

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  | C        | <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  | C        | <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  | H&S      | <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 requirements. New York DOH should change all references to “Byproduct</p>  |

| STATE SECTION |        | NRC SECTION | RATS ID | CATEGORY | SUBJECT and COMMENTS  |
|---------------|--------|-------------|---------|----------|---|
|               |        |             |         |          | <p>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  
 [3 amendment(s) reviewed is identified by a ★  
 at the beginning of the equivalent NRC requirement.]

Tracking Ticket Number: 10-33  
 Date: September 15, 2010

| RATS ID | NRC Chronology Identification  | Date Due for State Adoption | Incoming Package | Outgoing Package          | Notes  |
|---------|--|-----------------------------|------------------|---------------------------|--|
| 1991-1  | Safety Requirements for Radiographic Equipment<br>Part 34<br>55 FR 843<br><b>(Superceded by 1997-5)</b>  | 01/10/1994                  | Final            | No Comments               | NYSHD has not yet adopted Final Regulations equivalent to RATS ID: 1997-5<br><br>Adopted by NYS DOL which has since merged with the NYS DOH ML092190342. |
| 1991-2  | ASNT Certification of Radiographers<br>Part 34<br>56 FR 11504<br><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<br>Part 20<br>56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877;<br>58 FR 67657; 59 FR 41641; 60 FR 20183; | 01/01/1994                  | Final            | Comments<br>12/24/1997    | Adopted by NYS DOL which has since merged with the NYS DOH ML092190342.  |
| 1991-4  | Notification of Incidents<br>Parts 20, 30, 31, 34, 39, 40, 70<br>56 FR 64980;  | 10/15/1994                  | Final            | No Comments<br>01/28/2000 | Adopted by NYS DOL which has since merged with the NYS DOH ML092190342.  |
| 1992-1  | Quality Management Program and Misadministrations<br>Part 35<br>56 FR 34104<br><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<br>Parts 30, 35<br>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]<br>Parts 30, 40<br>58 FR 39628       | 10/25/1996                  | Final            | No Comments<br>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 Package | Outgoing Package          | Notes   |
|---------|---|-----------------------------|------------------|---------------------------|---|
| 1993-2  | Licensing and Radiation Safety Requirements for Irradiators<br>Part 36<br>58 FR 7715  | 07/01/1996                  | Final            | No Comments<br>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<br>Part 61<br>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<br>Parts 30, 40, 70<br>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<br>Part 40<br>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<br>Parts 30, 40, 70<br>59 FR 36026  | 08/15/1997                  | Final            | No Comments<br>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<br>Parts 30, 32, 35<br>59 FR 61767; 59 FR 65243; 60 FR 322 | 01/01/1998                  | Final            | No Comments<br>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<br>Part 20<br>60 FR 7900  | 03/13/1998                  | Final            | No Comments<br>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<br>Parts 20, 61<br>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.         |

| RATS ID | NRC Chronology Identification  | Date Due for State Adoption | Incoming Package        | Outgoing Package                         | Notes   |
|---------|--|-----------------------------|-------------------------|--|---|
| 1995-4  | Performance Requirements for Radiography Equipment Part 34<br>60 FR 28323<br><b>(Superseded by 1997-5)</b>                               | 06/30/1998                  | Final                   | No Comments<br>01/28/2000                | NYSHD has not yet adopted Final Regulations equivalent to RATS ID: 1997-5<br><br>Adopted by NYS DOL which has since merged with the NYS DOH ML092190342.  |
| 1995-5  | Radiation Protection Requirements: Amended Definitions and Criteria<br>Parts 19, 20<br>60 FR 36038                                       | 08/14/1998                  | Final                   | No Comments<br>01/28/2000                | Adopted by NYS DOL which has since merged with the NYS DOH ML092190342.   |
| 1995-6  | Clarification of Decommissioning Funding Requirements<br>Parts 30, 40, 70<br>60 FR 38235   | 11/24/1998                  | Final                   | No Comments<br>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<br>Parts 20, 35<br>60 FR 48623<br><b>(Superseded by 2002-2 and 2005-2)</b> | 10/20/1998                  |                         |  |   |
| 1996-1  | Compatibility with the International Atomic Energy Agency Part 71<br>60 FR 50248; 61 FR 28724<br><b>(Superseded by 2004-1)</b>           | 04/01/1999                  | Final                   | No Comments<br>01/28/2000                | NYSHD has not yet adopted Final Regulations equivalent to RATS ID: 2004-1.<br><br>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<br>Parts 30, 40, 70<br>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<br>Parts 20, 30, 40, 61, 70<br>61 FR 24669                   | 06/17/1999                  | Proposed<br>ML102020009 | No Comments<br>09/15/2010<br>ML102370215 |   |

