

January 21, 2005

Mr. Robert Walker, Director
Executive Office of Health and Human Services
Department of Public Health
Radiation Control Program
90 Washington Street
Dorchester, MA. 02121

Dear Mr. Walker:

We have reviewed the proposed changes to the Massachusetts regulations, "*Massachusetts Regulations for the Control of Radiation*", received by our office on November 23, 2004. Our review and comments are in response to the State's request for Nuclear Regulatory Commission (NRC) evaluation of the changes to Massachusetts' radiation control rules that incorporated the amendments identified on the States Regulation Status (SRS) Data Sheet. These regulations were reviewed by comparison to the equivalent NRC rules in 10 CFR Parts 30, 40, 70, 20, 61, 19, 150, 71, 34, 36, 35, 39, 31, 32 and the requirements of the 16 amendments identified in the enclosed SRS. We discussed our review of the regulations with Salifu Dakubu on December 22, 2004.

As a result of our review, we have 13 comments and two editorial suggestions. Under our current procedure, a finding that a State regulation meets the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final State regulation. Please provide a final amended version of your rules showing the location of any changes made in response to our comments. If there are any comments which the State believes are in error, the State should identify the section of their regulations that meet the designated compatibility category. Please note that we have limited our review to regulations required for compatibility and/or health and safety, but have determined that if these regulations are adopted, incorporating our comments and without significant change, they would meet the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

The SRS Data Sheet summarizes our knowledge of the status of other Massachusetts 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 STP website: <http://www.hrsd.ornl.gov/nrc/rulemaking.htm>.

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 me, or Shawn Rochelle Smith of my staff at (301) 415-2620 or srs3@nrc.gov.

Sincerely,

IRA By K.N. Schneider For

Josephine M. Piccone, Deputy Director
Office of State and Tribal Programs

Enclosures:
As stated

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Sheri Minnick/Duncan White, RSAO James Myers, ASPO Massachusetts File Document

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OFFICE	STP		STP		OGC		STP:DD	
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**COMPATIBILITY COMMENTS FOR
PROPOSED MASSACHUSETTS REGULATIONS**

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	120.226	20.1502	1998-5	H&S	<p>Conditions requiring individual monitoring of external and internal occupational dose</p> <p>Paragraph (b)(3) of 10 CFR Part 20.1502 is not included.</p> <p>The State needs to include paragraph (b)(3) of 10 CFR Part 20.1502 to meet the essential objectives for compatibility Category H&S.</p>
2	Omitted	36.23	1998-5	H&S	<p>Access Control</p> <p>The State omitted this provision.</p> <p>The State needs to include this provision to meet the essential objectives for compatibility Category H&S.</p>
3	120.282	20.2202	1998-5	C	<p>Notification of incidents</p> <p>In paragraph (a)(1)(ii) of 10 CFR Part 20.2202, "eye" should be replaced with "lens".</p> <p>The State needs to adopt this revision to meet the essential objectives for compatibility Category C.</p>
4	120.005	20.1003	1999-3	B	<p>Definitions: Supplied Air Respirator</p> <p>The definition for supplied air respirator was omitted.</p> <p>The State needs to include this definition to meet the essential objectives for compatibility Category B.</p>
5	Omitted	30.31	2001-1	C	<p>Types of Licenses</p> <p>The State omitted the requirements of 10 CFR Part 30.31.</p> <p>The State needs to include these requirements to meet the essential objectives for compatibility Category C.</p>

**COMPATIBILITY COMMENTS FOR
PROPOSED MASSACHUSETTS REGULATIONS**

6	Omitted	20.1301	2002-2	A	<p>Dose limits for individual members of the public</p> <p>The State omitted the requirements of 10 CFR Part 20.1301.</p> <p>The State needs to include these requirements to the essential objectives for compatibility Category A.</p>
7	Omitted	32.72	2002-2	B	<p>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35</p> <p>The State omitted the requirements of 10 CFR 32.72.</p> <p>The State needs to adopt these requirements to meet the essential objectives for compatibility Category B.</p>
8	Omitted	32.74	2002-2	B	<p>Manufacture and distribution of sources or devices containing byproduct material for medical use</p> <p>The State omitted the requirements of 10 CFR Part 32.74</p> <p>The State needs to adopt these requirements to meet the essential objectives for compatibility Category B.</p>
9	120.502	35.2	2002-2	C	<p>Definitions: Medical Use</p> <p>In the State definition for “Medical Use”, the word, “material”, is missing after radioactive.</p> <p>The State needs to adopt this revision to meet the essential objectives for compatibility Category C.</p>

