

May 18, 2010

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

Dear Mr. Gavitt:

We have reviewed the proposed changes to the New York State Department of Health regulations 10 NYCRR 16, received by our office on March 1, 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 five amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Robert Dansereau on May 17, 2010.

As a result of our review, we have 37 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 State 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 Michelle Beardsley at 610-337-6942 (michelle.beardsley@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

Distribution:

DIR RF (10-12)

DCD (SP05)

DJanda, RI

JKotton, RI

NY File

SUNSI Review Complete

Publicly Available

Non-Publicly Available

Non-Sensitive

Sensitive

ML of Incoming Document: ML100600745

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	ASPB	ASPB	OGC	ASPB:BC	MSSA:DD
NAME	MBeardsley / KNS	KSchneider	BJones	DWhite	TReis
DATE	04/12 /10	04/13/10	05/6 /10	05/18 /10	05/18/10

ML100890018

OFFICIAL RECORD COPY

Package ML100890015

COMPATIBILITY COMMENTS ON NEW YORK STATE PROPOSED REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	16.2 (78)	20.1003	2002-2	A	<p>Definitions: Occupational Dose</p> <p>New York (NY) proposed definition of “occupational dose” omits the phrase: ”from exposure to individuals administered radioactive materials and released according to Section 10 CFR 35.75”</p> <p>NY needs to add the above phrase to 10 NYCRR 16.2 (78) in order to meet the Compatibility Category A designation assigned to Section 10 CFR 20.1003 definition Occupational Dose.</p>
2	16.2 (89)	20.1003	2002-2	A	<p>Definitions: Public Dose</p> <p>NY’s proposed definition of “public dose” omit the following phrase: ”from exposure to individuals administered radioactive material and released under Section 10 CFR 35.75”.</p> <p>NY needs to add the above phrase to 10 NYCRR16.2 (89) in order to meet the Category A designation assigned to Section 10 CFR 20.1003 definition Public Dose.</p>
3	16.7	20.1301 (a) and (c)	2002-2	A	<p>Dose limits for individual members of the public</p> <p>In NYCCRR 16.7(a)(1)(ii), NY needs to delete the phrase “ and which results in a total effective dose equivalent to a member of the public which does not exceed 5 mSv (.5 rem) in a year”, which as written applies to all license activities and is not limited to members of the public under Part 35 as corresponds to Section 10 CFR 20.1301(c)(1).</p> <p>NY omits equivalent sections to Section 10 CFR 20.1301(c) from its regulations.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					NY needs to make the above changes to their regulation in the 10 NYCRR 16.7 in order to meet the Category A designation assigned to Section 10 CFR 1301(a) and (c).
4	38.35(j)	32.72	2002-2 2006-1 2007-1	B	<p>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35</p> <p>NY omits equivalent sections to 10 CFR 32.72(a)(2)(i), (a)(2)(iv), (a)(2)(v), (b), and (d).</p> <p>NY needs to add equivalent sections to those listed above to 18 NYCRR 38.35(j) in order to meet the Compatibility Category B designation assigned to Section 10 CFR 32.72.</p>
5	38.35 (i)	32.74	2002-2 2006-1 2007-1	B	<p>Manufacture and distribution of sources or devices containing byproduct material for medical use</p> <p>NY's proposed regulation omits the word "transmission" as stated in Section 10 CFR 32.74(a).</p> <p>NY also lists the wrong references in 18 NYCRR 38.35(i)(1)(iii). This paragraph should read "... to use radioactive material identified in section 35.65, 35.400, 35.500 and 35.600, as appropriate, of Part 35 of the Code of Federal Regulations ..."</p> <p>NY needs to make the above changes to their regulation in order to meet the Compatibility Category B designation assigned to Section 10 CFR 32.74.</p>
6	16.123 (a)(6)	35.2	2002-2	B	<p>Definition: Authorized Medical Physicist</p> <p>NY's proposed definition of authorized medical physicist states "...identified as a Radiation Therapy Physicist or ...". NY either needs to define Radiation Therapy Physicist or</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>change this to say "teletherapy physicist".</p> <p>NY omits the word "authorized" before medical physicist.</p> <p>NY omits equivalent sections to (2)(i)-(iv) in NRC's definition of authorized medical physicist.</p> <p>NY needs to make the above changes in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.2 definition Authorized Medical Physicist.</p>
