

October 25, 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 final R23-1.3-RAD, "*Rhode Island Rules and Regulations for the Control of Radiation*", received by this office on September 7, 2004. Our review and comments are in response to the State's request for NRC evaluation of the changes to Rhode Island's radiation control rules that incorporated the amendments identified on the enclosed State Regulation Status Data Sheet (SRS). The submitted final regulations were reviewed by comparison to the equivalent NRC regulations in 10 CFR Parts 19, 20, 30, 32, 34, 35, 36, 39, 61, 71, 150 and the requirements of the eleven amendments identified on the SRS Data Sheet. We discussed our review of the regulations with you, during an October 25, 2004 email transmittal.

As a result of our review, we have no new comments regarding these regulations and have found that all but five of the comments from our July 9, 2004 letter have been addressed and are now closed. However, the five comments that remain open from that letter are enclosed in the attached chart. We note that for comments number one, three, and four, the office committed, in our discussion, to addressing these in a future rulemaking, which is still an acceptable course of action. In regards to comment number two, from the July 9, 2004 letter, we did not find the correction to the multiplier factor, per your commitment. If this omission was an oversight, please include this change in your future rulemaking as well. In regards to comment number five, you committed to developing license conditions to apply to your current licensees. We did not find your rule text had been changed to meet this requirement, and if you have developed license conditions to address this, we request you submit the license conditions to the NRC for review.

When you have completed your future rulemaking, please provide an amended final version of your rules showing the location of any changes made by the State, in response to our comments. If there are any comments which Rhode Island believes are in error, the State should identify the sections of their regulations that meet the designated compatibility category for the areas in question and submit them to the NRC for review. Please note that we have limited our review to regulations required for compatibility and/or health and safety. However, we 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 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>.

Mr. John L. Ferruolo

-2-

October 25, 2004

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 John Zabko of my staff, at (301)415-2308 or JGZ@NRC.GOV.

Sincerely,

WRA BY K.N. SCHNEIDER FOR

Josephine Piccone, Deputy Director
Office of State and Tribal Programs

Enclosures:
As stated

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 John Zabko of my staff, at (301)415-2308 or JGZ@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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OFFICE	STP		STP		OGC		STP:DD	
NAME	OSiurano		JZabko		Streby		KNS for Jpiccone	
DATE	10/13/04*		10/13/04*		10/21/04*		10/25/04*	

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COMMENTS ON RHODE ISLAND PROPOSED REGULATIONS

Number	State Regulation	NRC Section	RATS ID	Category	Subject and Comments
1	A.0	71.4	1996-1	B	<p>a) The State’s proposed regulation does not include the following definition: “Certificate Holder”</p> <p>b) 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 this definition and remove the phrase “or other form” from their proposed definition for Normal Form Radioactive Material to meet compatibility.</p> <p>The previous comment on this section concerning the addition of the following definitions is withdrawn: Definition of A₁ and A₂, Conveyance, Package</p> <p>The State makes reference to 49 CFR 173, Subpart I, in Section C.7.4(a)(1)(i), which includes these definitions.</p>
2	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>

3	C.7.7	71.13	1996-1	B	<p>Previously Approved Package</p> <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>
4	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(g) which specifies quality assurance requirements and organization, including specific requirements for radiography containers.</p> <p>State needs to revise their regulations to include requirements for radiography containers as discussed in 71.101(g).</p>
5	N/A	40.36 H&S-- paragrap hs (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 §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 met with the §30.35 methodology.</p> <p>As written in §40.36 and §40.42, 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 source materials.</p> <p>The State rule in C.5.16 is not equivalent to §40.36. As such, the State needs to draft a rule equivalent to §40.36 to meet compatibility.</p>

Editorial Suggestions

1. Section C.5.8 (f)(4)(vi) - reference to paragraph (g) is incorrect. The correct reference should be to paragraph **(h)**.
2. Section C.5.8 (d) - C.5.16 is not equivalent to §40.36. Reference to C.5.16 should be revised.

STATE REGULATION STATUS

State: Rhode Island

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

Tracking Ticket Number: 4-276

Date: 10/25/2004

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
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
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

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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	F ML042520322	Y 10/25/04 ML043010048	
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	F ML042520322	N 10/25/04 ML043010048	
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
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	F-Y ML042520322	Y 10/25/04 ML043010048	
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	F ML042520322	N 10/25/04 ML043010048	
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2	ML042520322		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

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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
i Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524 (2/2/03)	1999-3	F ML04520322	N 10/25/04 ML043010048	
i Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	F ML04520322	N 10/25/04 ML043010048	
i New Dosimetry Technology-Parts 34, 36, 39	65 FR 63749; (1/8/04)	2000-2	F ML04250322	N 10/25/04 ML043010048	
i Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	F ML04520322	N 10/25/04 ML043010048	
i Revision of the Skin Dose Limit-Part 20	67 FR 1629; (4/5/05)	2002-1	F ML04520322	N 10/25/04 ML043010048	
i Medical Use of Byproduct Material-Parts 20, 32, 35	67 FR 20249; (10/25/05)	2002-2	F ML04520322	N 10/25/04 ML043010048	
i Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327 12/3/06	2003-1	F ML04520322	Y 10/25/04 ML043010048	
Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments - Part 71		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, May 3, 1995.
5. ADAMS ML Number