

June 30, 2008

Beverly Hall, Chief
Radiation Protection Section
Division of Environmental Health
Department of Environment and Natural Resources
3825 Barrett Drive
Raleigh, NC 27609-7221

Dear Ms. Hall:

We have reviewed the final revision to the North Carolina regulations, Regulations for Protection Against Radiation, received by our office on May 30, 2008. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 30, 32, 35, 71, and the requirements of the five amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Lee Cox on June 30, 2007.

As a result of our review, we have seven 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. We have determined that if these regulations are revised, 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 you revise your regulations to address our comments, 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 location of any changes made by North Carolina, in response to our comments, 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 North 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://nrc-stp.ornl.gov/rulemaking.html>.

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: kathleen.schneider@nrc.gov) or Monica Orendi at (301) 415-3938 (email: monica.orendi@nrc.gov).

Sincerely,

/ RA by ADWhite for /

James G. Luehman, Deputy Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management 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 Kathleen Schneider, State Regulation Review Coordinator at (301) 415-2320 (email: kathleen.schneider@nrc.gov) or Monica Orendi at (301) 415-3938 (email: monica.orendi@nrc.gov).

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 Office of Federal and State Materials and
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Enclosures: As stated

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OFFICE	SAISB		SAIS		OGC		SAIS:BC		MSSA:DD	
NAME	MOrendi		KSchneider		BJones		DWhite		JLuehman	
DATE	06/16/08*		06/17/08*		06/25/08*		06/30/08*		06/30/08*	

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COMPATIBILITY COMMENTS ON *NORTH CAROLINA* FINAL REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	11.0104 (129)	35.2	2002-2	[B]	<p>Definition: Sealed source</p> <p>North Carolina's definition of Sealed source is not essentially identical to NRC's definition in 35.2.</p> <p>North Carolina needs to change their definition of Sealed source to be essentially identical to NRC's definition in order to meet the Compatibility Category [B] designation assigned to 10 CFR 35.2 Definition Sealed source.</p>
2	N/A	35.49	2002-2	[C]	<p>Suppliers for sealed sources or devices for medical use</p> <p>North Carolina omits the essential objectives of 10 CFR 35.49 from its regulations.</p> <p>North Carolina needs to add the essential objective of 10 CFR 35.49 in order to meet the Compatibility Category [C] designation assigned to 10 CFR 35.49.</p>
3	N/A	35.69	2002-2	H&S	<p>Labeling of vials and syringes</p> <p>North Carolina omits the essential objectives of 10 CFR 35.69 from its regulations.</p> <p>North Carolina needs to add the essential objectives of 10 CFR 35.69 in order to meet the Compatibility Category H&S designation assigned to 10 CFR 35.69.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
4	N/A	35.400	2002-2	[C]	<p>Use of sealed sources for manual brachytherapy</p> <p>North Carolina omits the essential objectives of 10 CFR 35.400 from its regulations.</p> <p>North Carolina needs to add the essential objectives of 10 CFR 35.400 to its regulations in order to meet the Compatibility Category [C] designation assigned to 10 CFR 35.400.</p>
5	11.0318 (cc)	35.410	2002-2	H&S	<p>Safety instruction</p> <p>North Carolina omits 10 CFR 35.410 (a)(1) and (a)(2) from its regulation.</p> <p>North Carolina needs to add the above in order to meet the Compatibility category H&S designation assigned to 10 CFR 35.410.</p>
6	11.0117	10 CFR 71	2004-1	NRC	<p>Compatibility With IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments</p> <p>North Carolina adopted 10 CFR 71 in its entirety in 11.0117, including all sections reserved to NRC jurisdiction. North Carolina's regulations should not include sections designated Compatibility Category NRC as incorporated by reference</p> <p>North Carolina needs to add 71.14(b), 71.19, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.101(c)(2), (d), and (e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125 to a list of items not incorporated by reference in 11.0117 in order to meet the Compatibility Category NRC designation assigned to the above listed sections.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
7	11.0117	Multiple	Multiple	NRC	<p>Incorporation by reference</p> <p>North Carolina incorporates many sections of the 10 CFR which have regulation authority delegated to the NRC and not North Carolina.</p> <p>North Carolina needs to either remove these sections or list specific provisions which are not incorporated by reference in order to meet the Compatibility Category NRC designation assigned to sections of the 10 CFR that are delegated NRC authority.</p>