7	16.123 (a)(6)	35.2	2002-2	B	<p>Definition: Authorized Nuclear Pharmacist</p> <p>NY's definition of "authorized nuclear pharmacist" omits the equivalent requirements of paragraphs (2)(i), (ii), (iii), (iv) (3) and (4) of NRC's definition.</p> <p>NY needs to add the above in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.2 definition Authorized Nuclear Pharmacist.</p>
8	16.123 (a)(6)	35.2	2002-2	B	<p>Definition: Authorized User</p> <p>"NY needs to change the second half of their definition "... and is identified as an authorized user on ..." to be essential identical to paragraphs (2)(i), (ii), (iii) and (iv) of NRC's definition of Authorized User. This includes changing the word "and" in the above sentence to "or" and other revisions to be essential identical to paragraphs (2)(i), (ii), (iii) and (iv) of NRC's definition.</p> <p>NY needs to make the above change in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.2 definition Authorized User.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
9	N/A	35.2	2002-2	C	<p>Definition: Medical Use</p> <p>NY omits the definition of “medical use” from their regulations.</p> <p>NY needs to add the definition of “medical use” to 16.2 or 16.123 in order to meet the Compatibility Category C designation assigned to Section 10 CFR 35.2 definition Medical Use.</p>
10	16.2 (99)	35.2	2002-2 2005-2 2006-1	B	<p>Definition: Radiation Safety Officer</p> <p>NY’s definition of “Radiation Safety Officer” omits the requirements as stated in paragraphs (1) and (2) of NRC’s definition.</p> <p>NY needs to make the above change in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.2 definition Radiation Safety Officer.</p>
11	16.2 (114)	35.2	2002-2	[B]	<p>Definition: Sealed source</p> <p>NY needs to change its definition of Sealed source to be essentially identical to NRC’s definition of Sealed source. NRC defines Sealed source as any byproduct material that is encased in a capsule designed to prevent leakage or escape the byproduct material.</p> <p>NY needs to make the above change in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.2 definition Sealed source.</p>
12	N/A	35.6	2002-2	C	<p>Provision of Human Research Subjects</p> <p>NY omits this provision from their regulations.</p> <p>If NY does not allow research on human subjects then they would be more restrictive than NRC’s regulation and therefore would be compatible.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>However NY references human research subjects in other sections of their regulations leading NRC to believe that NY does allow for research on human subjects.</p> <p>NY either needs to state in writing that they do not allow research on human subjects or the need to add an equivalent section to Section 10 CFR 35.6 to their regulations in order to meet the Compatibility Category C designation assigned to Section 10 CFR 35.6.</p>
13	16.5 (c)	35.24 (b)	2002-2	H&S	<p>Authority and responsibilities for the radiation protection program</p> <p>NY's regulation does not require a written agreement between a licensee's management and the Radiation Safety Officer (RSO).</p> <p>NY needs to add this requirement to 16.5 in order to meet the Compatibility Category H&S designation assigned to Section 10 CFR 35.24.</p>
14	16.5 (d)	35.24 (f)	2002-2	H&S	<p>Authority and responsibilities for the radiation protection program</p> <p>Section 10 CFR 35.24(f) states "Licensees that are authorized for two or more different types of use of byproduct material under Subpart E..." NY's regulation in 16.5(d) states "... in hospitals and institutions of higher education ..." By being very specific NY is potentially eliminating certain licensees that 35.24(f) would apply to and therefore not meeting the adequacy aspect of this regulation.</p> <p>NY needs to change 16.5(d) to include licensees that are authorized for two or more different types of use of byproduct material in order to meet the Compatibility Category H&S designation assigned to Section 10 CFR 35.24 (f).</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