| RATS ID | NRC Chronology Identification   | Date Due for State Adoption | Incoming Package  | Outgoing Package   | Notes   |
|---------|---|-----------------------------|---|--|---|
| 1997-1  | Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act<br>Part 20<br>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<br>Part 150<br>62 FR 1662           | 02/27/2000                  | Final<br>ML092260295<br><br>License Condition<br>ML092260295    | No Comments<br>09/08/2009<br>ML092310687<br><br>No Comments<br>09/08/2009<br>ML092310687 |   |
| 1997-3  | Criteria for the Release of Individuals Administered Radioactive Material<br>Parts 20, 35<br>62 FR 4120   | 05/29/2000                  | Final<br>ML100120050  | Comments<br>03/08/2010<br>ML100330046  |   |
| 1997-4  | Fissile Material Shipments and Exemptions<br>Part 71<br>62 FR 5907<br><b>(Superseded 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<br>Parts 30, 34, 71, 150<br>62 FR 28947 | 06/27/2000                  | Proposed<br>ML100600746<br><br>License Condition<br>ML100600746 | Comments<br>05/06/2010<br>ML100890066<br><br>Comments<br>05/06/2010<br>ML100890066       | NYSHD are not authorizing laybarge, underwater or offshore radiography in these regulations.            |
| *1997-6 | Radiological Criteria for License Termination<br>Parts 20, 30, 40, 70<br>62 FR 39057  | 08/20/2000                  | Proposed<br>ML102020009   | Comments<br>09/15/2010<br>ML102370215  |   |
| 1997-7  | Exempt Distribution of a Radioactive Drug Containing One Micro curie of Carbon-14 Urea<br>Part 30<br>62 FR 63634                                    | 01/02/2001                  | License Condition<br>ML080170561                                | No Comments<br>03/20/2008<br>ML080800306   |   |
| 1998-1  | Deliberate Misconduct by Unlicensed Persons<br>Parts 30, 40, 61, 70, 71, 150<br>63 FR 1890; 63 FR 13773   | 02/12/2001                  |   |  |   |



| RATS ID | NRC Chronology Identification  | Date Due for State Adoption | Incoming Package  | Outgoing Package   | Notes   |
|---------|--|-----------------------------|---|--|---|
| 1998-2  | Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees<br>Parts 30, 40, 70<br>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<br>Part 35<br>63 FR 31604<br><b>(Superseded 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<br>Part 34<br>63 FR 37059                 | 07/09/2001                  | Proposed<br>ML100600746<br><br>License Condition<br>ML100600746 | Comments<br>05/06/2010<br>ML100890066<br><br>Comments<br>05/06/2010<br>ML100890066 | NYSHD are not authorizing laybarge, underwater or offshore radiography in these regulations.            |
| 1998-5  | Minor Corrections, Clarifying Changes, and a Minor Policy Change<br>Parts 20, 35, 36<br>63 FR 39477; 63 FR 45393                                       | 10/26/2001                  | Proposed<br>ML101310506   | Comments<br>07/07/2010<br>ML101580277  |   |
| 1998-6  | Transfer for Disposal and Manifests: Minor Technical Conforming Amendment<br>Part 20<br>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<br>Part 40<br>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<br>Part 31<br>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<br>Part 20<br>64 FR 54543; 64 FR 55524   | 02/02/2003                  | License Condition<br>ML092260298                                | No Comments<br>09/03/2009<br>ML092320011   |   |

