

May 4, 2004

Mr. John L. Ferruolo
Supervising Radiological Health Specialist
Office of Occupational and Radiological Health
Department of Health
3 Capitol Hill
Providence RI 02908-5097

Dear Mr. Ferruolo:

We have reviewed the proposed changes to the Rhode Island regulations, R23-1.3-RAD, "*Rhode Island Rules and Regulations for the Control of Radiation*", received by our office on March 16, 2004 and supplemented by e-mail on April 5, 2004. Our review and comments are in response to the State's request for Nuclear Regulatory Commission (NRC) evaluation of the changes to Rhode Island's radiation control rules that incorporated the amendments identified on the State Regulation Status Data Sheet (SRS). These regulations were reviewed by comparison to the equivalent NRC rules in 10 CFR Parts 20, 30, 32, 35, 39, 40, 70, 71 and 150 and the requirements of the eleven amendments identified in the enclosed SRS. We informed you of the results of our initial review in a conversation in which we discussed our review of the regulations with Mr. William Dundulis, of your staff, on March 31, 2004.

As a result of our review, we have ten comments. 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 Rhode Island 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](#), "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements." ([STP-02-075](#))

In STP-02-075, dated October 25, 2002, STP notified the Agreement States of the proposed revisions and changes to SA-200 regarding compatibility determinations, including changes to Part 71. Several compatibility designations were changed from "D" to "C" because the identified activities for Type B packages are needed in order to avoid a nationwide regulatory gap. These changes are not reflected in the 1999 Suggested State Regulations for the Control of Radiation (SSRCR) revision for Transportation regulations. We will be coordinating with the Conference of Radiation Control Program Directors to clarify and revise the SSRCR.

We have also identified a number of issues related to training and experience requirements of persons conducting activities under 10 CFR Part 35, "Medical Use of Byproduct Material." We understand that these items will be resolved at a later date when Rhode Island revises that part

of the regulations containing these requirements. We have included them in a separate chart for your convenience, and no action on these items is required at this time.

The SRS Data Sheet summarizes our knowledge of the status of other Rhode Island 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 Ms Patricia Eng of my staff at (301) 415-7206 or PLE@NRC.GOV.

Sincerely,

IRA BY K.N. SCHNEIDER FOR

Josephine Piccone, Deputy Director
Office of State and Tribal Programs

Enclosures: As stated

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Sincerely,

IRA BY K.N. SCHNEIDER FOR

Josephine Piccone, Deputy Director
Office of State and Tribal Programs

Enclosures: As stated

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Rhode Island DCD

PDR (YES)

DSollenberger, ASPO

DWhite RSAO

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OFFICE	STP		STP		OGC		STP:DD	
NAME	PLEng		JZabko		STreby		KNSchneider for JPiccone	
DATE	04/15/04*		04/15/04*		05/03/04*		05/04/04*	

COMMENTS ON PROPOSED RHODE ISLAND REGULATIONS

AGAINST COMPATIBILITY AND HEALTH AND SAFETY CATEGORIES

Number	State Regulation	NRC Section	RATS ID	Category	Subject and Comments
1	A.0	71.4	1996-1	B	<p>The State's proposed regulations do not include the following definitions:</p> <p>Definition of A₁ and A₂ Certificate Holder Conveyance Package</p> <p>In addition, the State's proposed regulations includes the phrase "or other form" in their proposed definition for Normal Form - Radioactive Material</p> <p>The state needs to include the definitions of Definition of A₁ and A₂, Certificate Holder, Conveyance and package; and remove the phrase "or other form" from their proposed definition for Normal form radioactive material to meet compatibility.</p>
2	C.8.30	35.200	2002-2	H&S	<p>Use of Unsealed Byproduct Materials for Imaging and Localization Studies for which a Written Directive is not Required.</p> <p>In paragraph (a) the State's proposed regulations use the phrase "involving measurements of the uptake, dilution or excretion studies," instead of "for imaging and localization studies for which a written directive is not required."</p> <p>The State needs to replace the phrase "involving measurements of the uptake, dilution or excretion studies," with the phrase "for imaging and localization studies for which a written directive is not required."</p>
3	C.7.6	71.12	1996-1	B	<p>General License: NRC-approved package.</p> <p>The State's proposed regulations did not include this requirement.</p> <p>The State needs to revise their regulations to include the requirement for an approved Quality Assurance Program.</p>