15	16.5 (f)	35.27	2002-2	H&S	<p>Supervision</p> <p>NY's regulation 16.5(f) does not require the supervision to be by an authorized user. Also NY needs to expand 16.5(f) to include a requirement to "instruct the supervised individual in the licensee's written radiation protection procedures, regulations of this chapter and license conditions with respect to the use of byproduct material" and to "Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures, regulations of this chapter, and license conditions with respect to medical use of byproduct material."</p> <p>NY needs to add the above to 16.5(f) in order to meet the Compatibility Category H&S designation assigned to Section 10 CFR 35.27.</p>
16	N/A	35.49	2002-2 2006-1	C	<p>Suppliers for sealed sources or devices for medical use</p> <p>NY omits an equivalent section to Section 10 CFR 35.49 from its regulations.</p> <p>NY needs to add the essential objectives of Section 10 CFR 35.49 to 10 NYCRR 16.123 in order to meet the Compatibility Category C designation assigned to Section 10 CFR 35.49.</p>
17	16.123 (d)(1)	35.50	2002-2 2005-2 2006-1 2009-1	B	<p>Training for Radiation Safety Officer</p> <p>NY does not include recognition by the NRC or other Agreement States of a specialty board's certification process.</p> <p>NY needs to remove "or" from the end of 16.123(d)(1)(i)(a) and replace it</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>with "To have its certification process recognized, a specialty board shall require all candidates for certification to:"</p> <p>NY needs to make the above changes to 16.123(d)(1) in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.50.</p>
18	16.123 (d)(2)	35.51	2002-2 2005-2 2006-1 2009-1	B	<p>Training for an authorized medical physicist</p> <p>NY needs to remove the introduction paragraph in 10 NYCRR 16.123(d)(2) or change it when they correct their definition of authorized medical physicist.</p> <p>NY does not include recognition by the NRC or other Agreement States of a specialty board's certification process;</p> <p>NY needs to make the above changes to 16.123(d)(2) in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.51.</p>
19	16.123 (d)(3)	35.55	2002-2 2005-2	B	<p>Training for an authorized nuclear pharmacist</p> <p>NY's regulation is not essentially identical to Section 10 CFR 35.55.</p> <p>NY needs to incorporate all of Section 10 CFR 35.55 into 16.123 (d)(3) in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.55.</p>
20	38.35 (j)(3)	35.61	2002-2	H&S	<p>Calibration of survey instruments</p> <p>NY's regulation omits the requirements in Section 10 CFR 35.61 (a)(1), (a)(2), and (b).</p> <p>NY needs to add the essential objectives above to 18 NYCRR 38.35(j)(3) in order to meet the Compatibility Category H&S</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					designation assigned to Section 10 CFR 35.61.
21	16.123(c)(4)	35.63	2002-2	H&S	<p>Determination of dosages of unsealed byproduct material for medical use</p> <p>NY's lists a wrong reference in 16.123(c)(4)(ii)(b)(1). It should say in 12 NYCRR 38.35(j) instead of 12 NYCRR 38.32(j).</p> <p>NY needs to make the above change in order to meet the Compatibility Category H&S designation assigned to Section 10 CFR 35.63.</p>
22	N/A	35.70	2002-2	H&S	<p>Surveys of ambient radiation exposure rate</p> <p>NY's omits this requirement from their regulations.</p> <p>NY needs to add the essential objectives of Section 10 CFR 35.70 to 10 NYCRR 16.123 in order to meet the Compatibility Category H&S designation assigned to Section 10 CFR 35.70.</p>
23	16.123 (b)(1)(i)	35.100	2002-2 2005-2 2006-1	H&S	<p>Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required</p> <p>NY's regulation omits the essential objectives of Section 10 CFR 35.100(a), (b), (c), and (d) which state where material for uptake, dilution and excretion studies can be obtained from and who it can be prepared by.</p> <p>NY needs to embody the essential objectives of Section 10 CFR 35.100 (a), (b), (c), and (d) in 16.123 (b)(1)(i) in order to meet the Compatibility Category H&S designation assigned to Section 10 CFR 35.100.</p>
24	16.123 (b)(1)(i)	35.190	2002-2 2005-2	B	Training for uptake, dilution and excretion studies

