

March 20, 2008

Steven Gavitt, CHP, Director  
Bureau of Environmental Radiation Protection  
New York State Health Department  
547 River Street  
Troy, NY 12180-2216

Dear Mr. Gavitt:

We have reviewed the New York legally binding requirements, license conditions for Updates Respiratory Protection and Controls to Restrict Internal Exposure-Restricted Areas, Gamma Stereotactic Radiosurgery Units, and High Dose Rate Remote Afterloader Units; variance from specific regulations for Carbon-14 Urea Capsules; and regulations for Transportation of Radioactive Materials received by our office on January 17, 2008. These requirements were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 30, 35, 71 and the requirements of the four amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with you on March 19, 2008.

As a result of our review, we have five comments that have been identified in the enclosure. Please note that we have limited our review to the legally binding requirements required for compatibility and/or health and safety. We have determined that if these requirements are revised, incorporating our comments and without other significant change, they would meet the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure [SA-200](#).

We request that when you revise your legally binding requirements to address our comments, a copy of the revised legally binding requirements be provided to us for review. As requested in FSME Procedure [SA-201](#), "Review of State Regulatory Requirements," please highlight the location of any changes made by New York, in response to our comments, and provide a copy to Division of Materials Safety and State Agreements, FSME.

The SRS Data Sheet summarizes our knowledge of the status of other New York regulations, as indicated. Please let us know if you note any inaccuracies, or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the FSME website: <http://www.hsrdr.gov/nrc/rulemaking.htm>.

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact Kathleen Schneider, State Regulation Review Coordinator at (301) 415-2320 (email: kxs@nrc.gov) or Monica Orendi at (301) 415-3938 (email: mlo1@nrc.gov).

Sincerely,

**\ RA by ADWhite \**

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

Enclosures:  
As stated

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact Kathleen Schneider, State Regulation Review Coordinator at (301) 415-2320 (email: kxs@nrc.gov) or Monica Orendi at (301) 415-3938 (email: mlo1@nrc.gov).

Sincerely,

**\ RA ADWhite \**

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

Enclosures:

As stated

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**COMPATIBILITY COMMENTS ON NEW YORK STATE HEALTH DEPARTMENT LEGALLY  
BINDING REQUIREMENTS**

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	License Condition	20.1003	1999-3	B	<p><b>Definition: Fit Test</b></p> <p>New York omits “or quantitatively” from its definition.</p> <p>New York needs to add the words “or quantitatively” to its definition for Fit test in order to meet the Compatibility Category B designation assigned to 10 CFR 20.1003 definition Fit test.</p>
2	N/A	20.1003	1999-3	B	<p><b>Definition: Hood</b></p> <p>New York omits the definition for “Hood” from its license condition.</p> <p>New York needs to add the definition for “Hood” to its license condition in order to meet the Compatibility Category B designation assigned to 10 CFR 20.1003 definition Hood.</p>
3	License Condition	20.1003	1999-3	B	<p><b>Definition: Qualitative Fit Test</b></p> <p>New York uses the words “pass/mail” instead of “pass fail” in its definition of Qualitative fit test.</p> <p>New York needs to change its license condition definition of Qualitative fit test to read “means a pass/fail fit test...” in order to meet the Compatibility Category B designation assigned to 10 CFR 20.1003 definition Qualitative fit test.</p>
4	License Condition	20.1705	1999-3	B	<p><b>Application for use of higher assigned protection factors</b></p> <p>New York references “...in excess of those specified in Appendix A to Part 16.” Since this is a license condition and New York is placing Appendix A in Table 1 attached to the license condition, New York should state “ in excess of those specified in attached</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>Table 1: Appendix A to Part 20.”</p> <p>New York needs to make the above reference change in order to meet the Compatibility Category B designation assigned to 10 CFR 20.1705.</p>
5	16.17	10 CFR 71	2004-1	NRC	<p><b>Transportation</b></p> <p>New York cites all of 10 CFR 71 by reference in Section 16.17. However in its regulations NY fails to omit those sections specifically designated Compatibility Category NRC (under NRC jurisdiction). NY has taken interim action by issuing a Policy/Procedure to its staff regarding which sections are the exclusive use of the NRC and are therefore not to be enforced. NY needs to add language to 16.17 specifically excluding 10 CFR 71.2, 71.6, 71.13(c) and (d), 71.14(b), 71.19, 71.101(c)(2) (d) and (e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125.</p> <p>New York needs to add language to 16.17 specifically excluding the above sections in order to meet the Compatibility Category NRC designations assigned in 10 CFR 71.</p>

## STATE REGULATION STATUS

State: New York State Health Department

Tracking Ticket Number: 8-7

[4 Amendment(s) reviewed is identified by a ★

Date: March 20, 2008

at the beginning of the equivalent NRC requirement.]