4	C.7.10	71.18	1996-1	B	<p>General License: Fissile Material, limited quantity per package</p> <p>The State's proposed regulations did not include paragraphs d & e for fissile materials. Also the transport index calculation appears to be in error. State defines a 15 gram minimum requirement for fissile material which is not discussed in this section of NRC regulations, and the multiplier for plutonium beryllium sources is noted as 0.026. NRC regulations state 0.025.</p> <p>The State needs to amend their regulations to incorporate the essential objectives of the text of 71.18.</p>
5	C.7.7	71.13	1996-1	B	<p>The State's proposed regulations at C.7.7.(b)(2) contains the phrase, "approval except approved under special arrangement in accordance with," instead of "approval as defined in."</p> <p>The State needs to revise its regulations and replace the phrase, "approval except approved under special arrangement in accordance with," with the phrase "approval as defined in."</p>
6	C.7.14	71.87	1996-1	B	<p>Routine Determinations</p> <p>The State's proposed regulations did not include the words "with its contents"</p> <p>The State needs to add the words, "with its contents" as noted in 71.87, thereby incorporating the essential objectives of the text of 71.87</p>

7	C.7.19	71.101 71.103 71.105	1996-1	C	<p>Quality Assurance Requirements; Quality Assurance Organization; Quality Assurance Program</p> <p>The State's proposed regulations regarding Quality Assurance did not include the language contained in 71.101(a), (b), (c) and (g) which specifies quality assurance requirements and organization, including specific requirements for radiography containers.</p> <p>State needs to revise their regulations to include design, purchase, fabrication, handling, storing, cleaning, inspection ,testing, operations, maintenance, repair and modification activities under a QA program. State should also include a discussion of QA organizations and programs similar to 71.103 in order to incorporate the essential objectives of the text of 71.101; and 71.103, including requirements for radiography containers as discussed in 71.101(g).</p>
8	N/A	40.36 H&S-- paragra phs (a), (b), (d), and (f).	1997-6 2003-1	H&S	<p>Financial assurance and recordkeeping for decommissioning (source material)</p> <p>The State's proposed regulations define financial assurance requirements for radioactive materials using the 30.35 model (Appendix B to Part 30 values times a multiplier). This approach does not work for source material (uranium and thorium). The 10 mCi and 100 mCi thresholds in 40.36 are not achieved met with the 30.35 methodology.</p> <p>The specific threshold for source material needs to be explicitly stated in the State regulation or other legally binding requirement to establish a compatible financial assurance system for unsealed source material.</p>

9	C.5.8	40.42	1997-6	H&S	<p>Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas</p> <p>The State's proposed regulations did not explicitly include the regulatory requirements defined in 40.42 paragraphs (c), (d), (e), (f), (g), (h), (i), (j), & (k)(1), (2), (3) regarding source material.</p> <p>The State needs to revise its regulations to include the regulatory requirements defined in 40.42 paragraphs (c), (d), (e), (f), (g), (h), (i), (j), & (k)(1), (2), (3) regarding source material.</p>
10	A.2.3	20.120 1	2002-1	A	<p>Occupational dose limits for adults</p> <p>The State's proposed regulations added the phrase "shallow dose equivalent" to the first sentence in paragraph A.2.3.c, and to the second sentence after the word, "assigned"</p> <p>The State also omitted the sentence, "The deep-dose equivalent, lens-dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable."</p> <p>The State needs to remove the two references to shallow-dose equivalent in paragraph A.2.3.c, and add the sentence noted above in order to incorporate the essential objectives of the text of 20.1201</p>

COMMENTS ON PROPOSED RHODE ISLAND REGULATIONS AGAINST COMPATIBILITY AND HEALTH AND SAFETY CATEGORIES FOR TRAINING REQUIREMENTS FOR MEDICAL LICENSEES