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
			2006-1 2007-1 2009-1		<p>NY does not include recognition by the NRC or other Agreement States of a specialty board's certification process</p> <p>NY omits "or equivalent NRC or other Agreement State requirements" as stated in Section 10 CFR 35.190 (b), (c)(1)(ii) and (c)(2);</p> <p>NY omits a reference to their equivalent of Section 10 CFR 35.57 (16.123(d)(5)) as stated in Section 10 CFR 35.190(c)(1)(ii) and (c)(2).</p> <p>NY needs to make the above changes in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.190.</p>
25	16.123 (b)(2)(i)	35.200	2002-2 2005-2 2006-1	H&S	<p>Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required</p> <p>NY's regulation omits the essential objectives of Section 10 CFR 35.200(a), (b), (c), and (d) which state where material for imaging and localization studies can be obtained from and who it can be prepared by.</p> <p>NY needs to embody the essential objectives of Section 10 CFR 35.200 (a), (b), (c), and (d) in 16.123 (b)(2)(i) in order to meet the Compatibility Category H&S designation assigned to Section 10 CFR 35.200.</p>
26	16.123 (b)(2)(iii)	35.204	2002-2	H&S	<p>Permissible molybdenum-99, strontium-82, and strontium-85 concentration</p> <p>NY's regulation states "milli"becquerel of molybdenum instead of "kilo"becquerel as stated in paragraph (a).</p> <p>NY needs to correct the prefix as stated above in 16.123(b)(2)(iii) in</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					order to meet the Compatibility Category H&S designation assigned to Section 10 CFR 35.204.
27	16.123 (b)(3)(i)	35.300	2002-2 2006-1	H&S	<p>Use of unsealed byproduct material for which a written directive is required</p> <p>NY's regulation omits the essential objectives of Section 10 CFR 35.300(a), (b), (c), and (d) which state where material for which a written directive is required can be obtained from and who it can be prepared by.</p> <p>NY needs to embody the essential objectives of Section 10 CFR 35.300 (a), (b), (c), and (d) in 16.123 (b)(3)(i) in order to meet the Compatibility Category H&S designation assigned to Section 10 CFR 35.300.</p>
28	16.123 (b)(3)(ii)	35.390	2002-2 2005-2 2006-1 2009-1	B	<p>Training for use of unsealed byproduct material for which a written directive is required</p> <p>In 16.123(b)(3)(ii)(b)(1)(ii) and 16.123(b)(3)(ii)(b)(2), NY requires all authorized users who are supervising work experience and providing preceptor attestation to also have experience in administering dosages in the same dose category or categories as the individual requesting authorized user status. In Section 10 CFR 35.390(b)(1)(ii) and 35.390(b)(2) NRC only requires this for authorized users who meet the requirements in Section 10 CFR 35.390(b). NY needs to change 16.123(b)(3)(ii)(b)(1)(ii) and 16.123(b)(3)(ii)(b)(2), to match NRC's Section 10 CFR 35.390(b)(1)(ii) and Section 10 CFR 35.390(b)(2).</p> <p>NY omits the phrase "or equivalent NRC or other Agreement State requirements" in 16.123(b)(3)(ii)(b)(1)(ii) and 16.123(b)(3)(ii)(b)(2).</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>NY omits their equivalent requirement to Section 10 CFR 35.57 (16.123(d)(5)) as stated in Section 10 CFR 35.390 (b)(1)(ii) and (b)(2).</p> <p>NY needs to make the above changes in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.390.</p>
29	16.123 (b)(3)(iii)	35.392	2002-2 2005-2 2006-1 2009-1	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>NY omits the phrase “or equivalent NRC or other Agreement State requirements” in 16.123(b)(3)(iii)(b), (c)(2), and (c)(3)</p> <p>NY omits their equivalent requirement to Section 10 CFR 35.57 (16.123(d)(5)) as stated in Section 10 CFR 35.392 (c)(2) and (3).</p> <p>NY needs to make the above changes in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.392</p>
30	16.123 (b)(3)(iii) **(should be (iv))	35.394	2002-2 2005-2 2006-1 2009-1	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>NY lists this section as 16.123(b)(3)(iii), however NY already has a section 16.123(b)(3)(iii). This should be recodified as 16.123(b)(3)(iv).</p> <p>NY states in 16.123(b)(3)(iii)(c)(2)(vi) “... that includes at least 3 cases involving the oral administration of greater than or equal to 33 millicuries ...”. This is incorrect. NY should state “...oral administration of greater than 33 millicuries ...”</p> <p>NY omits the phrase “or equivalent</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>NRC or other Agreement State requirements” in 16.123(b)(3)(iii)(c)(2)and (3). NY omits their equivalent requirement to Section 10 CFR 35.57 (16.123(d)(5)) as stated in paragraphs (c)(2) and (3).</p> <p>NY needs to make the above changes in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.394.</p>
31	16.123 (b)(3)(iv)	35.396	2005-2 2006-1 2009-1	B	<p>Training for the parenteral administration of unsealed byproduct material requiring a written directive</p> <p>NY omits the phrase “or equivalent NRC or other Agreement State requirements” in 16.123(b)(3)(iv)(a), (b), (d)(2), and (d)(3).</p> <p>NY omits their equivalent requirement to Section 10 CFR 35.57 (16.123(d)(5)) in paragraphs 16.123(b)(3)(iv)(d)(2) and (3).</p> <p>NY needs to make the above changes in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.396.</p>
