171 (72 FR 55864, 73 FR 42671) RATS ID # 2007-3 Effective date 11/30/07
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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 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 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			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171 (72 FR 55864, 73 FR 42671) RATS ID # 2007-3 Effective date 11/30/07
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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
				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 commercial, medical, or research activity. * * * *			
§20.1003	Definition: Discrete Source		H&S	**In § 20.1003, the definition of *Discrete source* is added to read as follows:**			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171 (72 FR 55864, 73 FR 42671) RATS ID # 2007-3 Effective date 11/30/07
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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
				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.			
§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		B	**In § 20.1003, the definition of *Waste* is added to read as follows:** *Waste* means those low-level radioactive wastes containing source,			

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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
				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 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		C	**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.			

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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
§20.2006 (e)	Transfer for disposal and manifests		B	**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 *Byproduct material* 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		B	**Section 20.2008 is added to read as follows:** (a) Licensed material as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171 (72 FR 55864, 73 FR 42671) RATS ID # 2007-3 Effective date 11/30/07
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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
				forth in §20.1003 may be disposed 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 *Byproduct material* 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	Annual Limits		A	**In Appendix B to part 20, the List**			

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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
Appendix B	on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage			**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		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 chapter, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171 (72 FR 55864, 73 FR 42671) RATS ID # 2007-3 Effective date 11/30/07
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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
				license issued in accordance with the regulations in this chapter.			
§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			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171 (72 FR 55864, 73 FR 42671) RATS ID # 2007-3 Effective date 11/30/07
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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
				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 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.			

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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
§30.3(c) (1), (2), (3), & (d)	Activities requiring license		D	N/A	N/A		
§30.4	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			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171 (72 FR 55864, 73 FR 42671) RATS ID # 2007-3 Effective date 11/30/07
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				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; 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			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171 (72 FR 55864, 73 FR 42671) RATS ID # 2007-3 Effective date 11/30/07
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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
				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.			
§30.4	Definition: Consortium		C	**In § 30.4, the definition of *Consortium,* is added to read as follows:** *Consortium* 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.			

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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
§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 energies usually in excess of 1 megaelectron volt. For purposes of			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171 (72 FR 55864, 73 FR 42671) RATS ID # 2007-3 Effective date 11/30/07
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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 definition, accelerator is an equivalent term.			
§30.15 (a)(1)(viii)	Certain items containing byproduct material		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		B	**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 in section 81 of the Act and from the regulations in parts			

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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
				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		B	**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, processed, produced, or initially transferred in accordance with a			

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				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		C	**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, with an Agreement State, or for a source or a device containing radium-226 or			

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				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, and, if applicable, the device; and (ii) Sufficient additional information to demonstrate that there is reasonable			

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				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		B	**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 authorized for medical use under part 35 of this chapter or equivalent Agreement State requirements shall include:			

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				(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. (4) Information identified in			

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				§ 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 made.			
§30.34(j)	Terms and		B	**In § 30.34, paragraph (j) is added to**			

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	conditions of licenses			**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 shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.			

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				(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 this chapter, or (ii) an individual under the supervision of an authorized nuclear pharmacist as specified in § 35.27 of this chapter.			

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				(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		B	**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:** See table at end of document.			

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§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 and/or an ionizing atmosphere		B	**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) * * * (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			

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				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 paragraph (c)(13)(iii)(D) of this section, represents a separate general licensee and requires a separate registration and fee.			

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§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 products containing radium-226		C	**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:** (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),			

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				(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 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.			

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				(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 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;			

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				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 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,			

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				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 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.			

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				(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. (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.			

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§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 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			

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				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 or radium- 226: Requirements for license to manufacture or initially transfer		B	**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 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: (a) The applicant satisfies the general requirements of § 30.33 of			

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				this chapter; (b) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including: (1) Chemical and physical form and maximum quantity of americium 241 or radium-226 in the source; (2) Details of construction and design; (3) Details of the method of incorporation and binding of the americium-241 or radium-226 in the source; (4) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that			

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				the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use; (5) Details of quality control procedures to be followed in manufacture of the source; (6) Description of labeling to be affixed to the source or the storage container for the source; (7) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source. (c) Each source will contain no more than 5 microcuries of americium-241 or radium-226. (d) The Commission determines, with respect to any type of source containing more than 0.005			