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
C.8.62	35.50	2002-2	B	<p>Training for Radiation Safety Officer</p> <p>The State has retained part of the previous Part 35 training requirements; however, in its letter transmitting this amendment, the State noted that it will amend training requirements for physician authorized users upon completion of NRC's current 10 CFR 35 rulemaking regarding training requirements for physician authorized users.</p> <p>The State should revise this requirement when the NRC rulemaking for Part 35 on training is completed.</p>
C.8.71	35.51	2002-2	B	<p>Training for an Authorized Medical Physicist</p> <p>The State has retained part of the previous Part 35 training requirements; however, in its letter transmitting this amendment, the State noted that it will amend training requirements for an authorized medical physicist on completion of NRC's current 10 CFR 35 rulemaking regarding pertinent training requirements.</p> <p>The State should revise this requirement when the NRC rulemaking for Part 35 on training is completed.</p>

C.8.76	35.55	2002-2	B	<p>Training for an authorized nuclear pharmacist</p> <p>The State has retained part of the previous Part 35 training requirements; however, in its letter transmitting this amendment, the State noted that it will amend training requirements for an authorized nuclear pharmacist upon completion of NRC's current 10 CFR 35 rulemaking regarding pertinent training requirements.</p> <p>The State should revise this requirement when the NRC rulemaking for Part 35 on training is completed.</p>
C.8.63 C.8.72 C.8.73 C.8.77	35.57	2002-2	B	<p>Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist</p> <p>The State has retained part of the previous Part 35 training requirements; however, in its letter transmitting this amendment noted that it will amend training requirements for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist upon completion of NRC's current 10 CFR 35 rulemaking regarding pertinent training requirements.</p> <p>The State should revise these requirements when the NRC rulemaking for Part 35 on training is completed.</p>

C.8.64	35.190	2002-2	B	<p>Training for uptake, dilution and excretion studies</p> <p>The State has retained part of the previous Part 35 training requirements; however, its letter transmitting this amendment noted that it will amend training requirements for uptake, dilution and excretion studies upon completion of NRC's current 10 CFR 35 rulemaking regarding pertinent training requirements.</p> <p>The State should revise these requirements when the NRC rulemaking for Part 35 on training is completed.</p>
C.8.65	35.290	2002-2	B	<p>Training for imaging and localization studies</p> <p>The State has retained part of the previous Part 35 training requirements; however, its letter transmitting this amendment noted that it will amend training requirements for imaging and localization studies upon completion of NRC's current 10 CFR 35 rulemaking regarding pertinent training requirements.</p> <p>The State should revise these requirements when the NRC rulemaking for Part 35 on training is completed.</p>

C.8.66	35.390	2002-2	B	<p>Training for use of unsealed byproduct material for which a written directive is required</p> <p>The State has retained part of the previous Part 35 training requirements; however, its letter transmitting this amendment noted that it will amend training requirements for use of unsealed byproduct material for which a written directive is required upon completion of NRC's current 10 CFR 35 rulemaking regarding pertinent training requirements.</p> <p>The State should revise these requirements when the NRC rulemaking for Part 35 on training is completed.</p>
N/A	35.392	2002-2	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 microcuries)</p> <p>The State does not have regulations for the the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 microcuries). In its letter transmitting this amendment, the State noted that it will amend training requirements upon completion of NRC's current 10 CFR 35 rulemaking regarding pertinent training requirements.</p> <p>The State should include regulations addressing this NRC requirement when the NRC rulemaking for Part 35 on training is completed.</p>

N/A	35.394	2002-2	B	<p>Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 microcuries)</p> <p>The State does not have regulations for the the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 microcuries). In its letter transmitting this amendment, the State noted that it will amend training requirements upon completion of NRC's current 10 CFR 35 rulemaking regarding pertinent training requirements.</p> <p>The State should include regulations addressing this NRC requirement when the NRC rulemaking for Part 35 on training is completed.</p>
C.8.67	35.490	2002-2	B	<p>Training for use of manual brachytherapy sources</p> <p>The State has retained part of the previous Part 35 training requirements; however, its letter transmitting this amendment noted that it will amend training requirements for use of manual brachytherapy sources upon completion of NRC's current 10 CFR 35 rulemaking regarding pertinent training requirements.</p> <p>The State should revise these requirements when the NRC rulemaking for Part 35 on training is completed.</p>

