

September 23, 2008

Terry L. O'Clair, P.E. Director
Division of Air Quality
Environmental Health Section
Department of Health
Gold Seal Center,
918 E. Divide Ave.
Bismarck, ND 58501-1947

Dear Mr. O'Clair:

We have reviewed the proposed changes to the North Dakota regulations Radiological Health Rules 33-10-01 through 33-10-22, except for Chapters 2, 6, 7, 8, 11, 15, and 16, dated August 1, 2008. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 19, 20, 30, 31, 32, 34, 35, 36, 39, 40, 61, 70, 71, and 150. We discussed our review of the regulations with Don Harman on September 23, 2008.

As a result of our review, we have 12 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 North Dakota 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 North Dakota 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 North Dakota 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>.

O'Clair

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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 (Kathleen.Schneider@nrc.gov) or Shirley Xu at 301-415-7640 (Shirley.Xu@nrc.gov).

Sincerely,

/RA K.N.Schneider for/

James 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 (Kathleen.Schneider@nrc.gov) or Shirley Xu at 301-415-7640 (Shirley.Xu@nrc.gov).

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Environmental Management Programs

Enclosures: As stated

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NAME	S Xu		K Schneider		BJones		D White		J Luehman
DATE	09/ 10 /08		09/ 10 /08		09/ 19 /08		09/ 23 /08		09/ 23 /08