STATE REGULATION STATUS

State: North Carolina

Tracking Ticket Number: 8-63

[5 amendment(s) reviewed is identified by a ★

Date: June 30, 2008

at the beginning of the equivalent NRC requirement.]

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1991-1	Safety Requirements for Radiographic Equipment Part 34 55 FR 843 (Superceded by 1997-5)	01/10/1994	Final	No Comments 8/18/00	North Carolina has adopted Final Regulations equivalent to RATS ID: 1997-5.
1991-2	ASNT Certification of Radiographers Part 34 56 FR 11504 (Superceded by 1997-5)	none	Not Required	Not Required	North Carolina has adopted Final Regulations equivalent to RATS ID: 1997-5.
1991-3	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;	01/01/1994	Final	No Comments 10/25/1995	
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980;	10/15/1994	Final	No Comments 08/18/2000	
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 (Superceded by 2002-2)	01/27/1995	Final	No Comments 08/18/2000	North Carolina has not yet adopted Final Regulations equivalent to RATS ID: 2002-2.
1992-2	Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions Parts 30, 35 57 FR 45566	none	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1993-1	Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites] Parts 30, 40 58 FR 39628	10/25/1996	Final	No Comments 08/18/2000	
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	Final	No Comments 08/18/2000	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Final	No Comments 08/18/2000	
1994-1	Self-Guarantee as an Additional Financial Mechanism Parts 30, 40, 70 58 FR 68726; 59 FR 1618	none	Final	No Comments 08/18/2000	These regulation changes are not required to be adopted for purposes of Compatibility.
1994-2	Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards Part 40 59 FR 28220	07/01/1997	Not Applicable	Not Applicable	North Carolina does not have authority to regulate this material under its Agreement.
1994-3	Timeliness in Decommissioning Material Facilities Parts 30, 40, 70 59 FR 36026	08/15/1997	Final	No Comments 08/18/2000	
1995-1	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	01/01/1998	Final	No Comments 08/18/2000	
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment	03/13/1998	Final	No Comments 08/18/2000	
1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20, 61 60 FR 15649; 60 FR 25983	03/01/1998	Final	No Comments 08/18/2000	
1995-4	Performance Requirements for Radiography Equipment Part 34 60 FR 28323 (Superceded by 1997-5)	06/30/1998	Final	No Comments 08/18/2000	North Carolina has adopted Final Regulations equivalent to RATS ID: 1997-5.
1995-5	Radiation Protection Requirements: Amended Definitions and Criteria Parts 19, 20 60 FR 36038	08/14/1998	Final	No Comments 08/18/2000	
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40, 70	11/24/1998	Final	No Comments 08/18/2000	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
	60 FR 38235				
1995-7	Medical Administration of Radiation and Radioactive Materials Parts 20, 35 60 FR 48623 (Superceded by 2002-2 and 2005-2)	10/20/1998	Final	No Comments 08/18/2000	North Carolina has not yet adopted Final Regulations equivalent to RATS IDs: 2002-2 and 2005-2.
1996-1	Compatibility with the International Atomic Energy Agency Part 71 60 FR 50248; 61 FR 28724 (Superceded by 2004-1)	04/01/1999	Final	No Comments 08/18/2000	North Carolina has not yet adopted Final Regulations equivalent to RATS ID: 2004-1.
1996-2	One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses Parts 30, 40, 70 61 FR 1109	02/15/1999	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1996-3	Termination or Transfer of Licensed Activities: Record keeping Requirements Parts 20, 30, 40, 61, 70 61 FR 24669	06/17/1999	Final	No Comments 08/18/2000	
1997-1	Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120	01/9/2000	Final	No Comments 08/18/2000	
1997-2	Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State Part 150 62 FR 1662	02/27/2000	Final	No Comments 08/18/2000	
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120	05/29/2000	Final	No Comments 08/18/2000	
1997-4	Fissile Material Shipments and Exemptions Part 71 62 FR 5907 (Superceded by 2004-1)	02/10/2000	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-97-078)

