

December 11, 2001

Mr. Jay Hyland, P.E., Manager
Radiation Control Program
Division of Health Engineering
10 State House Station
Augusta, ME 04333

Dear Mr. Hyland:

We have reviewed the final State of Maine regulations related to Radiation Protection (10-144A CMR 220, Parts A through E, G, and J) which became effective on August 1, 2001. The regulations were sent on June 6, 2001. The final regulations are in response to the 19 amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. The regulations were reviewed by comparison to the equivalent NRC regulations in 10 CFR Parts 19, 20, 30, 31, 34, 35, 36, 39, 40, 70, and 150. We also discussed our review of the regulations with you and Shawn Seeley on May 24, 2001.

As a result of the NRC review, we have identified 13 comments, as enclosed. These comments must be addressed to meet the compatibility and health and safety categories established in Office of State and Tribal Programs (STP) Procedure SA-200.

The SRS Data Sheet summarizes our knowledge of other Maine regulations. 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 Web Site: <http://www.hsr.d.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 Duncan White at 610-337-5042 or ADW@NRC.GOV.

Sincerely,

/RA/
Frederick C. Combs, Deputy Director
Office of State and Tribal Programs

Enclosures:
As stated

Jay Hyland

December 11, 2001

Distribution:

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DCD (SP05) PDR (YES)

Maine File

Response to Incoming: ML012710492

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OFFICIAL AGENCY RECORD

STP-AG-13

**COMMENTS ON FINAL MAINE REGULATIONS
AGAINST COMPATIBILITY AND HEALTH AND SAFETY CATEGORIES**

State Regulation or SSR	NRC Regulation or SSR	RATS ID	Category	Subject and Comments
J.3.	10 CFR 19.12	1995-5	C	<p><u>Instruction to Workers</u></p> <p>The changes to 10 CFR 19.12 were omitted. Unless the essential objectives of the section is adopted, the regulation would not meet the compatibility category.</p>
E.16.D.	10 CFR 34.43	1997-5	B	<p><u>Additional Training Requirements</u></p> <p>The requirement to provide instruction or training to radiographic personnel on (1) copies of the regulations, license and licensee's procedures; and (2) use of the licensee's equipment was omitted. Unless essentially identical requirements are adopted, the regulation would not meet the compatibility category.</p>
D.13.	10 CFR 20.1208	1998-5	A	<p><u>Dose to an Embryo/Fetus</u></p> <p>The term "dose" is used instead of "dose equivalent" four times in this section. Unless the term "dose equivalent" is used, the regulation would not meet compatibility requirements.</p>
D.23.B.	10 CFR 20.1702	1999-3	D/H&S	<p><u>Use of Other Controls</u></p> <p>This section omitted that the licensee may consider safety factors other than radiological factors. Unless the omitted requirement is included, the regulation would not meet compatibility requirements.</p>
D.40.D.	10 CFR 20.2101	1999-3	C	<p><u>General Provisions</u></p> <p>The term "eye dose" is used instead of "lens dose." Unless the term "lens dose" is used, the regulation would not meet compatibility requirements.</p>

State Regulation or SSR	NRC Regulation or SSR	RATS ID	Category	Subject and Comments
A.2.	10 CFR 20.1003	1999-3	C	<p><u>Definitions</u></p> <p>The definition of respiratory protection device was omitted. Unless this definition is included, the regulation would not meet compatibility requirements.</p>
E.23; E.26	34.71	1995-4	B	<p><u>Utilization Logs</u></p> <p>The State regulations need to include the requirements for a description including the make, model, and serial number of the radiographic exposure device, transport, or container in which a sealed source is located.</p>
C.15	30.36(d)(3)&(4);(h)(1)&(2);(i) 40.42(d)(3)&(4);(h)(1) &(2);(i)	1995-4	D H&S	<p><u>Expiration and Termination of Licenses</u></p> <p>The State regulations omit the requirement that sites that are inactive for 24 months must be decommissioned; omit requirement that decommissioning be completed within 24 months of submission of decommissioning plan unless good cause is shown.</p>
E.5.D.5	34.20 (c)(5)	1995-4	B	<p><u>Performance Requirements for Industrial Radiography Equipment</u></p> <p>The State regulations must delete the phrase "other than 'J' tubes" in order to achieve compatibility.</p>
C.11.I	32.72	1995-7	B	<p><u>Manufacture and Distribution of Radiopharmaceuticals</u></p> <p>The State regulations omit several labeling requirements. The regulation does site FDA criteria but lacks the reference for the FDA criteria.</p> <p>The State needs to either use the labeling criteria established in 10 CFR 32.72 or site the specific FDA reference they are basing the State requirement on.</p>

