

March 16, 2004

Ms. Beverly O. Hall, Acting Director
Division of Radiation Protection
Department of Environment and Natural Resources
3825 Barrett Drive
Raleigh, NC 27609-7221

Dear Ms. Hall:

We have reviewed the proposed revisions to North Carolina Administrative Code, Chapter 11 (15A NCAC 11), Radiation Protection Regulations, received electronically by our office on February 10, 2004. Our review and comments are in response to the State's request for Nuclear Regulatory Commission (NRC) evaluation of the changes to North Carolina's radiation control rules that incorporated the amendments identified on the States Regulation Status Data Sheet (SRS). These regulations were reviewed by comparison to the equivalent NRC rules in 10 CFR Parts 20, 30, 31, 32, 34, 35, 36, and 39 and the requirements of the 4 amendments identified in the enclosed SRS. We discussed our review of the regulations with you on March 16, 2004.

As a result of our review, we have 14 comments and three editorial suggestions. 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 the State 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](#).

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 Regulatory Requirements*", 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 North Carolina 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.orni.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 Lloyd Boiling, at 301-415-2327 or LAB@NRC.GOV.

Sincerely,

IRA By C.H. Maupin

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

Enclosure: As stated

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Sincerely,

RA By C.H. Maupin For
Josephine M. Piccone, Deputy Director
Office of State and Tribal Programs

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OFFICE	STP		STP		OGC		STP:DD	
NAME	Boiling		JZabko		STreby		JPiccone	
DATE	2/27/04*		3/2/04*		3/11/04*		3/12/04*	

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COMPATIBILITY COMMENTS ON NORTH CAROLINA PROPOSED REGULATIONS

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	15A NCAC 11.1620(a)(7)(C)& (D)	20.1703(g)(3)& (4)	1999-3	<p>H & S</p> <p>Use of individual respiratory protection equipment</p> <p>The State has incorrect units in (7)(C) "Carbon Monoxide (CO) content of ..." The correct units are "10 ppm or less"; and the limit for carbon dioxide has been omitted in (7)(E). It should read " Carbon dioxide content of 1,000 ppm or less"</p> <p>The State needs to accurately include both of these items to achieve compatibility.</p>
2	15A NCAC 11.1308(b)	39.35(b)	2000-1	<p>Leak testing of sealed sources</p> <p>The State is missing the Agency approval requirement for the leak test kit or method.</p> <p>The State needs to add the following: "The leak test kit or method must be approved by the Agency" as a new second sentence to achieve compatibility.</p>
3	15A NCAC 11.1308(e)(1)(5)	39.35(e)(5)	2000-1	<p>Leak testing of sealed sources</p> <p>The State has omitted reference to neutron emitting devices.</p> <p>The State needs to add "or neutron" between alpha- and -emitting to achieve compatibility.</p>
4	15A NCAC 11.1324(c)(1)(ii) & (d)(9)	39.77(a)(c) & (d)	2000-1	<p>Notification of incidents: abandonment procedures for irretrievable sources</p> <p>There is no regulation allowing the abandonment of an irretrievable source, because of immediate threat to public health and safety and prior to receiving Agency approval.</p> <p>The State needs to include this requirement to meet compatibility.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
5	????	30.34(a)(b)(c)	2001-1	C	<p>Terms and conditions of licenses</p> <p>The State does not have an equivalent section which covers terms and conditions for specific licenses.</p> <p>The State needs to add this section to achieve compatibility.</p>
6	????	30.34(h)	2001-1	H & S	<p>Terms and conditions of licenses</p> <p>The State does not have a section which addresses bankruptcy issues for general licensees.</p> <p>The State needs to include this section to achieve compatibility.</p>
7	15A NCAC 11.0309(c)(7)	31.5(c)(8)(iii)	2001-1	B	<p>Certain measuring, gauging or controlling devices</p> <p>The State has omitted the requirement in (c)(8)(iii) that requires written Agency approval before transferring the device to any other specific licensee not specifically identified in this section.</p> <p>The State needs to add this section in order to achieve compatibility.</p>
8	15A NCAC 11.0309(c) (11)	31.5(c)(13)	2001-1	B	<p>Certain measuring, gauging or controlling devices</p> <p>The State has used the incorrect reporting time requirements.</p> <p>To achieve compatibility, in section (c)(11) the State needs to delete "when required by the Agency" and add "within 30-days".</p> <p>The State does not intend to grant reciprocity to GL's from other jurisdictions. This is contrary to Compatibility Category "B" for this entire requirement.</p>
9	15A NCAC 11.0309(c) (15)	31.5(c)(15)	2001-1	B	<p>Certain measuring, gauging or controlling devices</p> <p>The State has omitted the two year exemption for devices in storage.</p> <p>To achieve compatibility, in section (c)(15), the State needs to add the following sentence, "Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby."</p>

