

September 15, 2010

Stephen M. Gavitt, CHP, Director  
Bureau of Environmental Radiation Protection  
New York State Department of Health  
547 River Street  
Troy, New York 12180

Dear Mr. Gavitt:

We have reviewed the proposed changes to the New York State Department of Health regulations, 16.113, 16.114, 16.2 and 16.103, received by our office on July 26, 2010. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 30, 40, 61, 70 and the requirements of the three amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Robert Dansereau on September 14, 2010.

As a result of our review, we have four comments that have been identified in the enclosure. Please note that we have limited our review to regulations required for compatibility and/or health and safety. Under our current procedure, a finding that the New York State regulations meet the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final New York State regulations. However, we have determined that if your proposed regulations were adopted, 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 the proposed regulations are adopted and published as final regulations, a copy of the "as published" regulations be provided to us for review. As requested in FSME Procedure [SA-201](#), "Review of State Regulatory Requirements," please highlight the final changes, 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://nrc-stp.ornl.gov/rulemaking.html>.

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 ([kathleen.schneider@nrc.gov](mailto:kathleen.schneider@nrc.gov)) or Antonio Dias at 301-415-6805 ([antonio.dias@nrc.gov](mailto:antonio.dias@nrc.gov)).

Sincerely,

***/RA A.D. White for/***

Terrence Reis, Deputy Director  
Division of Materials Safety and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

Enclosures: As stated

**[Concurrence Page]**

Enclosures: As stated

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**COMPATIBILITY COMMENTS ON *NEW YORK DEPARTMENT OF HEALTH (DOH)*  
PROPOSED REGULATIONS**

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	16.113(g)	20.1401(d)	1997-6	<p><b>General provisions and scope</b></p> <p>New York DOH has omitted the requirements of 20.1401(d). This requirement mandates that the peak annual TEDE be calculated for the first 1,000 years after termination of the license. This requirement is important in determining the potential exposure to members of the public.</p> <p>New York DOH needs to add this paragraph to 16.113(g) to meet the Compatibility Category C designation assigned to 10 CFR 20.1401.</p>
2	16.103(d)	20.1406	1997-6	<p><b>Minimization of contamination</b></p> <p>New York DOH has omitted the requirements of 20.1406. This requirement mandates the licensee describe how the facility design and procedures for operations will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.</p> <p>New York DOH needs to add this requirement to 16.103(d) to meet the Compatibility Category C designation assigned to 10 CFR 20.1406.</p>
3	16.114 (a) & (b)	40.36	2003-1	<p><b>Financial assurance and recordkeeping for decommissioning</b></p> <p>New York DOH uses “byproduct” material instead of “radioactive” material within this section. This creates a gap, since source material will not be included under these</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>requirements. New York DOH should change all references to “Byproduct Material” to “Radioactive Material.”</p> <p>Also, New York DOH omits an equivalent section to 10 CFR 40.36 which requires financial assurance and recordkeeping for decommissioning requirements for “...a specific license authorizing the possession and use of more than 100mCi of source material in a readily dispersible form ...” and for “...a specific license authorizing the possession and use of quantities of source material greater than 10mCi but less than or equal to 100mCi in a readily dispersible form...”.</p> <p>New York DOH needs to make the above changes to 16.114 and Table 16-A to meet the Compatibility Category H&amp;S designation assigned to 10 CFR 40.36.</p>
4	16.114	70.25	2003-1	H&S	<p><b>Financial assurance and recordkeeping for decommissioning</b></p> <p>NYDOH uses “byproduct” material instead of “radioactive” material within this section. This creates a gap, since special material will not be included under these requirements. NYDOH should change all references to “Byproduct Material” to “Radioactive Material.”</p>

**STATE REGULATION STATUS**

State: New York State Health Department

Tracking Ticket Number: 10-33

[3 amendment(s) reviewed is identified by a ★

Date: September 15, 2010

at the beginning of the equivalent NRC requirement.]

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
1991-1	Safety Requirements for Radiographic Equipment Part 34 55 FR 843 <b>(Superseded by 1997-5)</b>	01/10/1994	Final	No Comments	NYSHD has not yet adopted Final Regulations equivalent to RATS ID: 1997-5  Adopted by NYS DOL which has since merged with the NYS DOH ML092190342.
1991-2	ASNT Certification of Radiographers Part 34 56 FR 11504 <b>(Superseded 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	Final	Comments 12/24/1997	Adopted by NYS DOL which has since merged with the NYS DOH ML092190342.
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980;	10/15/1994	Final	No Comments 01/28/2000	Adopted by NYS DOL which has since merged with the NYS DOH ML092190342.
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 <b>(Superseded 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	Final	No Comments 01/28/2000	Adopted by NYS DOL which has since merged with the NYS DOH ML092190342.

