

June 27, 2007

Aaron Gantt, Director
Bureau of Radiological Health
Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201

Dear Mr. Gantt:

We have reviewed the proposed changes to the South Carolina Radiological Health Rules, R61-63, Radioactive Materials, Part II and Part IV, received by our office on May 7, 2007. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 30, 31, 32, and 35, and the requirements of the four amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with James Pederson on June 26, 2007.

As a result of our review, we have five 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 the South Carolina regulations meet the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final South Carolina regulations. However, we have determined that if your proposed regulations were adopted, incorporating our comments and without other significant change, they would meet the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) 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 FSME Procedure SA-201, "Review of State Regulatory Requirements," please highlight the final changes, and provide a copy to Division of Materials Safety and State Agreements, FSME.

The SRS Data Sheet summarizes our knowledge of the status of other South Carolina 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 FSME website: <http://www.hsrp.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 Kathleen Schneider, State Regulation Review Coordinator at (301) 415-2320, (email: kxs@nrc.gov) or Randy Erickson at (817) 860-8143, (email: rre@nrc.gov).

Sincerely,

/RA By D.White For/

Scott W. Moore, Deputy Director
Division of Materials Safety and State Agreements
Office of Federal State Materials and
Environmental Management Programs

Enclosures:
As stated

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Enclosures:
As stated

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COMPATIBILITY COMMENTS ON SOUTH CAROLINA PROPOSED REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	R.61-63, Radioactive Materials Part 4 Section 4.22.1	35.55	2005-2	B	<p>Training for an authorized nuclear pharmacist</p> <p>South Carolina's regulation states "...who meets the requirements in paragraph (b)(2) of this section.". This is an incorrect reference as there is no section (b)(2) in South Carolina regulation 4.22.1.</p> <p>South Carolina uses the word "certification" instead of the word "attestation" in South Carolina regulation 4.22.3.</p> <p>South Carolina needs to make the above changes in this section in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.55.</p>
2	R.61-63, Radioactive Materials Part 4 Section 4.23	35.57	2005-2	B	<p>Training for experienced Radiation Safety Officer</p> <p>South Carolina omits the word "authorized" before medical physicist and nuclear pharmacist in 4.23.1.</p> <p>South Carolina needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 35.57.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
3	R.61-63, Radioactive Materials Part 4 Section 4.43	35.390	2005-2 2006-1	B	<p>Training for use of unsealed byproduct material for which a written directive is required.</p> <p>South Carolina has omitted the wording, "for which a written directive is required;" after 4.43.2.2.7.1, 4.43.2.2.7.3, and 4.43.2.2.7.4.</p> <p>South Carolina uses the word "certification" instead of the word "attestation" in South Carolina regulation 4.43.3.</p> <p>South Carolina needs to make the above corrections in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.390.</p>
4	R.61-63, Radioactive Materials Part 4 Section 4.44	35.392	2005-2 2006-1	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 millicuries).</p> <p>South Carolina uses the word "certification" instead of the word "attestation" in South Carolina regulation 4.44.1.5.</p> <p>South Carolina needs to change the word "certification" to "attestation" in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.392(c)(3).</p>

STATE SECTION		NRC SECTION	FAS/ID	CATEGORY	S
R.61-63, Radioactive Materials Part 4 Section 4.45.1.5		35.394	005-2 006-1		<p>Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).</p> <p>South Carolina uses the word "certification" instead of the word "attestation" in South Carolina regulation 4.45.1.5.</p> <p>South Carolina needs to change the word "certification" to "attestation" in order to meet the Compatibility Category B designation assigned to Section 10 CFR 35.394(c)(3).</p>

STATE REGULATION STATUS

State: South Carolina

[4 amendments reviewed identified by a ★
at the beginning of the equivalent NRC requirement.]