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|---------|---|-----------------------------|---|---|--|
| 2000-1  | Energy Compensation Sources for Well Logging and Other Regulatory Clarifications<br>Part 39<br>65 FR 20337                      | 05/17/2003                  | License Condition<br>ML100120053                                | No Comments<br>02/23/2010<br>ML100350697  |  |
| 2000-2  | New Dosimetry Technology<br>Parts 34, 36, 39<br>65 FR 63750   | 01/08/2004                  | Final<br>ML100050662  | No Comments<br>03/08/2010<br>ML100321001  |  |
| 2001-1  | Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material<br>Parts 30, 31, 32<br>65 FR 79162 | 02/16/2004                  | License Condition for 32.52 (a) & (b) only<br>ML040770455       | No Comments<br>04/02/2004<br>ML040930388  | Adopted by NYS DOL which has since merged with the NYS DOH<br>ML092190342. |
| 2002-1  | Revision of the Skin Dose Limit<br>Part 20<br>67 FR 16298   | 04/05/2005                  | Proposed<br>ML101310506   | No Comments<br>07/07/2010<br>ML101580277  |  |
| 2002-2  | Medical Use of Byproduct Material<br>Parts 20, 32, 35<br>67 FR 20249  | 10/24/2005                  | Proposed<br>ML100600745<br><br>License Condition<br>ML080170561 | Comments<br>05/18/2010<br>ML100890015<br><br>No Comments<br>03/20/2008<br>ML080800306 | Part 35 with respect to gamma stereotactic radiosurgery and HDR only       |
| *2003-1 | Financial Assurance for Materials Licensees<br>Parts 30, 40, 70<br>68 FR 57327  | 12/03/2006                  | Proposed<br>ML102020009   | Comments<br>09/15/2010<br>ML102370215   |  |
| 2004-1  | Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments<br>Part 71<br>69 FR 3697     | 10/01/2007                  | Final<br>ML092590171  | Comments<br>10/23/2009<br>ML092710056   |  |
| 2005-1  | Security Requirements for Portable Gauges Containing Byproduct Material<br>Part 30<br>70 FR 2001                                | 07/11/2008                  | License Condition<br>ML092590174                                | No Comments<br>10/07/2009<br>ML092710325  |  |

| RATS ID | NRC Chronology Identification   | Date Due for State Adoption | Incoming Package                 | Outgoing Package                         | Notes   |
|---------|---|-----------------------------|----------------------------------|--|---|
| 2005-2  | Medical Use of Byproduct Material - Recognition of Specialty Boards<br>Part 35<br>70 FR 16336; 71 FR 1926   | 04/29/2008                  | Proposed<br>ML100600745          | Comments<br>05/18/2010<br>ML100890015    |   |
| 2005-3  | Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090)<br>70 FR 72128  | 12/01/2005                  | License Condition<br>ML053120138 | No Comments<br>11/10/2005<br>ML053180041 |   |
| 2006-1  | Minor Amendments<br>Parts 20, 30, 32, 35, 40 and 70<br>71 FR 15005  | 03/27/2009                  | Proposed<br>ML100600745          | Comments<br>05/18/2010<br>ML100890015    |   |
| 2006-2  | National Source Tracking System - Serialization Requirements<br>Part 32 with reference to Part 20 Appendix E<br>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.<br>ML070330060 |
| 2006-3  | National Source Tracking System<br>Part 20<br>71 FR 65685, 72 FR 59162  | 01/31/2009                  | License Condition<br>ML083240082 | No Comments<br>12/11/2008<br>ML083390393 |   |
| 2007-1  | Medical Use of Byproduct Material - Minor Corrections and Clarifications<br>Parts 32 and 35<br>72 FR 45147, 54207   | 10/29/2010                  | Proposed<br>ML100600745          | Comments<br>05/18/2010<br>ML100890015    |   |
| 2007-2  | Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements<br>Parts 30, 31, 32, 150<br>72 FR 58473 | 12/17/2010                  |                                  |  |   |
| 2007-3  | Requirements for Expanded Definition of Byproduct Material<br>Parts 20, 30, 31, 32, 33, 35, 61, 150<br>72 FR 55864  | 11/30/2010                  |                                  |  |   |

| RATS ID | NRC Chronology Identification  | Date Due for State Adoption | Incoming Package        | Outgoing Package                      | Notes |
|---------|--|-----------------------------|-------------------------|---------------------------------------|-------|
| 2007-4  | Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material<br>NRC Order EA-07-305<br>72 FR 70901 | 06/05/2008                  | Final<br>ML091730154    | Comments<br>08/04/2009<br>ML091820407 |       |
| 2008-1  | Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent<br>Parts 19, 20<br>72 FR 68043   | 02/15/2011                  |                         |                                       |       |
| 2009-1  | Medical Use of Byproduct Material – Authorized User Clarification<br>Part 35<br>74 FR 33901  | 09/28/2012                  | Proposed<br>ML100600745 | Comments<br>05/18/2010<br>ML100890015 |       |

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