

June 8, 2010

Gene Miskin, Director
Office of Radiological Health
New York City Department of Health
2 Lafayette Street, 11th Floor
New York, NY 10007

Dear Mr. Miskin:

We have reviewed the proposed changes to the New City Health Code, Article 175, received by our office on May 2, 2010. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 30, 32, 35, 40, 70, 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 Tobias Lickerman on June 8, 2010.

As a result of our review, we have 17 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 City 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 City 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 City 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) or Monica Orendi at (301) 415-3938 or (monica.orendi@nrc.gov).

Sincerely,

/RA/

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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ML101370076

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COMPATIBILITY COMMENTS ON NEW YORK CITY PROPOSED REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	175.02(a)(164)	20.1003	2002-2	A	<p>Definition: Public Dose</p> <p>NYC omits “or to radioactive material released by a licensee or to any other source of radiation under the control of the licensee” from its definition of public dose.</p> <p>NYC needs to add the above wording to its definition of public dose in order to meet the Compatibility Category A designation assigned to 10 CFR 20.1003 Definition Public Dose.</p>
2	175.02(a)(18)	35.2	2002-2 2006-1	B	<p>Definition: Authorized Medical Physicist</p> <p>NYC needs to remove “or, before October 24, 2005, meets the requirements in §§35.961(a), or (b), and 175.103(j)(15);” from 175.02(a)(18)(a).</p> <p>NYC needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition Authorized Medical Physicist.</p>
3	175.02(a)(20)	35.2	2002-2 2006-1	B	<p>Definition: Authorized User</p> <p>NYC lists the wrong reference in 175.02(a)(20)(i). NYC needs to remove “175.103(j)(15)(a)” and replace it with “175.103(j)(12)(a)”.</p> <p>NYC needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition Authorized User.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
4	175.103(a)(5)	35.11	2002-2	[C]	<p>License Required</p> <p>NYC needs to remove 175.103(a)(5)(c)(1) & (c)(2) from its regulations.</p> <p>NYC needs to make the above change in order to meet the Compatibility Category [C] designation assigned to 10 CFR 35.11.</p>
5	175.103(j)(1)	35.50	2002-2 2005-2 2006-1	B	<p>Training for a Radiation Safety Officer</p> <p>NYC lists two wrong references in 175.103(j)(1)(iii). NYC states "... for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in paragraphs (d) and (e) of this section; or". However this should be changed to read "... for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in paragraphs (iv) and (v) of this section; or".</p> <p>NYC needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 35.50.</p>
6	175.103(j)(2)	35.51	2002-2 2005-2 2006-1	B	<p>Training for an Authorized Medical Physicist</p> <p>NYC needs to add "NRC or" between "equivalent" and "Agreement" in 175.103(j)(2)(ii)(B).</p> <p>NYC needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 35.51.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
7	175.103(j)(14)	35.57	2002-2 2005-2	B	<p>Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist</p> <p>NYC needs to change the text of 175.103(j)(14)(c) to read “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 Department licenses for the same uses for which these individuals are authorized.”</p> <p>NYC needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 35.57.</p>