Tracking Ticket Number: 7-39

Date: June 27, 2007

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F) Rule / License Condition (LC) ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation (Effective Date)
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1	F	N 6/14/95	5/26/93
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 8/25/99	9/10/98
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	F	N 6/14/95	5/26/93
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1	F	N 6/14/95	5/26/93
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 8/25/99	6/28/96
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2	F	N 8/25/99	6/28/96
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3	F	N 6/14/95	6/21/94
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	N 8/25/99	6/28/96
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 8/25/99	9/10/98
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2	F	N 8/25/99	9/10/98
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983 (3/1/98)	1995-3	F	N 8/25/99	6/28/96

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Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	F	N 8/25/99	9/10/98
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F	N 8/25/99	9/10/98
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F	N 8/25/99	9/10/98
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7	F	N 8/25/99	9/10/98
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 8/25/99	9/10/98
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 8/25/99	9/10/98
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 6/21/99	
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 ML003701447	Y 5/19/00 ML003714086	5/26/00
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	P ML003701447	N 5/19/00 ML003714086	5/26/00
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	P ML003701447	N 5/19/00 ML003714086	5/26/00
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6	P	Y 6/21/99	
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea- Part 30	62 FR 63634; (1/02/01)	1997-7	P ML003701447	N 5/19/00 ML003714086	5/26/00
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 150	63 FR 1890; 63 FR 13773 (2/12/01)	1998-1	P ML003701447	N 5/19/00 ML003714086	5/26/00
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	P ML020990037	Y 4/19/02 ML021090339	

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F) Rule / License Condition (LC) ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation (Effective Date)
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 ML020990037	N 4/19/02 ML021090339	
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	F	N 8/25/99	6/28/96
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1			Not required ³
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 ML030550104	N 3/12/03 ML030720133	
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	F ML030550104	N 3/12/03 ML030720133	
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	F ML030550104	N 3/12/03 ML030720133	
★Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	R ^{7,9} ML071310178	N 6/27/07 ML071780011	
Revision of the Skin Dose Limit -Part 20	67 FR 16298; 4/5/05	2002-1	F ML051580125	N 6/30/05 ML051810477	
Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; 10/24/05	2002-2	F ML051580125	N 6/30/05 ML051810477	
Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327; (12/3/06)	2003-1	F ML070310150	N 2/23/07 ML070520002	
Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71.	69 FR 3697; (10/01/07)	2004-1	F ML070310150	N 2/23/07 ML070520002	
★Security Requirements for Portable Gauges Containing Byproduct Material - Part 30	70 FR 2001; (7/11/08)	2005-1	P ML07131078	N 6/27/07 ML071780011	
★Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35	70 FR 16336; 71 FR 1926 (4/29/08)	2005-2	P ML071310178	Y 6/27/07 ML071780011	

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F) Rule / License Condition (LC) ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation (Effective Date)
Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) ⁶	70 FR 72128; (12/1/05)	2005-3	LC ML052850130	N 10/13/05 ML052870003	
★Minor Amendments - Part 20,30,32,35,40 and 70	71FR15005 (3/27/09)	2006-1	P ML071310178	Y 6/27/07 ML07178011	
National Source Tracking System - Serialization Requirements - Part 32 with reference to Part 20 Appendix E	71 FR 65685 (2/6/07)	2006-2			
National Source Tracking System - Part 20	71 FR 65865 (11/15/07) & (11/30/07)	2006-3 ⁸			

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
6. By letter dated September 2, 2005, from Paul H. Lohaus, Director, Office of State and Tribal Programs, Agreement States were given 90 days to issue legally binding requirements satisfying the requirements of NRC Order EA-05-090.
7. A re-review was completed on this item due to change in compatibility of 31.5 and 31.6. More information can be found in the All Agreement States letter STP 05-072.
8. RATS ID 2006-3 will not be considered under the Non-Common Performance Indicator "Compatibility Requirements" for IMPEP reviews until such time as the National Source Tracking System is ready for use. Revisions in the implementation date for Agreement States will be provided to the States under separate correspondence and the SRS sheet will be revised as appropriate.
9. R stands for proposed changes made to final regulations