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	Final	No Comments 01/28/2000	Adopted by NYS DOL which has since merged with the NYS DOH ML092190342.
1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Not Applicable	Not Applicable	NYSHD does not have authority to regulate this material under its portion of the Agreement. (NYDEC)
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	Final	No Comments 01/28/2000	Adopted by NYS DOL which has since merged with the NYS DOH ML092190342.
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	Final	No Comments 01/28/2000	Adopted by NYS DOL which has since merged with the NYS DOH ML092190342.
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment Part 20 60 FR 7900	03/13/1998	Final	No Comments 01/28/2000	Adopted by NYS DOL which has since merged with the NYS DOH ML092190342.
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>(Superseded by 1997-5)</b>	06/30/1998	Final	No Comments 01/28/2000	NYSHD has not yet adopted Final Regulations equivalent to RATS ID: 1997-5  Adopted by NYS DOL which has since merged with the NYS DOH

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
					ML092190342.
1995-5	Radiation Protection Requirements: Amended Definitions and Criteria Parts 19, 20 60 FR 36038	08/14/1998	Final	No Comments 01/28/2000	Adopted by NYS DOL which has since merged with the NYS DOH ML092190342.
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235	11/24/1998	Final	No Comments 01/28/2000	Adopted by NYS DOL which has since merged with the NYS DOH ML092190342.
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	Final	No Comments 01/28/2000	NYSHD has not yet adopted Final Regulations equivalent to RATS ID: 2004-1.  Adopted by NYS DOL which has since merged with the NYS DOH ML092190342.
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	Proposed ML102020009	No Comments 09/15/2010 ML102370215	
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	Final ML092260295  License Condition ML092260295	No Comments 09/08/2009 ML092310687  No Comments 09/08/2009 ML092310687	

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120	05/29/2000	Final ML100120050	Comments 03/08/2010 ML100330046	
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	Proposed ML100600746  License Condition ML100600746	Comments 05/06/2010 ML100890066  Comments 05/06/2010 ML100890066	NYSHD are not authorizing laybarga, underwater or offshore radiography in these regulations.
*1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000	Proposed ML102020009	Comments 09/15/2010 ML102370215	
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 ML080170561	No Comments 03/20/2008 ML080800306	
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71, 150 63 FR 1890; 63 FR 13773	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	Proposed ML100600746  License Condition ML100600746	Comments 05/06/2010 ML100890066  Comments 05/06/2010 ML100890066	NYSHD are not authorizing laybarga, underwater or offshore radiography in these regulations.



RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
1998-5	Minor Corrections, Clarifying Changes, and a Minor Policy Change Parts 20, 35, 36 63 FR 39477; 63 FR 45393	10/26/2001	Proposed ML101310506	Comments 07/07/2010 ML101580277	
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 Part 31 64 FR 42269	10/04/2002	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1999-3	Respiratory Protection and Controls to Restrict Internal Exposure Part 20 64 FR 54543; 64 FR 55524	02/02/2003	License Condition ML092260298	No Comments 09/03/2009 ML092320011	
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	License Condition ML100120053	No Comments 02/23/2010 ML100350697	
2000-2	New Dosimetry Technology Parts 34, 36, 39 65 FR 63750	01/08/2004	Final ML100050662	No Comments 03/08/2010 ML100321001	
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material Parts 30, 31, 32 65 FR 79162	02/16/2004	License Condition for 32.52 (a) & (b) only ML040770455	No Comments 04/02/2004 ML040930388	Adopted by NYS DOL which has since merged with the NYS DOH ML092190342.
2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Proposed ML101310506	No Comments 07/07/2010 ML101580277	

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
2002-2	Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249	10/24/2005	Proposed ML100600745  License Condition ML080170561	Comments 05/18/2010 ML100890015  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	Proposed ML102020009	Comments 09/15/2010 ML102370215	
2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007	Final ML092590171	Comments 10/23/2009 ML092710056	
2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	License Condition ML092590174	No Comments 10/07/2009 ML092710325	
2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35	04/29/2008	Proposed ML100600745	Comments 05/18/2010 ML100890015	
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC)	12/01/2005	License Condition ML053120138	No Comments 11/10/2005 ML053180041	
2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70 71 FR 15005	03/27/2009	Proposed ML100600745	Comments 05/18/2010 ML100890015	
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>1</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 65685, 72 FR 59162	01/31/2009	License Condition ML083240082	No Comments 12/11/2008 ML083390393	
2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010	Proposed ML100600745	Comments 05/18/2010 ML100890015	

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
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	Final ML091730154	Comments 08/04/2009 ML091820407	
2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20 72 FR 68043	02/15/2011			
2009-1	Medical Use of Byproduct Material – Authorized User Clarification Part 35 74 FR 33901	09/28/2012	Proposed ML100600745	Comments 05/18/2010 ML100890015	

<sup>1</sup> IMPEP Team: verify that New York does not have any licensees subject to these regulations during each review.