C.8.68	35.491	2002-2	B	<p>Training for ophthalmic use of strontium-90</p> <p>The State has retained part of the previous Part 35 training requirements; however, its letter transmitting this amendment noted that it will amend training requirements for ophthalmic use of strontium-90 upon completion of NRC's current 10 CFR 35 rulemaking regarding pertinent training requirements.</p> <p>The State should revise these requirements when the NRC rulemaking for Part 35 on training is completed.</p>
C.8.69	35.590	2002-2	B	<p>Training for use of sealed sources for diagnosis</p> <p>The State has retained part of the previous Part 35 training requirements; however, its letter transmitting this amendment noted that it will amend training requirements for use of sealed sources for diagnosis upon completion of NRC's current 10 CFR 35 rulemaking regarding pertinent training requirements.</p> <p>The State should revise these requirements when the NRC rulemaking for Part 35 on training is completed.</p>

C.8.70	35.690	2002-2	B	<p>Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units</p> <p>The State has retained part of the previous Part 35 training requirements; however, its letter transmitting this amendment noted that it will amend training requirements for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units upon completion of NRC's current 10 CFR 35 rulemaking regarding pertinent training requirements.</p> <p>The State should revise these requirements when the NRC rulemaking for Part 35 on training is completed.</p>
A.0	35.2	2002-2	B	<p>Definition of Authorized User</p> <p>The State failed to include specific references to requirement equivalent to 35.392 & 35.394. These requirements are related to training issues and should be resolved when Rhode Island revises their training requirements.</p> <p>The State should include revision of the training requirements and inclusion of these requirements in their regulations when they incorporate the Part 35 T&E changes.</p>

STATE REGULATION STATUS

State: Rhode Island

11 amendments reviewed are identified by a ★
at the beginning of each equivalent NRC regulation.

Tracking Ticket Number: 4-61

Date: 05/04/04

NRC Chronology Identification	FR Notice (Date Due for State Implementation)	RATS ID	Proposed (P) / Final (F) ¹ Rule / ML # ⁴	NRC Review / Y, N ² / Date / ML # ⁴	Final State Regulation ¹ (Effective Date)
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1			
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-N	10/16/97	4/21/95
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	F-N	9/22/99	6/95
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1	F-N	9/22/99	6/95
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-N	3/27/00	7/99
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2			Not applicable
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			Not applicable
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618 (none)	1994-1	F-N	3/27/00	Not required ³ (7/99)
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	F-N	3/27/00	7/99
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	3/27/00	7/99

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Frequency of Medical Examinations for Use of Respiratory Protection Equipment- Part 20	60 FR 7900; (3/13/98)	1995-2	F-N	3/27/00	7/99
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983 (3/1/98)	1995-3	F-N	3/27/00	7/99
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	F-N	3/27/00	7/99
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F-Y	3/27/00	7/99
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F-N	3/27/00	7/99
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7	F-N	3/27/00	7/99
★ 10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28723 (4/1/99)	1996-1	P-Y ML040760420	5/04/04 ML041340017	
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	3/27/00	7/99
★ Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65120; (1/9/00)	1997-1	P-N ML040760420	5/04/04 ML041340017	
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			
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F-N	3/27/00	7/99
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4			Not required ³

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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-N	3/27/00	7/99
★ Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39058; (8/20/00)	1997-6	P-Y ML040760420	5/04/04 ML041340017	
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	3/27/00	7/99
★ Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773 (2/12/01)	1998-1	P-N ML040760420	5/04/04 ML041340017	
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-N	3/27/00	7/99
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-N	3/27/00	7/99
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	F-N	3/27/00	7/99
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			Not required ³
★ Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524 (2/2/03)	1999-3	P-N ML040760420	5/04/04 ML041340017	
★ Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	P-N ML040760420	5/04/04 ML041340017	

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★ New Dosimetry Technology-Parts 34, 36, 39	65 FR 63749; (1/8/04)	2000-2	P-N ML040760420	5/04/04 ML041340017	
★ Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	P-N ML040760420	5/04/04 ML041340017	
★ Revision of the Skin Dose Limit-Part 20	67 FR 1629; (4/5/05)	2002-1	P-Y ML040760420	5/04/04 ML041340017	
★ Medical Use of Byproduct Material-Parts 20, 32, 35	67 FR 20249; (10/25/05)	2002-2	P-Y ML040760420	5/04/04 ML041340017	
★ Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327 12/3/06	2003-1	P-Y ML040760420	5/04/04 ML	

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