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
10	15A NCAC 11.0310(4)	32.51(a)(4)(5)	2001-1	<p>Byproduct material contained in devices for use under §31.5: Requirements for license to manufacture or initially transfer</p> <p>The State has omitted the requirement for including a serial number in registration.</p> <p>In section .0310 (4), the State needs to add "and serial..." after "...device, model...", to achieve compatibility.</p>
11	15A NCAC 11.0310(8)(a)	32.52	2001-1	<p>Same: Material transfer reports and records</p> <p>The State has omitted the jurisdiction requirements of 32.52.</p> <p>After "Rule .0111...", the State needs to add "or to the Agreement State with jurisdiction over the general licensee." Also, add "For general licensees in NRC jurisdiction" before "the information.....", to achieve compatibility.</p>
12	15A NCAC 11.0523(a) (11)	34.83(d)	2000-2	<p>Records of personnel monitoring procedures</p> <p>The State has omitted part of the record retention requirements of this section.</p> <p>To achieve compatibility, the State needs to add the following sentence: "Records of estimates of exposures as a result of: off-scale personal direct reading dosimeters, or lost or damaged personnel dosimeters until the Agency terminates the license."</p>
13	????	36.55(a)	2000-2	<p>Personnel monitoring</p> <p>The State has omitted this section.</p> <p>The State need to include this section to achieve compatibility.</p>
14	15A NCAC 11.1316(c)	39.65(a)	2000-2	<p>Personnel monitoring</p> <p>The State has omitted the time requirements for dosimeter processing.</p> <p>To achieve compatibility, the State needs to add the following sentence "After replacement, each personnel dosimeter must be promptly processed"</p>

Editorial Suggestions

1. 15A NCAC 11.0104 Definitions - (99) spelling "Pressure". Also in (143) after (SAR) add, "or airline respirator".
2. 15A NCAC 11.1620(a) after intakes, add, "of radioactive material,..." and (a)(6) spelling "provide".
3. 15A NCAC 11.0309(c)(12)(F) delete second "of".

STATE REGULATION STATUS

State: **NORTH CAROLINA**

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

Tracking Ticket Number: 4-34

Date: 03/12/04

NRC Chronology Identification	FR Notice (State Due Date)	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	N 8/18/00	34819
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 10/25/95	34334
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	F	N 8/18/00	34819
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1	F	N 8/18/00	34819
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 8/18/00	36007
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2	F	N 8/18/00	8/1/98 (By reference)
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3	F	N 8/18/00	36007
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618 (none)	1994-1	F	N 8/18/00	Not required ³ 8/1/98
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 8/18/00	36007

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F)¹ Rule / ML #⁵	NRC Review / Y, N² / Date / ML #⁵	Final State Regulation¹ (Effective Date)
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 8/18/00	36007
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2	F	N 8/18/00	36007
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983 (3/1/98)	1995-3	F	N 8/18/00	4/1/99 (By reference)
Performance Requirements for Radiography Equipment-Part 34	60 FR 28324; (6/30/98)	1995-4	F	N 8/18/00	34819
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F	N 8/18/00	36250
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F	N 8/18/00	36250
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7	F	N 8/18/00	34819
10 CAR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28724 (4/1/99)	1996-1	F	N 8/18/00	8/1/98 (By reference)
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 8/18/00	36007
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65120; (1/9/00)	1997-1	F	N 8/18/00	36007
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	N 8/18/00	4/1/99 (By reference)
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F	N 8/18/00	36007

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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	N 8/18/00	36250
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6	F	N 8/18/00	36250
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 8/18/00	36250
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 150	63 FR 1890; 63 FR 13773 (2/12/01)	1998-1	P ML020990028	N 4/19/02 ML021090532	Adopted by Reference
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			
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 ML020990028	N 4/19/02 ML021090532	
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6			
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	P 2/18/04 ML040560247	Y 3/16/04 ML040760474	
★Energy Compensation Sources for Well Logging and Other Regulatory	65 FR 20337; (5/17/03)	2000-1	P 2/18/04 ML040560247	Y 3/16/04 ML040760474	

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Clarifications-Part 39					
★New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	P 2/18/04 ML040560247	Y 3/16/04 ML040760474	
★Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	P 2/18/04 ML040560247	Y 3/16/04 ML040760474	
Revision of the Skin Dose Limit-Part 20	67 FR 16298; 4/5/05	2002-1			
Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; 4/24/05	2002-2			
Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327 12/3/06	2003-1			

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