**COMPATIBILITY COMMENTS FOR
PROPOSED MASSACHUSETTS REGULATIONS**

10	120.526	35.55	2002-2	B	<p>Training for an authorized nuclear pharmacist</p> <p>In Section 120.526(B)(2) of the State regulations, it states that the individual should be able to independently operate a nuclear pharmacy. 10 CFR Part 35.55 states that the individual should be able to operate independently as an authorized nuclear pharmacist.</p> <p>The State needs to adopt the language in 10 CFR 35.55 to meet the essential objectives for compatibility Category B.</p>
11	Omitted	35.433	2002-2	H&S	<p>Decay of strontium-90 sources for ophthalmic treatments</p> <p>The State has omitted the requirements of 10 CFR Part 35.433.</p> <p>The State needs to include these requirements to meet the essential objectives for compatibility Category H&S.</p>
12	120.587	35.690	2002-2	B	<p>Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units</p> <p>The State omitted 10 CFR Part 35.690 (b)(1)(ii)(E) and (F).</p> <p>The State needs to adopt the requirements of 10 CFR Part 35.690 (b)(1)(ii)(E) and (F) to meet the essential objectives for compatibility Category B.</p>
13	Omitted	61.80	1995-3	C	<p>Maintenance of records, reports, and transfers</p> <p>The State omitted the requirements of 10 CFR Part 61.80.</p> <p>The State needs to adopt the requirements of 10 CFR Part 61.80 to meet the essential objectives for compatibility Category C.</p>

Editorial Suggestions

1. In the first paragraph of section 120.558, “greater” is missing between “quantities” and “than”.
2. In the first paragraph of section 120.577, “teletherapy unit” should be replaced with “remote after loader”.

STATE REGULATION STATUS

State: Massachusetts
[16 amendments reviewed are identified by a ★
at the beginning of the equivalent NRC regulation.]

Tracking Ticket Number: 4-336
Date: January 21, 2005

NRC Chronology Identification	FR Notice (Date Due For State Implementation)	RATS ID	Proposed (P) / Final (F)²Rule / ML #⁵	NRC Review / Y, N² / Date / ML #⁵	Final State Regulation¹ (Effective Date)⁶
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1	F	N 3/3/97	3/21/97
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2			Not Required
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; (1/1/94)	1991-3	F	N 3/3/97	3/21/97
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	F	N 3/3/97	3/21/97
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1	F	N 3/3/97	3/21/97
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35	57 FR 45566; (none)	1992-2			Not Required
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628; (10/25/96)	1993-1	F	N 3/3/97	3/21/97
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2	F	N 3/3/97	3/21/97
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3	F	N 3/3/97	3/21/97
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618; (none)	1994-1	F	N 3/3/97	3/21/97
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2			Not Applicable
★ Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3	P ML043510327	N 1/21/05 ML050250339	
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; (1/1/98)	1995-1	F	N 9/21/99	7/9/99
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2			
★ Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983; (3/1/98)	1995-3	P ML043510327	Y 1/21/05 ML050250339	
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4			
★ Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	P ML043510327	N 1/21/05 ML050250339	

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★ Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	P ML043510327	N 1/21/05 ML050250339	
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7	F	N 9/21/99	7/9/99
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28724; (4/1/99)	1996-1	F	N 9/21/99	7/9/99
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses- Parts 30, 40, 70	61 FR 1109; (none)	1996-2			Not Required
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3	F	N 9/21/99	7/9/99
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act- Part 20	61 FR 65120; (1/9/00)	1997-1	F	N 9/21/99	7/9/99
★ Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150	62 FR 1662; (2/27/00)	1997-2	P ML043510327	N 1/21/05 ML050250339	
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F	N 9/21/99	7/9/99
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4			Not Required
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28947; (6/27/00)	1997-5	F	N 9/21/99	7/9/99
★ Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6	P ML043510327	N 1/21/05 ML050250339	
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea-Part 30	62 FR 63634; (1/02/01)	1997-7	F	N 9/21/99	7/9/99
★ Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773; (2/12/01)	1998-1	P ML043510327	N 1/21/05 ML050250339	
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2			Not Required
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			Not Required
★ Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4	P ML043510327	N 1/21/05 ML050250339	
★ Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39477; 63 FR 45393; (10/26/01)	1998-5	P ML043510327	Y 1/21/05 ML050250339	

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★ Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	P ML043510327	N 1/21/05 ML050250339	
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1			Not Applicable
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269; (none)	1999-2			
★ Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524; (2/2/03)	1999-3	P ML043510327	Y 1/21/05 ML050250339	
★ Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	P ML043510327	N 1/21/05 ML050250339	
★ New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	P ML043510327	N 1/21/05 ML050250339	
★ Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material-Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	P ML043510327	Y 1/21/05 ML050250339	
★ Revision of the Skin Dose Limit-Part 20	67 FR 16298; (4/5/05)	2002-1	P ML043510327	N 1/21/05 ML050250339	
★ Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; (4/24/05)	2002-2	P ML043510327	Y 1/21/05 ML050250339	
Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327 12/3/06	2003-1			
Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71	69 FR 3697; (10/01/07)	2004-1			

1. Or other generic Legally Binding Requirements.
2. (Y/N) Y means “Yes,” there are comments in the review letter that the State needs to address.
N means “No,” there are no comments in the review letter.
3. Not Required means these regulations are not required for purposes of compatibility.
4. A State need not adopt a specific regulation if the State has no licensees that would be subject to that regulation. See “Final Policy Statement on Adequacy and Compatibility of Agreement State Programs.” III.1. Time Frame for Adoption of Compatible State Regulations, p.6, SECY-95-112, May3, 1995.
5. ADAMS ML Number.