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COMPATIBILITY COMMENTS ON NORTH DAKOTA PROPOSED REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	33-10-21-01	§32.201	2006-2	B	<p>Serialization of nationally tracked sources</p> <p>North Dakota omits the reference to 10 CFR 32.201 in this section from its regulations.</p> <p>North Dakota needs to adopt the essentially identical regulations in order to meet the Compatibility Category B designation assigned to 10 CFR 32.201.</p>
2	33-10-21-01	§32.11	2007-2	NRC	<p>Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license</p> <p>North Dakota adopts by reference of 10 CFR 32.11 in section 33-10-21-01. Due to a recent change in Compatibility, 10 CFR 32.11 is designated a Compatibility Category NRC. North Dakota needs to delete the reference to this section in their regulations.</p> <p>North Dakota needs to omit the reference to 10 CFR 32.11 from its regulations in order to meet the Compatibility Category NRC designation assigned to 10 CFR 32.11.</p>
3	33-10-21-01	§32.12	2007-2	NRC	<p>Same: Records and material transfer reports</p> <p>North Dakota adopts by reference 10 CFR 32.12 in section 33-10-21-01. Due to a recent change in Compatibility, 10 CFR 32.12 is designated a Compatibility Category NRC. North Dakota needs to delete the reference to this section in their regulations.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					North Dakota needs to omit the reference to 10 CFR 32.12 from its regulations in order to meet the Compatibility Category NRC designation assigned to 10 CFR 32.12.
4	33-10-04.2-01	§20.2008	2007-3	B	<p>Disposal of certain byproduct material</p> <p>North Dakota omits reference to 10 CFR 20.2008 in this section from its regulations.</p> <p>North Dakota needs to adopt the essentially identical regulations in order to meet the Compatibility Category B designation assigned to 10 CFR 20.2008.</p>
5	33-10-03.1-01	§30.3(b) (1), (2), & (3)	2007-3	NRC	<p>Activities requiring license</p> <p>North Dakota adopts by reference 10 CFR 30.3(b) (1), (2), and (3) in section 33-10-03.1-01. Due to a recent change in Compatibility, 10 CFR 30.3(b) (1), (2), & (3) is designated a Compatibility Category NRC. North Dakota needs to delete the reference to these sections in their regulations.</p> <p>North Dakota needs to omit the references to 10 CFR 30.3(b) (1), (2), and (3) from its regulations in order to meet the Compatibility Category NRC designation assigned to 10 CFR 30.3(b) (1), (2), and (3).</p>
6	33-10-21-01	§32.1 (c)(1)	2007-3	NRC	<p>Purpose and scope</p> <p>North Dakota adopts by reference of 10 CFR 32.1 (c)(1) in section 33-10-21-01. Due to a recent change in Compatibility, 10 CFR 32.1 (c)(1) is designated a Compatibility Category NRC. North Dakota needs to delete the reference to this section in their regulations.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					North Dakota needs to omit the reference to 10 CFR 32.1 (c)(1) from its regulations in order to meet the Compatibility Category NRC designation assigned to 10 CFR 32.1 (c)(1).
7	33-10-07.2-01	§35.11 (c)(1)	2007-3	NRC	<p>License required</p> <p>North Dakota adopts by reference 10 CFR 35.11 (c)(1) in section 33-10-07.2-01. Due to a recent change in Compatibility, 10 CFR 35.11 (c)(1) is designated a Compatibility Category NRC. North Dakota needs to delete the reference to this section in their regulations.</p> <p>North Dakota needs to omit the reference to 10 CFR 35.11 (c)(1) from its regulations in order to meet the Compatibility Category NRC designation assigned to 10 CFR 35.11 (c)(1).</p>
8	33-10-07.2-01	§35.13 (a)(1)	2007-3	NRC	<p>License amendments</p> <p>North Dakota adopts by reference 10 CFR 35.13 (a)(1) in section 33-10-07.2-01. Due to a recent change in Compatibility, 10 CFR 35.13 (a)(1) is designated a Compatibility Category NRC. North Dakota needs to delete the reference to this section in their regulations.</p> <p>North Dakota needs to omit the reference to 10 CFR 35.13 (a)(1) from its regulations in order to meet the Compatibility Category NRC designation assigned to 10 CFR 35.13 (a)(1).</p>
9	33-10-04.2-01	§20.1905 (g)	2008-1	NRC	<p>Exemptions to labeling requirements</p> <p>North Dakota adopts by reference of 10 CFR 20.1905 (g) in section 33-10-</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>04.2-01. Due to a recent change in Compatibility, 10 CFR 20.1905 (g) is designated a Compatibility Category NRC. North Dakota needs to delete the reference to this section in their regulations.</p> <p>North Dakota needs to omit the reference to 10 CFR 20.1905 (g) from its regulations in order to meet the Compatibility Category NRC designation assigned to 10 CFR 20.1905 (g).</p>
10	33-10-03.1-01	§30.21 (c)		NRC	<p>Radioactive drug: Capsules containing carbon-14 urea for "in vivo" diagnostic use for humans</p> <p>North Dakota adopts by reference of 10 CFR 30.21 (c) in section 33-10-03.1-01. 10 CFR 30.21 (c) is designated a Compatibility Category NRC which North Dakota should not adopt by reference this section in their regulations.</p> <p>North Dakota needs to omit the reference to 10 CFR 30.21 (c) from its regulations in order to meet the Compatibility Category NRC designation assigned to 10 CFR 30.21 (c).</p>
11	33-10-03.1-01	§30.34 (d)(e)(1) and (e)(3)		NRC	<p>Terms and conditions of licenses</p> <p>North Dakota adopts by reference 10 CFR 30.34 (d), (e)(1) and (e)(3) in section 33-10-03.1-01. 10 CFR 30.21 (c) is designated a Compatibility Category NRC, which North Dakota should not adopt by reference this section in their regulations.</p> <p>North Dakota needs to omit the reference to 10 CFR 30.34 (d), (e)(1) and (e)(3) from its regulations in order to meet the Compatibility Category NRC designation assigned to 10 CFR 30.34 (d), (e)(1) and (e)(3).</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
12	33-10-17-01	§40.41 (f)		H&S	<p>Terms and conditions of licenses</p> <p>North Dakota does not adopt by reference 10 CFR 40.41 (f) this section of its regulation.</p> <p>North Dakota needs to embody the essential objectives of the requirements for terms and conditions in order to meet the Compatibility Category H&S designation assigned to 10 CFR 40.41(f).</p>

STATE REGULATION STATUS

State: North Dakota

Tracking Ticket Number: 8-77

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

Date: September 23, 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 ML031010635	No Comments 04/28/2003 ML031220151	North Dakota 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	Final ML031010635	No Comments 04/28/2003 ML031220151	North Dakota 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 10/17/97	
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980;	10/15/1994	Final ML031010635	No Comments 04/28/2003 ML031220151	
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 (Superceded by 2002-2)	01/27/1995	Final ML031010635	No Comments 04/28/2003 ML031220151	North Dakota 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 ML031010635	No Comments 04/28/2003 ML031220151	
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	Not Applicable ¹	Not Applicable	North Dakota does not have any licensees subject to these regulations. (See SECY-95-112)

