



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

February 8, 2016

Mr. Stephen M. Gavitt, Director
Bureau of Environmental Radiation Protection
New York State Department of Health
Empire State Plaza
Corning Tower, 12th Floor
Albany, NY 12237

Dear Mr. Gavitt:

We have reviewed the New York Department of Health legally binding requirements for the Physical Protection of Byproduct Material, received by our office on December 17, 2015. These requirements were reviewed by comparison to the equivalent U.S. Nuclear Regulatory Commission (NRC) rules and the requirements of the three amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the legally binding requirements with Robert Dansereau on February 5, 2016.

As a result of our review, we have two comments that have been identified in the enclosure. While we note that Comment No. 2 is not related to Part 37 requirements (i.e. 30.13), it is part of RATS ID 2013-1, and therefore has been included for completeness. 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 Nuclear Material Safety and Safeguards (NMSS) Procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements."

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 NMSS 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 Material Safety, State, Tribal, and Rulemaking Programs, NMSS.

The SRS Data Sheet summarizes our knowledge of the status of other New York Department of Health 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 NMSS State Communication Portal:

<https://scp.nrc.gov/rulemaking.html>.

Additionally, please note that NRC has previously issued certain security Orders to one New York DOH licensee. We have not listed the name of the licensee in this letter because that information is Official Use Only and cannot be made publicly available. Because the NRC-issued Orders are still legally binding, they must be rescinded by NRC concurrent with New York's promulgation of final regulations. Accordingly, close coordination is needed between NRC and your office to ensure there are no conflicts, duplications, or gaps regarding the security-related requirements for these licensees. Please contact Adelaide Giantelli, Branch Chief, Source Management and Protection Branch, NMSS (Adelaide.giantelli@nrc.gov) for information regarding the affected New York licensees and for coordination with rescission of the NRC-issued Orders and New York imposition of the legally binding requirement on this licensee.

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 Michelle Beardsley, State Regulation Review Coordinator, at (610) 337-6942 (Michelle.Beardsley@nrc.gov) or Donna Janda at (610) 337-5371 (Donna.Janda@nrc.gov).

Sincerely,

/RA Paul Michalak for/

Pamela J. Henderson, Deputy Director
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Enclosures:

1. Compatibility Comments
2. New York Department of Health SRS Data Sheet

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/RA Paul Michalak for/

Pamela J. Henderson, Deputy Director
Division of Material Safety, State, Tribal
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Office of Nuclear Material Safety
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DIR RF (16-29)
Donna Janda, RSAO
New York File

OFFICE	RI	ASPB	OGC	ASPB:BC	MSTR:DD
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DATE	12/30/15	12/30/15	2/5/16	2/8/16	2/8/16

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OFFICIAL RECORD COPY

Package ML15355A039

**COMPATIBILITY COMMENT ON NEW YORK DEPARTMENT OF HEALTH
LEGALLY BINDING REQUIREMENTS**

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	LC 2.(d)	Part 37	N/A	N/A	<p>General comment: Implementation date</p> <p>New York has set an implementation date of 9 months from the effective date of the amendment for licensees to meet the requirements in 10 CFR Part 37 and an implementation date of 90 days from the effective date of the amendment for reviewing officials to meet the requirements in 10 CFR 37.21(c).</p> <p>New York needs to set an implementation date of no later than March 19, 2016, in order to meet the effective date for the implementation of RATS ID 2013-1 as described in the NMSS letter STC-15-072, Effective Date for Implementation of Part 37 Requirements, dated September 11, 2015.</p>
2	10 NYCRR 16.1(b)(2)	30.13	2013-1	B	<p>Carriers</p> <p>New York omits “freight forwarders and warehousemen from 10 NYCRR 16.1(b)(2).</p> <p>New York needs to add freight forwarders and warehouseman to 10 NYCRR 16.1(b)(2) in order to meet the Compatibility Category B designation assigned to 10 CFR 30.13.</p>

STATE REGULATION STATUS

State: New York State Department of Health

Tracking Ticket Number: 16-29

Date: 02/08/2016

[3 amendment(s) reviewed identified by a *at the beginning of the equivalent NRC requirement.]