State Regulation or SSR	NRC Regulation or SSR	RATS ID	Category	Subject and Comments
Part G	35.52	1995-7	D H&S	<p><u>Possession, Use, and Calibration of Instruments</u></p> <p>The State regulations do not specifically require instruments to measure dosages of alpha- or beta-emitting radionuclides.</p>
Part G	35.100, 35.200, & 35.300	1995-7	D H&S	<p><u>Use of Unsealed Byproduct Material</u></p> <p>The State regulations do not limit from whom unsealed byproduct material may be obtained for medical use.</p>
C.8.F.4(f)	10 CFR 30.35(g)	1995-6	D/H&S	<p><u>Financial Assurance and Recordkeeping for Decommissioning</u></p> <p>The section does not include the requirement to transfer records important to decommissioning to the new licensee. Unless this requirement is included, the regulation would not meet the compatibility requirements.</p>

STATE REGULATION STATUS

State: Maine

[19 final amendments (6/6/01) reviewed are identified by a ★ at the beginning of each equivalent NRC regulation.]

Tracking Ticket Number: 1-116

Date: December 11, 2001

NRC Chronology Identification	FR Notice (Date Due for State Implementation)	RATS ID	Proposed (P) / Final (F) ¹ Rule / ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (Effective Date)
★ Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1	F ML012710492	N 12/11/01 ML013520336	8/1/01
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2			Not required 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; (1/1/94)	1991-3	F ML012710492	N 12/11/01 ML013520336	8/1/01
★ Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	F ML012710492	Y 12/11/01 ML013520336	8/1/01
★ Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1	F ML012710492	N 12/11/01 ML013520336	8/1/01
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35	57 FR 45566; (none)	1992-2			Not required ³
★ Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628; (10/25/96)	1993-1	F ML012710492	N 12/11/01 ML013520336	8/1/01
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2			Not applicable SECY-95-112 ⁴
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			Not applicable SECY-95-112 ⁴
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618 (none)	1994-1			Not required ³
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2			Not applicable SECY-95-112 ⁴
★ Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3	F ML012710492	N 12/11/01 ML013520336	8/1/01
★ 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 ML012710492	N 12/11/01 ML013520336	8/1/01

NRC Chronology Identification	FR Notice (Date Due for State Implementation)	RATS ID	Proposed (P) / Final (F)¹ Rule / ML #⁵	NRC Review / Y, N² / Date / ML #⁵	Final State Regulation¹ (Effective Date)
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2	F	N 11/24/99	8/26/99
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983 (3/1/98)	1995-3			
★ Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	F ML012710492	Y 12/11/01 ML013520336	8/1/01
★ Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F ML012710492	Y 12/11/01 ML013520336	8/1/01
★ Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F ML012710492	Y 12/11/01 ML013520336	8/1/01
★ Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7	F ML012710492	Y 12/11/01 ML013520336	8/1/01
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28723 (4/1/99)	1996-1			
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses- Parts 30, 40, 70	61 FR 1109; (none)	1996-2			Not required ³
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3	F	N 11/24/99	8/26/99
★ Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act- Part 20	61 FR 65120; (1/9/00)	1997-1	F ML012710492	N 12/11/01 ML013520336	8/1/01
★ 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	F ML012710492	N 12/11/01 ML013520336	(LBR) 8/1/01
★ Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F ML012710492	N 12/11/01 ML013520336	8/1/01
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4			Not required ³
★ Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28948; (6/27/00)	1997-5	F ML012710492	Y 12/11/01 ML013520336	8/1/01
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39058; (8/20/00)	1997-6	F	N 11/24/99	8/26/99
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 11/24/99	8/26/99
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773 (2/12/01)	1998-1			

NRC Chronology Identification	FR Notice (Date Due for State Implementation)	RATS ID	Proposed (P) / Final (F)¹ Rule / ML #⁵	NRC Review / Y, N² / Date / ML #⁵	Final State Regulation¹ (Effective Date)
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees-Parts 30, 40, 70	63 FR 29535; (none)	1998-2			Not required ³
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			Not required ³
★ Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4	F ML012710492	N 12/11/01 ML013520336	8/1/01
★ Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39477; 63 FR 45393 (10/26/01)	1998-5	F ML012710492	Y 12/11/01 ML013520336	8/1/01
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6			
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1			Not applicable SECY-95-112 ⁴
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269; (none)	1999-2			Not required ³
★ Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55525 (2/2/03)	1999-3	F ML012710492	Y 12/11/01 ML013520336	8/1/01
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1			
★ New Dosimetry Technology-Parts 34, 36, 39	65 FR 63749; (1/8/04)	2000-2	F ML012710492	N 12/11/01 ML013520336	8/1/01

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, May 3, 1995.
5. ADAMS ML Number