

September 3, 2009

ALL AGREEMENT STATES, MICHIGAN, NEW JERSEY

**REVISION OF THE CHRONOLOGY OF NUCLEAR REGULATORY COMMISSION (NRC) AMENDMENTS INCLUDING THE SUMMARY OF CHANGE DOCUMENT FOR MEDICAL USE OF BYPRODUCT MATERIAL—AUTHORIZED USER CLARIFICATION, PART 35. [RATS ID 2009-1] (FSME-09-077)**

**Purpose:** To provide the Agreement States with the Chronology of the U.S. Nuclear Regulatory Commission (NRC) Amendments including the addition, RATS ID 2009-1, Medical Use Of Byproduct Material—Authorized User Clarification, Part 35 (effective date September 28, 2009) and the Summary of Change Document.

**Background:** The NRC is amending its regulations to clarify that individuals who do not need to comply with the training and experience requirements as described in the applicable regulations for the medical use of byproduct material (i.e., are “grandfathered”) may serve as preceptors and work experience supervisors for individuals seeking recognition on NRC licenses for the same medical uses of byproduct material.

**Discussion:** The final rules are posted in the *Federal Register*, 74 FR 33901, the effective date confirmed in 74 FR 43619, and can be accessed through this website: <http://www.gpoaccess.gov/fr/index.html>. The chronology is enclosed in its entirety and includes RATS ID: 2009-1, 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 summary of change for the September 28, 2009 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. These regulations are due for adoption by the Agreement States no later than September 28, 2012.

If you have any questions regarding this correspondence, please contact me or the individual named below.

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Enclosures:

1. Chronology of NRC Amendments
2. Summary of Change Document

### 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

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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
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic	63 FR 37059; (7/9/01)	1998-4

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Operations-Part 34		
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
Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090)	70 FR 72128 (12/01/2005)	2005-3
Minor Amendments -Parts 20, 30,32, 35, 40, 70	71 FR 15005 (03/27/09)	2006-1

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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
Medical Use of Byproduct Material—Authorized User Clarification, Part 35	74 FR 33901 (09/28/12)	2009-1

**Medical Use of Byproduct Material—Authorized User Clarification, Part 35  
(74 FR 33901) RATS ID # 2009-1 Effective date 09/28/09  
Date Due for State Adoption 09/28/12**

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
§ 35.50	Training for Radiation Safety Officer		B	<p><b>In § 35.50, paragraph (a)(2)(ii)(B) is revised to read as follows:</b></p> <p>*****</p> <p>(a) ***</p> <p>(2) ***</p> <p>(ii) ***</p> <p>(B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.57, 35.290, or 35.390;</p>			
§ 35.51	Training for an authorized medical physicist.		B	<p><b>In § 35.51, paragraphs (a)(2)(ii) and (b)(2) are revised to read as follows:</b></p> <p>(a) ***</p> <p>(2) ***</p> <p>(ii) In clinical radiation</p>			

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				<p>facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in § 35.57, 35.490, or 35.690; and * * * * *</p> <p>(b) * * *</p> <p>(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (a)(2), or (b)(1) and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in §§ 35.51, 35.57, or equivalent Agreement State requirements for an</p>			

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				<p>authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and * * * * *</p>			
§ 35.57	<p>Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.</p>		B	<p><b>In § 35.57, a new paragraph (c) is added to read as follows:</b></p> <p>(c) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC licenses for the same uses for which these individuals are authorized.</p>			
§ 35.190	<p>Training for uptake, dilution, and excretion studies.</p>		B	<p><b>In § 35.190, the introductory text of paragraph (c)(1)(ii) and paragraph (c)(2) are revised to read as follows:</b></p> <p>(c)(1) * * * (ii) Work experience, under</p>			

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				<p>the supervision of an authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, 35.390, or equivalent Agreement State requirements, involving— * * * * *</p> <p>(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.</p>			
§ 35.290	Training for imaging and localization studies.		B	<p><b>In § 35.290, the introductory text of paragraph (c)(1)(ii) and paragraph (c)(2) are revised to read as follows:</b></p> <p>(c)(1) * * * (ii) Work experience, under</p>			

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				<p>the supervision of an authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, involving— * * * * *</p> <p>(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.</p>			
§ 35.390	Training for use of unsealed byproduct material for which a written directive is		B	<p><b>In § 35.390, the introductory text of paragraph (b)(1)(ii) and paragraph (b)(2) are revised to read as follows:</b></p> <p>(b)(1) * * *</p> <p>(ii) Work experience, under the supervision of an</p>			

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	required.			<p>authorized user who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must involve—</p> <p>* * * * *</p> <p>(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) and (b)(1)(ii)(G) or (b)(1) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State</p>			

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				requirements. The preceptor authorized user, who meets the requirements in § 35.390(b) must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status.			
§ 35.392	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).		B	<p><b>In § 35.392, the introductory text of paragraph (c)(2) and paragraph (c)(3) are revised to read as follows:</b></p> <p>(c) * * *</p> <p>(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b) must also have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(2). The work experience must involve—</p> <p>* * * * *</p> <p>(3) Has obtained written</p>			

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				<p>attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must also have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(2).</p>			
§ 35.394	Training for the oral administration of sodium iodide I-131 requiring a written		B	<p><b>In § 35.394, the introductory text of paragraph (c)(2) and paragraph (c)(3) are revised to read as follows:</b></p> <p>(c) * * *</p> <p>(2) Has work experience, under the supervision of an authorized user who meets</p>			

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	directive in quantities greater than 1.22 gigabecquerels (33 millicuries).			<p>the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). The work experience must involve—</p> <p>*****</p> <p>(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must also</p>			

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
				have experience in administering osages as specified in § 35.390(b)(1)(ii)(G)(2).			

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§ 35.396	Training for the parenteral administration of unsealed byproduct material requiring a written directive.		B	<p><b>In § 35.396, the introductory text of paragraph (d)(2) and paragraph (d)(3) are revised to read as follows:</b></p> <p>(d) * * *</p> <p>(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in § 35.390 must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4). The work experience must involve—</p> <p>* * * * *</p> <p>(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b) or (c) of this section, and</p>			

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§ 35.490	Training for use of manual brachytherapy sources.		B	<p><b>In § 35.490, the introductory text of paragraph (b)(1)(ii) and paragraphs (b)(2) and (b)(3) are revised to read as follows:</b></p> <p>(b)(1) * * *</p> <p>(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements at a medical institution, involving— * * * * *</p> <p>(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of</p>			

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				<p>Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and</p> <p>(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1), or paragraphs (b)(1) and (b)(2), of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.</p>			
§ 35.491	Training for ophthalmic use of strontium-90.		B	<p><b>In § 35.491, paragraph (b)(3) is revised to read as follows:</b></p> <p>(b) * * *</p>			

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				(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.490, 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.			
§ 35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.		B	<p><b>In § 35.690, the introductory text of paragraph (b)(1)(ii) and paragraphs (b)(2) and (b)(3) are revised to read as follows:</b></p> <p>(b)(1) * * *</p> <p>(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements at a medical institution, involving—</p> <p>* * * * *</p>			

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				<p>(2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and</p> <p>(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (a)(1) or paragraphs (b)(1) and (b)(2), and paragraph (c), of this section, and has achieved a level of</p>			

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				<p>competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and</p>			

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