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1991-1	Safety Requirements for Radiographic Equipment Part 34 55 FR 843 (Superceded by 1997-5)	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 (Superceded by 1997-5)	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 and 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 (Superceded by 2002-2)	01/27/1995			
1992-2	Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions Parts 30 and 35 57 FR 45566	none	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 Letter	Outgoing Package	Notes
1993-1	Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites] Parts 30 and 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.
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 and 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 and 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 and 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.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
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 and 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 (Superceded by 1997-5)	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 ML092190342.
1995-5	Radiation Protection Requirements: Amended Definitions and Criteria Parts 19 and 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 and 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 and 35 60 FR 48623 (Superceded by 2002-2 and 2005-2)	10/20/1998			Only Part 20 provisions need to be adopted. See ML13197A356

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1996-1	Compatibility with the International Atomic Energy Agency Part 71 60 FR 50248; 61 FR 28724 (Superceded by 2004-1)	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 and 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 and 70 61 FR 24669	06/17/1999	License Condition ML14007A059	No Comments 02/20/2014 ML14007A056	
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	
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20 and 35 62 FR 4120	05/29/2000	Final ML100120050	Comments 03/08/2010 ML100330046	

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1997-4	Fissile Material Shipments and Exemptions Part 71 62 FR 5907 (Superceded by 2004-1)	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 and 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 laybarge, underwater or offshore radiography in these regulations.
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40 and 70 62 FR 39057	08/20/2000	License Condition ML14007A059	No Comments 02/20/2014 ML14007A056	
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 and 150 63 FR 1890; 63 FR 13773	02/12/2001	Legally Binding Requirements ML13121A233	Comments 06/19/2013 ML13150A207	
1998-2	Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees Parts 30, 40 and 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 (Superceded by 2002-2)	07/10/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-98-074)

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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 laybarge, underwater or offshore radiography in these regulations.
1998-5	Minor Corrections, Clarifying Changes, and a Minor Policy Change Parts 20, 32, 35, 36 and 39 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	

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2000-2	New Dosimetry Technology Parts 34, 36 and 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 and 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	
2002-2	Medical Use of Byproduct Material Parts 20, 32 and 35 67 FR 20249	10/24/2005	Proposed ML100600745 License Condition ML080170561 Final ML13150A109	Comments 05/18/2010 ML100890015 No Comments 03/20/2008 ML080800306 Comments 08/08/2013 ML13197A356	Part 35 with respect to gamma stereotactic radiosurgery and HDR only Part 35 only
2003-1	Financial Assurance for Materials Licensees Parts 30, 40 and 70 68 FR 57327	12/03/2006	License Condition ML14007A059	No Comments 02/20/2014 ML14007A056	
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	

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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 70 FR 16336; 71 FR 1926	04/29/2008	Final ML13150A107	No Comments 08/08/2013 ML13197A356	
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) 70 FR 72128	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 Final ML13150A107	Comments 05/18/2010 ML100890015 Comments 08/08/2013 ML13197A356	Part 35 only
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 ¹	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	

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2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010	Proposed ML100600745 Final ML13150A107	Comments 05/18/2010 ML100890015 No Comments 08/08/2013 ML13197A356	Part 35 only
2007-2	Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements Parts 30, 31, 32 and 150 72 FR 58473	12/17/2010			
2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61 and 150 72 FR 55864	11/30/2010	Final ML13150A107	No Comments 08/08/2013 ML13197A356	Part 35 only
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 and 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	Final ML13150A107	No Comments 08/08/2013 ML13197A356	
2011-1	Decommissioning Planning Parts 20, 30, 40 and 70 76 FR 35512	12/17/2015			

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2011-2	Licenses, Certifications, and Approvals for Materials Licensees Parts 30, 36, 39, 40, 70, and 150 76 FR 56951	11/14/2014			
2012-1	Change of Compatibility of 10 CFR 31.5 and 31.6 (See RATS ID: 2001-1 for Rule text) 77 FR 3640	01/25/2015			
2012-2	Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste Part 71 77 FR 34194	08/10/2015			
2012-3	Technical Corrections Part 30, 34, 40 and 71 77 FR 39899	08/06/2015			
2012-4	Requirements for Distribution of Byproduct Material Parts 30, 31, 32, 40 and 70 77 FR 43666	10/23/2015			
*2013-1	Physical Protection of Byproduct Material, 10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, and 71 78 FR 16922	03/19/2016	Proposed ML15355A046	Comment 02/08/16 ML15355A039	
2013-2	Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions, Parts 30, 40 and 70 78 FR 32310	08/27/2016			
2015-1	Domestic Licensing of Special Nuclear Material – Written Reports and Clarifying Amendments Part 70 79 FR 57721, 80 FR 143	01/26/2018			

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*2015-2	Safeguards Information - Modified Handling Categorization, Change for Materials Facilities Parts 30, 37, 73 and 150 79 FR 58664, 80 FR 3865	01/28/2018	Proposed ML15355A046	No Comments 02/08/16 ML15355A039	
2015-3	Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements Part 71 80 FR 33987	07/13/2018			
*2015-4	Miscellaneous Corrections, Parts 37 and 40 80 FR 45841	09/02/2018	Proposed ML15355A046	No Comments 02/08/16 ML15355A039	
2015-5	Miscellaneous Corrections, Parts 19, 20, 30, 32, 37, 40, 61, 70, 71, and 150 80 FR 74974	12/31/2018			

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