



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

(FSME-07-099, October, Program, Chronology, Part 32, 35)
October 31, 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, "Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35" [RATS ID 2007-1] (FSME-07- 099)

Purpose: To Provide the Agreement States with the Chronology of the U.S. Nuclear Regulatory Commission (NRC) Amendments including the addition, RATS ID 2007-1 , Medical Use of Byproduct Material – Minor Corrections and Clarifications (effective date October 29, 2007) and the Summary of Change Document.

Contents:

- Chronology of NRC Amendments
- Summary of Change Document

Background: The NRC is amending its regulations to correct or clarify the rule language in two sections in the Code of Federal Regulations (CFR). The final rules are posted in the *Federal Register*, 72 FR 45147, 54207 and can be accessed through this website: <http://www.gpoaccess.gov/fr/index.html>. The chronology is enclosed in its entirety and includes final regulations adopted through October 3, 2007, 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 for the October 29, 2007 amendments has been enclosed with this letter. These summaries are for your use to identify the changes to the CFR text as well as the compatibility categories associated with the changes. The implementation date for Agreement States is October 29, 2010.

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

POINT OF CONTACT: Monica Orendi
TELEPHONE: (301) 415-3938

INTERNET: MLO1@NRC.GOV
FAX: (301) 415-3502

/RA/

Janet R. Schlueter, Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Enclosures:
As stated

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
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1

NRC Chronology Identification	FR Notice Number (State Implementation Due Date)	RATS ID
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 (11/15/07 Cat I and 11/30/07 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

**Medical Use of Byproduct Material - Minor Corrections and Clarifications 10 CFR Parts 32 and 35
 (72 FR 45147, 54207) RATS ID # 2007-1 Effective date 10/29/07
 Date Due for State Adoption 10/29/10**

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
§32.72 (b)(5)	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35.		B	<p>In Sec. 32.72, paragraph (b)(5) is revised to read as follows:</p> <p>(b) * * *</p> <p>(5) Shall provide to the Commission a copy of each individual's:</p> <p>(i)(A) Certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in Sec. 35.55(a) of this chapter with the written attestation signed by a preceptor as required by Sec. 35.55(b)(2) of this chapter; or</p> <p>(B) The Commission or Agreement State license; or</p> <p>(C) The permit issued by a licensee of broad scope;</p>			

**Medical Use of Byproduct Material - Minor Corrections and Clarifications 10 CFR Parts 32 and 35
 (72 FR 45147, 54207) RATS ID # 2007-1 Effective date 10/29/07
 Date Due for State Adoption 10/29/10**

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
				<p>and (ii) State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to work as an authorized nuclear pharmacist.</p>			
§32.74(a)	Manufacture and distribution of sources or devices containing byproduct material for medical use		B	<p>In Sec. 32.74, the introductory text of paragraph (a) is revised to read as follows:</p> <p>(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed under part 35 of this chapter for use as a</p>			

**Medical Use of Byproduct Material - Minor Corrections and Clarifications 10 CFR Parts 32 and 35
(72 FR 45147, 54207) RATS ID # 2007-1 Effective date 10/29/07
Date Due for State Adoption 10/29/10**

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
				calibration, transmission, or reference source or for the uses listed in Sec. Sec. 35.400, 35.500, 35.600, and 35.1000 of this chapter will be approved if: * * * * *			
§35.2	Definitions: Medium dose-rate remote afterloader		D	N/A	N/A		
§35.41(b)(4)	Procedures for administrations requiring a written directive			N/A	N/A		
§35.75(a)	Release of individuals containing unsealed byproduct material or implants containing byproduct	D C		In Sec. 35.75, the text of paragraph (a) is republished and footnote 1 is revised to read as follows: a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants			

**Medical Use of Byproduct Material - Minor Corrections and Clarifications 10 CFR Parts 32 and 35
 (72 FR 45147, 54207) RATS ID # 2007-1 Effective date 10/29/07
 Date Due for State Adoption 10/29/10**

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
	material			<p>containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).\1\ * * * * *</p> <p>\1\ The current revision of NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses" describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).</p>			
§35.92	Decay-in-storage is an: "H&S" for States authorizing this activity and "D"	H&S		<p>In Sec. 35.92, the introductory text of paragraph (a) is revised to read as follows:</p> <p>(a) A licensee may hold</p>			

**Medical Use of Byproduct Material - Minor Corrections and Clarifications 10 CFR Parts 32 and 35
(72 FR 45147, 54207) RATS ID # 2007-1 Effective date 10/29/07
Date Due for State Adoption 10/29/10**

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
	for States that do not authorize this activity			byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it-- * * * * *			
§35.190	Training for uptake, dilution, and excretion studies	B		In Sec. 35.190, paragraph (a)(1) is revised to read as follows: (a) * * * (1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(F) of this section; and * * * * *			
§35.290	Training for imaging and localization studies	B		10. In Sec. 35.290, paragraph (a)(1) is revised to read as follows: (a) * * * (1) Complete 700 hours of			

**Medical Use of Byproduct Material - Minor Corrections and Clarifications 10 CFR Parts 32 and 35
 (72 FR 45147, 54207) RATS ID # 2007-1 Effective date 10/29/07
 Date Due for State Adoption 10/29/10**

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
				training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(G) of this section; and * * * * *			