

April 1, 2002

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

Dear Mr. Hyland:

As requested, we have reviewed the proposed regulations to the State of Maine Rules Relating to Radiation Protection (Parts A, C, D, E, G, J, K, and L) in your letters dated January 7 and 23, 2002. The proposed regulations are in response to the 12 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, 32,34, 35, 39, 61 and 71. We also discussed our review of the regulations with Shawn Seeley on March 28, 2002.

As a result of our review, we have 19 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 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. However, we have determined that if your proposed regulations were adopted incorporating the comments and without other significant change, they would meet the compatibility and health and safety categories established in Office of State and Tribal Programs (STP) 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 STP Procedure SA-201, *Review of State Regulations* (November 10, 1998), please highlight the final changes and send one copy to STP in a computer readable format, if possible.

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.hsrdo.nrc.gov/nrc/rulemaking.htm>.

If you have any questions regarding the comments, the compatibility and health 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/

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

Enclosures:
As stated

Jay Hyland

Distribution:

DIR RF [2-14]

DCD (SP05) PDR (YES_✓)

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Maine File

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DATE	02/21/02	02/21/02	03/27/02	03/01/02 04/01/02

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

State Regulation or SSR	NRC Regulation or SSR	RATS ID	Category	Subject and Comments
G.300	35.300	1995-7	D/H&S	<p><u>Use of unsealed byproduct material for therapeutic administration</u></p> <p>The State must replace “imaging and localization studies” with “therapeutic administration” in order to achieve compatibility.</p>
D.38	20.2006	1995-3	B	<p><u>Transfers for disposal and manifests</u></p> <p>This section was not amended by the State. Unless essentially identical requirements are adopted, the regulation would not meet the compatibility category.</p>
None	61.80	1995-3	C	<p><u>Maintenance of records, reports and transfers</u></p> <p>The State does not have an equivalent section in their regulations. Unless requirements meeting the essential objectives are adopted, the regulation would not meet the compatibility category.</p>
L.3.A.	71.4	1996-1	B	<p><u>Definitions</u></p> <p>The State did not include the following seven definitions: fissile material package, low toxicity alpha emitters, maximum normal operating pressure, natural thorium, surface contaminated object (SCO), natural uranium, SCO/CSA, and enriched uranium. Unless essentially identical requirements are adopted, the regulation would not meet the compatibility category.</p>
L.3.A.5	71.4	1996-1	B	<p><u>Definitions</u></p> <p>The State’s definition of fissile material includes two classes not in the NRC definition and omits part of the NRC definition. Unless essentially identical requirements are adopted, the regulation would not meet the compatibility category.</p>

State Regulation or SSR	NRC Regulation or SSR	RATS ID	Category	Subject and Comments
L.3.A.6	71.4	1996-1	B	<p><u>Definitions</u></p> <p>The State's definition of low specific activity does not include the LSA-1, LSA-2 or LSA-3 groups. Unless essentially identical requirements are adopted, the regulation would not meet the compatibility category.</p>
L.3.A.13	71.4	1996-1	B	<p><u>Definitions</u></p> <p>The State's definition of Type B package does not include the normal operating pressure. Unless essentially identical requirements are adopted, the regulation would not meet the compatibility category.</p>
L.6.A	71.5(a)	1996-1	B	<p><u>Transportation of Licensed Material</u></p> <p>The State's regulation did not include "transport on public highways" and the list of appropriate DOT regulations. Unless essentially identical requirements are adopted, the regulation would not meet the compatibility category.</p>
L.6.B	71.5(b)	1996-1	B	<p><u>Transportation of Licensed Material</u></p> <p>The State's regulation omits the specific DOT regulations referenced. Unless essentially identical requirements are adopted, the regulation would not meet the compatibility category.</p>
L.5.B	71.10(a)	1996-1	B	<p><u>Exemptions for low level material</u></p> <p>The State's regulation applies only to the delivery of the package for transport whereas the NRC requirement applies to shipment and carriage of the package. Unless essentially identical requirements are adopted, the regulation would not meet the compatibility category.</p>
L.5.C	71.10(b)	1996-1	NRC	<p><u>Exemptions for low level material</u></p> <p>The State included this section in their regulations which is reserved for only the NRC.</p>