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1997-5	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations Parts 30, 34, 71, 150 62 FR 28947	06/27/2000	Final	No Comments 08/18/2000	
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000	Final	No Comments 08/18/2000	
1997-7	Exempt Distribution of a Radioactive Drug Containing One Micro curie of Carbon-14 Urea Part 30 62 FR 63634	01/02/2001	Final	No Comments 08/18/2000	
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71,	02/12/2001	Final ML061990608	No Comments 08/15/2006 ML062280005	
1998-2	Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees Parts 30, 40, 70 63 FR 29535	07/01/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1998-3	License Term for Medical Use Licenses Part 35 63 FR 31604 (Superceded by 2002-2)	07/10/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-98-074)
1998-4	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059	07/09/2001	Final ML062840118	No Comments 10/23/2006 ML062970032	
1998-5	Minor Corrections, Clarifying Changes, and a Minor Policy Change Parts 20, 35, 36 63 FR 39477; 63 FR 45393	10/26/2001	Final ML061990608	No Comments 08/15/2006 ML062280005	
1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127	11/20/2001	Final ML042320535	No Comments 09/02/2004 ML042460091	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1999-1	Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506	06/11/2002	Not Applicable	Not Applicable	North Carolina does not have authority to regulate this material under its Agreement.
1999-2	Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information Part 31 64 FR 42269	10/04/2002	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1999-3	Respiratory Protection and Controls to Restrict Internal Exposure Part 20 64 FR 54543; 64 FR 55524	02/02/2003	Final ML061990608	No Comments 08/15/2006 ML062280005	
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	Final ML061990608	No Comments 08/15/2006 ML062280005	
2000-2	New Dosimetry Technology Parts 34, 36, 39 65 FR 63750	01/08/2004	Final ML061990608	No Comments 08/15/2006 ML062280005	
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct	02/16/2004	Final ML061990608	Comments 08/15/2006 ML062280005	
2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Final ML061790305	No Comments 08/04/2006 ML062160419	
★2002-2	Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249	10/24/2005	Final ML081680728	Comments 06/30/2008 ML081820320	
2003-1	Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327	12/03/2006	Final ML061790305	No Comments 08/04/2006 ML062160419	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
★2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007	Final ML081680728	Comments 06/30/2008 ML081820320	
★2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	License Condition ML081680728	No Comments 06/30/2008 ML081820320	
★2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35	04/29/2008	Final ML081680728	No Comments 06/30/2008 ML081820320	
2005-3	Increased Controls for Risk-Significant Radioactive Sources	12/01/2005	License Condition ML052720130	No Comments 10/04/2005 ML052780077	
2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70	03/27/2009			
2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	Not Applicable ¹	Not Applicable	North Carolina responded on 02/16/2007 to FSME-06-110 stating that they currently had no licensees applicable to this rule. ML070460135
★2006-3	National Source Tracking System Part 20 71 FR 65865, 72 FR 59162	01/31/2009	License Condition ML081680728	No Comments 06/30/2008 ML081820320	
2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010			
2007-2	Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements Parts 30, 31, 32, 150 72 FR 58473	12/17/2010			
2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61, 150 72 FR 55864	11/30/2010			

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
2007-4	Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material NRC Order EA-07-305 72 FR 70901	06/05/2008	License Condition ML080660061	No Comments 03/20/2008 ML080800385	
2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20 72 FR 68043	02/15/2011			

¹ IMPEP Team: verify that North Carolina does not have any licensees subject to these regulations during each review.