32	16.123 (b)(4)(ii)	35.490	2002-2 2005-2 2006-1 2009-1	B	<p>Training for use of manual brachytherapy sources</p> <p>NY omits the phrase “or equivalent NRC or other Agreement State requirements” in 16.123(b)(4)(ii)(c)(1)(ii), (c)(2), and (c)(3).</p> <p>NY omits their equivalent requirement to Section 10 CFR 35.57 (16.123(d)(5)) in 16.123(b)(4)(ii)(c)(1)(ii), (c)(2), and (c)(3).</p> <p>NY needs to make the above changes in order to meet the Compatibility</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					Category B designation assigned to Section 10 CFR 35.490.
33	16.123 (b)(5)	35.500	2002-2	C	<p>Use of sealed sources for diagnosis</p> <p>NY needs to add “as approved in the Sealed Source and Device Registry” to the end of 16.123(b)(5)i(a) and (b).</p> <p>NY needs to make the above change in order to meet the Compatibility Category C designation assigned to Section 10 CFR 35.500.</p>
34	16.123 (b)(6)(ii)	35.690	2002-2 2005-2 2006-1 2009-1	B	<p>Training for use of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units</p> <p>NY omits the phrase “or equivalent NRC requirements” in 16.123(b)(6)(ii)(c)(1)(ii), (c)(2), and (c)(3).</p> <p>NY omits their equivalent requirement to Section 10 CFR 35.57 (16.123(d)(5)) in 16.123(b)(6)(ii)(c)(1)(ii), (c)(2), and (c)(3).</p> <p>NY needs to make the above changes in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.690.</p>
35	16.25	35.3045	2002-2	C	<p>Report and notification of a medical event</p> <p>NY’s regulation omits “or tissue” after “organ” in 16.25(b)(1)(ii).</p> <p>NY omits the phrase “50 rem shallow dose equivalent to the skin” from 16.25(b)(1)(ii).</p> <p>NY omits equivalent requirements of Section 10 CFR 35.3045 (a) (1) (ii) and (iii).</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					NY needs to make the above changes in order to meet the Compatibility Category C designation assigned to Section 10 CFR 35.3045.
36	16.15	35.3047	2002-2	C	<p>Report and notification of a dose to an embryo/fetus or a nursing child</p> <p>NY omits an equivalent provision to 35.3047(b)(2) from their regulation.</p> <p>NY allows for 30 days for submission of the written report in 16.15(c)(1). NRC requires a written report within 15 days.</p> <p>NY omits an equivalent section to Section 10 CFR 35.3047(e) and (f)(2) from their regulations</p> <p>NY needs to make the above changes in order to meet the Compatibility Category C designation assigned to Section 10 CFR 35.3047.</p>
37	16.15(f)	35.3067	2002-2	C	<p>Report of a leaking source</p> <p>NY's regulation omits the following from what the written report must include: leaking source model and serial number, if assigned, the radionuclide and its estimated activity, and the date of the test.</p> <p>NY needs to add the above to 16.15(f) in order to meet the Compatibility Category C designation assigned to Section 10 CFR 35.3067.</p>

STATE REGULATION STATUS

State: New York State Health Department

Tracking Ticket Number: 10-12

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

Date: May 18, 2010

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 (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, 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			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	Incoming Package	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 (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.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
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 (Superceded by 2002-2 and 2005-2)	10/20/1998			
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, 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	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	Incoming Package	Outgoing Package	Notes
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 (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, 150 62 FR 28947	06/27/2000			
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 ML080170561	No Comments 03/20/2008 ML080800306	
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71,	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 (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			

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	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			
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			
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct	02/16/2004	License Condition for 32.52 (a) & (b) only	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			

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	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			
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	12/01/2005	License Condition ML053120138	No Comments 11/10/2005 ML053180041	
*2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70	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 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	
*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	Incoming Package	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	

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