8	175.103(c)(2)	35.60	2002-2	H&S	<p>Possession, use, and calibration of instruments to measure the activity of unsealed byproduct material</p> <p>NYC lists a wrong reference. NYC needs to remove “175.103(3)(4)” from 175.103(c)(2)(a) and replace it with “175.103(c)(4)”.</p> <p>NYC needs to make the above change in order to meet the Compatibility Category H&S designation assigned to 10 CFR 35.60.</p>
9	175.103(j)(4)	35.190	2002-2 2005-2 2006-1 2007-1	B	<p>Training for uptake, dilution and excretion studies</p> <p>NYC needs to add “NRC or” between “equivalent” and “Agreement” in 175.103(j)(4)(b), (c)(1)(ii), and (c)(2).</p> <p>NYC needs to remove the reference to (c)(1) from 175.103(j)(4)(b).</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					NYC needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 35.190.
10	175.103(j)(5)	35.290	2002-2 2005-2 2006-1 2007-1	B	<p>Training for imaging and localization studies NYC needs to rewrite 175.103(j)(5)(c)(1)(ii) to state: “Work experience, under the supervision of an authorized user who meets the requirements in §§175.103(j)(14), 175.103(j)(5), or 175.103(j)(5)(c)(1)(ii)(G) and 175.103(j)(6) or equivalent Agreement State requirements, involving—”.</p> <p>NYC needs to add “NRC or” between “equivalent” and “Agreement” in 175.103(j)(5)(b), (c)(1)(ii), and (c)(2).</p> <p>NYC needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 35.290.</p>
11	175.103(j)(6)	35.390	2002-2 2005-2 2006-1	B	<p>Training for use of unsealed byproduct material for which a written directive is required</p> <p>NYC needs to add “NRC or” between “equivalent” and “Agreement” in 175.103(j)(6)(b)(1)(ii).</p> <p>NYC needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 35.390.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
12	175.103(j)(7)	35.392	2002-2 2005-2 2006-1	B	<p>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)</p> <p>NYC needs to add “NRC or” between “equivalent” and “Agreement” in 175.103(j)(7)(b), (c)(2), and (c)(3).</p> <p>NYC needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 35.392.</p>
13	175.103(j)(8)	35.394	2002-2 2005-2 2006-1	B	<p>Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries)</p> <p>NYC needs to add “NRC or” between “equivalent” and “Agreement” in 175.103(j)(8)(b), (c)(2), and (c)(3).</p> <p>NYC needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 35.394.</p>
14	175.103(j)(9)	35.396	2005-2 2006-1	B	<p>Training for the parenteral administration of unsealed byproduct material requiring a written directive.</p> <p>NYC needs to add “NRC or” between “equivalent” and “Agreement” in 175.103(j)(9)(a), (b), (d)(2), and (d)(3).</p> <p>NYC needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 35.396.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
15	175.103(j)(10)	35.490	2002-2 2005-2 2006-1	B	<p>Training for use of manual brachytherapy sources</p> <p>NYC needs to add “NRC or” between “equivalent” and “Agreement” in 175.103(j)(10)(b)(1)(ii), (b)(2), and (b)(3).</p> <p>NYC needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 35.490.</p>
16	175.103(j)(11)	35.491	2002-2 2005-2 2006-1	B	<p>Training for ophthalmic use of strontium-90</p> <p>NYC needs to add “NRC or” between “equivalent” and “Agreement” in 175.103(j)(11)(a) and (b)(3).</p> <p>NYC needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 35.491.</p>
17	175.103(j)(13)	35.690	2002-2 2005-2 2006-1	B	<p>Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units</p> <p>NYC needs to add “NRC or” between “equivalent” and “Agreement” in 175.103(j)(13)(b)(1)(ii), (b)(2) and (b)(3).</p> <p>NYC needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 35.690.</p>