State Regulation or SSR	NRC Regulation or SSR	RATS ID	Category	Subject and Comments
L.9	71.13(a)&(b)	1996-1	B	<p><u>Previously approved package</u></p> <p>The State regulations do not include the requirements in 10 CFR 71.13(b) and Section L.9.A(2) references the incorrect section of the DOT regulations regarding multilateral approval. Unless essentially identical requirements are adopted, the regulation would not meet the compatibility category.</p>
L.11	71.16	1996-1	B	<p><u>General license: Use of foreign approved package</u></p> <p>The State regulations do not include the requirements in 10 CFR 71.16(b). Unless essentially identical requirements are adopted, the regulation would not meet the compatibility category.</p>
L.16.H. through J.	71.47	1996-1	B	<p><u>External radiation standards for all packages</u></p> <p>The State regulations do not include the requirements in 10 CFR 71.47(c) and (d). Unless essentially identical requirements are adopted, the regulation would not meet the compatibility category.</p>
L.14	71.83	1996-1	B	<p><u>Assumptions as to unknown properties</u></p> <p>The State regulations used the term “nuclear reactivity” instead of neutron multiplication.” Unless essentially identical requirements are adopted, the regulation would not meet the compatibility category.</p>
L.15	71.85	1996-1	B	<p><u>Preliminary determinations</u></p> <p>Section L.15.A. of the State’s regulations specifies that “defects in which could impact on compliance with the standards specified in 10 CFR 71, Subparts E & F” whereas 10 CFR 71.85(a) specifies “cracks, pinholes, uncontrolled voids or other defects which could significantly reduce the effectiveness of the packaging.” Unless essentially identical requirements are adopted, the regulation would not meet the compatibility category.</p>

State Regulation or SSR	NRC Regulation or SSR	RATS ID	Category	Subject and Comments
L.16	71.87	1996-1	B	<p><u>Routine determinations</u></p> <p>The State regulations do not include the requirements in 10 CFR 71.87(g). Unless essentially identical requirements are adopted, the regulation would not meet the compatibility category.</p>
L.17	71.88	1996-1	B	<p><u>Air transportation of plutonium</u></p> <p>The State regulations do not include the requirements in 10 CFR 71.88(b) and (c). Unless essentially identical requirements are adopted, the regulation would not meet the compatibility category.</p>
L.20	71.97	1996-1	B	<p><u>Advance notification of shipment of irradiated reactor fuel and nuclear waste</u></p> <p>a. The quantity limit for licensed materials in a single package found in Section L.20.B.(3) are different than those in 10 CFR 71.97(b)(3).</p> <p>b. The retention period for documents in Sections L.20 is one year whereas 10 CFR 71.97 requires a retention period of three years.</p> <p>Unless essentially identical requirements are adopted, the regulation would not meet the compatibility category.</p>

STATE REGULATION STATUS

State: Maine

**[12 amendments reviewed are identified by a ★
at the beginning of each equivalent NRC regulation.]**

Tracking Ticket Number: 2-14

Date: April 1, 2002

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

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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
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	P ML020280357	Y 4/1/02 ML020940414	
★ Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	F ML012710492 P ML020280357	Y 12/11/01 ML013520336 N 4/1/02 ML020940414	8/1/01
★ Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F ML012710492 P ML020280357	Y 12/11/01 ML013520336 N 4/1/02 ML020940414	8/1/01
★ Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F ML012710492 P ML020280357	Y 12/11/01 ML013520336 N 4/1/02 ML020940414	8/1/01
★ Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7	F ML012710492 P ML020280357	Y 12/11/01 ML013520336 Y 4/1/02 ML020940414	8/1/01
★ 10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28724 (4/1/99)	1996-1	P ML020280357	Y 4/1/02 ML020940414	
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

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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 28947; (6/27/00)	1997-5	F ML012710492 P ML020280357	Y 12/11/01 ML013520336 N 4/1/02 ML020940414	8/1/01
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (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	P ML020280357	N 4/1/02 ML020940414	
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 P ML020280357	Y 12/11/01 ML013520336 N 4/1/02 ML020940414	8/1/01
★ Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	P ML020280357	N 4/1/02 ML020940414	

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)
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 55524 (2/2/03)	1999-3	F ML012710492 P ML020280357	Y 12/11/01 ML013520336 N 4/1/02 ML020940414	8/1/01
★ Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	P ML020280357	N 4/1/02 ML020940414	
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	F ML012710492	N 12/11/01 ML013520336	8/1/01
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material-Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1			

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, May 3, 1995.
5. ADAMS ML Number