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				microcurie of americium-241 or radium-226, that: (1) The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and (2) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.102, Schedule C, of this part.			
§32.58	Same: labeling of devices		B	**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			

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				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 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)			

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§32.59	Same: Leak testing of each source		B	**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 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			

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				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		B	**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) * * * (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 Iodine-125 in units not			

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				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		B	**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) * * * (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			

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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
				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, and the licensee has received an approved license amendment 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			

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				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 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			

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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
				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 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		B	**In § 32.102, the heading and the introductory paragraph are revised to read as follows:**			

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	or reference sources containing americium-241			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: Cyclotron		D	N/A	N/A		
§35.2	Definition: Positron Emission Tomography (PET) radionuclide		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)*			

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	production facility			*radionuclide production facility* is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.			
§35.10(a)& (g)	Implementation		D	N/A	N/A		
§35.11(a)	License required		C	**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 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-			

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				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 (a)(1)	License amendments		NRC	**In § 35.13, paragraphs (a)(1) is 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			

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				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 regarding Type A specific licenses of broad scope		D	N/A	N/A		
§35.57 (a)(3) & (b)(3)	Training for experienced Radiation Safety Officer, teletherapy or medical		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
	physicist, authorized user, and nuclear pharmacist						
§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-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			

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				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 excretion studies for which a written directive is not required		H&S	**In § 35.100, 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			

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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
				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 (b) Excluding production of PET radionuclides, prepared by:			
§35.204 (a)	Permissible molybdenum-99 concentrations		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:			

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				(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-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).			
§35.204 (c) & (d)	Permissible molybdenum-99 concentrations		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			

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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
				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-99 concentrations		D	N/A	N/A		
§50.2	Definition: Byproduct Material		NRC	**In § 50.2, 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;			

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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
				(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 (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,			

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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
				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.			
§61.2	Definition: Waste		B	**In § 61.2, the definition for *Waste* is revised to read as follows:** *Waste* 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			

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				definition of *Byproduct material* set forth in § 20.1003 of this chapter.			
§ 62.2	Definition: Low- Level radioactive waste		NRC	**In § 62.2, the definition for *Low-level radioactive waste (LLW)* is revised to read as follows:** *Low-level radioactive waste (LLW)* means radioactive material that— (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 *Byproduct Material* set forth in § 20.1003 of this chapter); and (2) The NRC, consistent with existing law and in accordance with paragraph (1) of this definition, classifies as low level radioactive waste.			
§ 72.3	Definition: Byproduct Material		NRC	**In § 72.3, the definition for *Byproduct material* is revised to read as follows:** *Byproduct material* means— (1) Any radioactive material (except			

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				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 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			

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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
				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.			
§110.2	Definition: Accelerator produced radioactive material		NRC	**In § 110.2, 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.			
§110.2	Definition: Discrete Source		NRC	In § 110.2, definition of *Discrete source* is added to read as follows: *Discrete source* means a radionuclide that has been processed so that its			

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				concentration within a material has been purposely increased for use for commercial, medical, or research activities.			
§110.2	Definition: Particle accelerator		NRC	**In § 110.2, 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.			
§150.3	Definition: Byproduct material		H&S*** **(***please note 10 CFR 150.3 Definition of Byproduct Material**	**In § 150.3, the definition of *Byproduct material* is revised to read as follows:** *Byproduct material* means— (1) Any radioactive material (except			

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			was changed from a Compatibility Category A to a Compatibility Category H&S)	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 activity; or			

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				(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 commercial,			

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				medical, or research activity.			
§150.3	Definition: Discrete source		H&S	**In § 150.3, 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.			

Appendix B

List of Elements

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

			Table 1 Occupational Values			Table 2 Effluent Concentration		Table 3 Releases to Sewers
			Col 1	Col 2	Col 3	Col 1	Col. 2	
			Oral Ingestion	Inhalation				
Atomic No.	Radionuclide	Class	ALI (μCi)	ALI (μCi/ml)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average 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	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 μCi/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	Release fraction	Quantity (curies)
* * * * *		
Radium-226	0.001	100
* * * * *		

National Source Tracking System Part 20
(71 FR 65865; 72 FR 59162, October 19, 2007) RATS ID **2006-3** Effective: October 19, 2007
Date due for State adoption: January 31, 2009

NRC Section	Section Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If difference, why or why not comment generated
§20.1003	Definitions-Nationally tracked sources		B	**Added Definition:** Nationally tracked source means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix E of this Part. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.			