STATE REGULATION STATUS

State: New York City Department of Health
 [4 amendment(s) reviewed is identified by a ★
 at the beginning of the equivalent NRC requirement.]

Tracking Ticket Number: 10-25
 Date: June 8, 2010

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 (Superceded by 1997-5)	01/10/1994	Not Applicable	Not Applicable	NYCDH does not have authority to regulate this material under its portion of the Agreement.
1991-2	ASNT Certification of Radiographers Part 34 56 FR 11504 (Superceded by 1997-5)	none	Not Required	Not Required	These regulations 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	No Comments 10/14/1997	
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 (Superceded by 2002-2)	01/27/1995			
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			

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	Not Applicable	Not Applicable	NYCDH does not have authority to regulate this material under its portion of the Agreement.
1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Not Applicable	Not Applicable	NYCDH does not have authority to regulate this material under its portion of the Agreement.
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	NYCDH 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 ML061290502	No Comments 06/12/2006 ML061630264	
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 Part 20 60 FR 7900	03/13/1998	Final ML061290502	No Comments 06/12/2006 ML061630264	
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	NYCDH 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 60 FR 28323 (Superceded by 1997-5)	06/30/1998	Not Applicable	Not Applicable	NYCDH does not have authority to regulate this material under its portion of the Agreement.
1995-5	Radiation Protection Requirements: Amended Definitions and Criteria Parts 19, 20 60 FR 36038	08/14/1998	Final ML070290581	No Comments 02/23/2007 ML070520527	
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235	11/24/1998	Final ML061290502	No Comments 06/12/2006 ML061630264	
1995-7	Medical Administration of Radiation and Radioactive Materials Parts 20, 35 60 FR 48623 (Superceded by 2002-2 and 2005-2)	10/20/1998			NYCDH has not yet adopted final regulations equivalent to RATS IDs: 2002-2 and 2005-2.
1996-1	Compatibility with the International Atomic Energy Agency Part 71 60 FR 50248; 61 FR 28724 (Superceded by 2004-1)	04/01/1999	Proposed	No Comments 02/09/1999	NYCDH has not yet 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	Final ML061290502	No Comments 06/12/2006 ML061630264	
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	NYCDH 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
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 ML070290581	No Comments 02/23/2007 ML 070520527	
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 (Superseded 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, 150 62 FR 28947	06/27/2000	Not Applicable	Not Applicable	NYCDH does not have authority to regulate this material under its portion of the Agreement.
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000	Final ML070290581	No Comments 02/23/2007 ML070520527	
1997-7	Exempt Distribution of a Radioactive Drug Containing One Micro curie of Carbon-14 Urea Part 30 62 FR 63634	01/02/2001	Not Applicable	Not Applicable	NYCDH does not have authority to regulate this material under its portion of the Agreement.
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71, 150 63 FR 1890; 63 FR 13773	02/12/2001	Final ML061290502	No Comments 06/12/2006 ML061630264	
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.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
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)
1998-4	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059	07/09/2001	Not Applicable	Not Applicable	NYCDH does not have authority to regulate this material under its portion of the Agreement.
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			
1999-1	Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506	06/11/2002	Not Applicable	Not Applicable	NYCDH 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	Final ML061290502	No Comments 06/01/2006 ML061530099	
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	Not Applicable	Not Applicable	NYCDH 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
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	Not Applicable	Not Applicable	NYCDH does not have authority to regulate this material under its portion of the Agreement.
2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Final ML061290502	No Comments 06/01/2006 ML061530099	
*2002-2	Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249	10/24/2005	Proposed ML101260366	Comments 06/08/2010 ML101370069	
2003-1	Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327	12/03/2006	Final ML092010319	No Comments 08/17/2009 ML092100446	
2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007	Final ML092010319	Comments 08/17/2009 ML092100446	
2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	Not Applicable	Not Applicable	NYCDH does not have authority to regulate this material under its portion of the Agreement.
*2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35 70 FR 16336; 71 FR 1926	04/29/2008	Proposed ML101260366	Comments 06/08/2010 ML101370069	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) 70 FR 72128	12/01/2005	License Condition ML052910113	No Comments 10/20/2005 ML052940009	
*2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70 71 FR 15005	03/27/2009	Proposed ML101260366	Comments 06/08/2010 ML101370069	
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	Not Applicable	NYCDH does not have authority to regulate this material under its portion of the Agreement.
2006-3	National Source Tracking System Part 20 71 FR 65685, 72 FR 59162	01/31/2009	License Condition ML090080848	No Comments 01/22/2009 ML090120617	
*2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010	Proposed ML101260366	Comments 06/08/2010 ML101370069	
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 ML092010319	No Comments 08/17/2009 ML092100446	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
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			