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1991-1	Safety Requirements for Radiographic Equipment Part 34 55 FR 843 <b>(Superceded by 1997-5)</b>	01/10/1994			NYSHD has not yet adopted Final Regulations equivalent to RATS ID: 1997-5.
1991-2	ASNT Certification of Radiographers Part 34 56 FR 11504 <b>(Superceded by 1997-5)</b>	none	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1991-3	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;	01/01/1994			
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980;	10/15/1994			
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 <b>(Superceded by 2002-2)</b>	01/27/1995			NYSHD has not yet adopted Final Regulations equivalent to RATS ID: 2002-2.
1992-2	Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions Parts 30, 35 57 FR 45566	none	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1993-1	Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites] Parts 30, 40 58 FR 39628	10/25/1996			
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996			

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996			
1994-1	Self-Guarantee as an Additional Financial Mechanism Parts 30, 40, 70 58 FR 68726; 59 FR 1618	none	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1994-2	Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards Part 40 59 FR 28220	07/01/1997	Not Applicable	Not Applicable	NYSHD does not have authority to regulate this material under its portion of the Agreement.
1994-3	Timeliness in Decommissioning Material Facilities Parts 30, 40, 70 59 FR 36026	08/15/1997			
1995-1	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	01/01/1998			
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment	03/13/1998			
1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20, 61 60 FR 15649; 60 FR 25983	03/01/1998	Not Applicable	Not Applicable	NYSHD does not have authority to regulate this material under its portion of the Agreement.
1995-4	Performance Requirements for Radiography Equipment Part 34 60 FR 28323 <b>(Superceded by 1997-5)</b>	06/30/1998			NYSHD has not yet adopted Final Regulations equivalent to RATS ID: 1997-5.
1995-5	Radiation Protection Requirements: Amended Definitions and Criteria Parts 19, 20 60 FR 36038	08/14/1998			
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235	11/24/1998			

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1995-7	Medical Administration of Radiation and Radioactive Materials Parts 20, 35 60 FR 48623 <b>(Superceded by 2002-2 and 2005-2)</b>	10/20/1998			
1996-1	Compatibility with the International Atomic Energy Agency Part 71 60 FR 50248; 61 FR 28724 <b>(Superceded by 2004-1)</b>	04/01/1999	Not Required	Not Required	New York has adopted Final Regulations equivalent to RATS ID: 2004-1.
1996-2	One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses Parts 30, 40, 70 61 FR 1109	02/15/1999	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1996-3	Termination or Transfer of Licensed Activities: Record keeping Requirements Parts 20, 30, 40, 61, 70 61 FR 24669	06/17/1999			
1997-1	Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120	01/9/2000	Not Applicable	Not Applicable	NYSHD does not have authority to regulate this material under its portion of the Agreement.
1997-2	Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State Part 150 62 FR 1662	02/27/2000			
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120	05/29/2000			
1997-4	Fissile Material Shipments and Exemptions Part 71 62 FR 5907 <b>(Superceded by 2004-1)</b>	02/10/2000	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-97-078)
1997-5	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations Parts 30, 34, 71, 150 62 FR 28947	06/27/2000			



RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000			
★1997-7	Exempt Distribution of a Radioactive Drug Containing One Micro curie of Carbon-14 Urea Part 30 62 FR 63634	01/02/2001	License Condition ML08017056 1	No Comments 03/20/2008 ML080800306	
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71, 150	02/12/2001			
1998-2	Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees Parts 30, 40, 70 63 FR 29535	07/01/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1998-3	License Term for Medical Use Licenses Part 35 63 FR 31604 <b>(Superceded by 2002-2)</b>	07/10/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-98-074)
1998-4	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059	07/09/2001			
1998-5	Minor Corrections, Clarifying Changes, and a Minor Policy Change Parts 20, 35, 36 63 FR 39477; 63 FR 45393	10/26/2001			
1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127	11/20/2001	Not Applicable	Not Applicable	NYSHD does not have authority to regulate this material under its portion of the Agreement.
1999-1	Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506	06/11/2002	Not Applicable	Not Applicable	NYSHD does not have authority to regulate this material under its portion of the Agreement.
1999-2	Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information	10/04/2002	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
	Part 31 64 FR 42269				
★1999-3	Respiratory Protection and Controls to Restrict Internal Exposure Part 20 64 FR 54543; 64 FR 55524	02/02/2003	License Condition ML08017056 1	Comments 03/20/2008 ML080800306	
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003			
2000-2	New Dosimetry Technology Parts 34, 36, 39 65 FR 63750	01/08/2004			
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material	02/16/2004			
2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005			
★2002-2	Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249	10/24/2005	License Conditions ML08017056 1	No Comments 03/20/2008 ML080800306	Part 35 with respect to gamma stereotactic radiosurgery and HDR only
2003-1	Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327	12/03/2006			
★2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007	Final ML08017561	Comments 03/20/2008 ML080800306	
2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008			
2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35	04/29/2008			
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-	12/01/2005	License Condition ML05312013	No Comments 11/10/2005 ML053180041	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70	03/27/2009			
2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	Not Applicable <sup>i</sup>	Not Applicable	NYSHD responded on 02/02/2007 to FSME-06-110 stating that they currently had no licensees applicable to this rule. ML070330060
2006-3	National Source Tracking System Part 20 71 FR 65865, 72 FR 59162	01/31/2009			
2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010			
2007-2	Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements Parts 30, 31, 32, 150 72 FR 58473	12/17/2010			
2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61, 150 72 FR 55864	11/30/2010			
2007-4	Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material NRC Order EA-07-305 72 FR 70901	06/05/2008			
2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20 72 FR 68043	02/15/2011			

<sup>i</sup> IMPEP Team: verify that Alabama does not have any licensees subject to these regulations during each review.