NRC Section	Section Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If difference, why or why not comment generated
§20.2207 (a)	Reports of transactions involving nationally tracked sources		B	**Added Section:** Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in paragraphs (a) through (e) of this section for each type of transaction. (a) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information: (1) The name, address, and license number of the reporting licensee; (2) The name of the individual preparing the report; (3) The manufacturer, model, and serial number of the source; (4) The radioactive material in the source; (5) The initial source strength in becquerels (curies) at the time of manufacture; and (6) The manufacture date of the source.			

NRC Section	Section Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If difference, why or why not comment generated
§20.2207 (b)	Reports of transactions involving nationally tracked sources		B	**Added Section:** (b) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information: (1) The name, address, and license number of the reporting licensee; (2) The name of the individual preparing the report; (3) The name and license number of the recipient facility and the shipping address; (4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source; (5) The radioactive material in the source; (6) The initial or current source strength in becquerels (curies); (7) The date for which the source strength is reported; (8) The shipping date; (9) The estimated arrival date; and (10) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source			

NRC Section	Section Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If difference, why or why not comment generated
§20.2207 (c)	Reports of transactions involving nationally tracked sources		B	(c) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information: (1) The name, address, and license number of the reporting licensee; (2) The name of the individual preparing the report; (3) The name, address, and license number of the person that provided the source; (4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source; (5) The radioactive material in the source; (6) The initial or current source strength in becquerels (curies); (7) The date for which the source strength is reported; (8) The date of receipt; and (9) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.			

NRC Section	Section Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If difference, why or why not comment generated
§20.2207 (d)	Reports of transactions involving nationally tracked sources		B	**Added Section:** (d) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information: (1) The name, address, and license number of the reporting licensee; (2) The name of the individual preparing the report; (3) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source; (4) The radioactive material in the source; (5) The initial or current source strength in becquerels (curies); (6) The date for which the source strength is reported; (7) The disassemble date of the source.			

NRC Section	Section Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If difference, why or why not comment generated
§20.2207 (e)	Reports of transactions involving nationally tracked sources		B	**Added Section:** (e) Each Licensee who disposes of nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information: (1) The name, address, and license number of the reporting licensee; (2) The name of the individual preparing the report; (3) The waste manifest number; (4) The container identification with the nationally tracked source; (5) The date of disposal; and (6) The method of disposal.			

NRC Section	Section Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If difference, why or why not comment generated
§20.2207 (f)	Reports of transactions involving nationally tracked sources		B	**Added Section:** (f) The reports discussed in paragraphs (a) through (e) of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using: (1) The on-line National Source Tracking System; (2) Electronically using a computer-readable format; (3) By facsimile; (4) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or (5) By telephone with followup by facsimile or mail.			

NRC Section	Section Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If difference, why or why not comment generated
§20.2207 (g)	Reports of transactions involving nationally tracked sources		B	**Added Section:** (g) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs (a) through (e) of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.			

NRC Section	Section Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If difference, why or why not comment generated
§20.2207 (h)	Reports of transactions involving nationally tracked sources		B	**Added Section:** (h) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tacked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified by paragraph (f)(1) through (f)(4) of this section. The initial inventory report must include the following information: (1) The name, address, and license number of the reporting licensee; (2) The name of the individual preparing the report; (3) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source; (4) The radioactive material in the sealed source; (5) The initial or current source strength in becquerels (curies); and (6) The date for which the source strength is reported.			

NRC Section	Section Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If difference, why or why not comment generated
§20 Appendix E	Nationally tracked sources threshold		B	**Added Appendix:** See table at end of document			

Appendix E Part 20-Nationally Tracked Source Thresholds

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1600	0.6	16
Americium-241/Be	60	1600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1400	0.5	14
Cesium-137	100	2700	1	27
Gadolinium-153	1000	27000	10	270
Iridium-192	80	2200	0.8	22
Plutonium-238	60	1600	0.6	16
Plutonium-239/Be	60	1600	0.6	16
Polonium-210	60	1600	0.6	16

Promethium-147	40000	1100000	400	11000
Radium-226	40	1100	0.4	11
Selenium-75	200	5400	2	54
Strontium-90	1000	27000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20000	540000	200	5400
Ytterbium-169	300	8100	3	81