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	Not Applicable ¹	Not Applicable	North Dakota does not have any licensees subject to these regulations. (See SECY-95-112)
1994-1	Self-Guarantee as an Additional Financial Mechanism Parts 30, 40, 70 58 FR 68726; 59 FR 1618	none	Not Required	Not Required	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 Dakota 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 ML031010635	No Comments 04/28/2003 ML031220151	
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 ML031010635	No Comments 04/28/2003 ML031220151	
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment	03/13/1998	Final ML031010635	No Comments 04/28/2003 ML031220151	
1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20, 61 60 FR 15649; 60 FR 25983	03/01/1998	Final ML031010635	No Comments 04/28/2003 ML031220151	
1995-4	Performance Requirements for Radiography Equipment Part 34 60 FR 28323 (Superceded by 1997-5)	06/30/1998	Final ML031010635	No Comments 04/28/2003 ML031220151	North Dakota 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 ML031010635	No Comments 04/28/2003 ML031220151	
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235	11/24/1998	Final ML031010635	No Comments 04/28/2003 ML031220151	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
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 ML031010635	No Comments 04/28/2003 ML031220151	North Dakota has not yet adopted Final Regulations equivalent to RATS ID: 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 ML031010635	No Comments 04/28/2003 ML031220151	North Dakota 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 ML031010635	No Comments 04/28/2003 ML031220151	
1997-1	Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120	01/9/2000	Final ML031010635	No Comments 04/28/2003 ML031220151	
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 ML031010635	No Comments 04/28/2003 ML031220151	
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120	05/29/2000	Final ML031010635	No Comments 04/28/2003 ML031220151	
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)

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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 ML031010635	No Comments 04/28/2003 ML031220151	
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000	Final ML031010635	No Comments 04/28/2003 ML031220151	
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 ML031010635	No Comments 04/28/2003 ML031220151	
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71, 150	02/12/2001	Final ML031010635	No Comments 04/28/2003 ML031220151	
1998-2	Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees Parts 30, 40, 70 63 FR 29535	07/01/2001	Final ML031010635	No Comments 04/28/2003 ML031220151	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) North Dakota has adopted Final Regulations equivalent to RATS ID: 2002-2.
1998-4	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059	07/09/2001	Final ML031010635	No Comments 04/28/2003 ML031220151	
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 ML031010635	No Comments 04/28/2003 ML031220151	
1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127	11/20/2001	Final ML031010635	No Comments 04/28/2003 ML031220151	

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 Dakota 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	Final ML031010635	No Comments 04/28/2003 ML031220151	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 ML031010635	No Comments 04/28/2003 ML031220151	
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	Final ML031010635	No Comments 04/28/2003 ML031220151	
2000-2	New Dosimetry Technology Parts 34, 36, 39 65 FR 63750	01/08/2004	Final ML031010635	No Comments 04/28/2003 ML031220151	
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material	02/16/2004	Final ML031010635	No Comments 08/31/2006 ML062410064	
2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Final ML031010635	No Comments 04/28/2003 ML031220151	
2002-2	Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249	10/24/2005	Final ML031010635	No Comments 04/28/2003 ML031220151	
2003-1	Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327	12/03/2006			
★2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007	Proposed ML082210420	No Comments 09/23/2008 ML082530327	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
★2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	Proposed ML082210420	No Comments 09/23/2008 ML082530327	
★2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35	04/29/2008	Proposed ML082210420	No Comments 09/23/2008 ML082530327	
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-	12/01/2005	License Condition ML052620195	No Comments 09/26/2005 ML052690322	
★2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70	03/27/2009	Proposed ML082210420	No Comments 09/23/2008 ML082530327	
★2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	Proposed ML082210420	Comments 09/23/2008 ML082530327	
★2006-3	National Source Tracking System Part 20 71 FR 65685, 72 FR 59162	01/31/2009	Proposed ML082210420	No Comments 09/23/2008 ML082530327	
★2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010	Proposed ML082210420	No Comments 09/23/2008 ML082530327	
★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	Proposed ML082210420	Comments 09/23/2008 ML082530327	
★2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61, 150 72 FR 55864	11/30/2010	Proposed ML082210420	Comments 09/23/2008 ML082530327	
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 ML081130312	No Comments 05/02/2008 ML081230204	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
★2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20 72 FR 68043	02/15/2011	Proposed ML082210420	Comments 09/23/2008 ML082530327	

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