



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 8, 2018

Terry L. O'Clair, Director
North Dakota Department of Health
Division of Air Quality, 2nd Floor
918 East Divide Ave.
Bismarck, ND 58501-1947

Dear Mr. O'Clair:

We have reviewed the final revisions to the North Dakota Radiological Health Rules in Article 33-10, received by our office on January 2, 2018. These regulations were reviewed by comparison to the equivalent U.S. Nuclear Regulatory Commission (NRC) rules and Regulation Amendment Tracking System Identification Numbers (RATS IDs) 2015-1, 2015-3, and 2015-5 as identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Dale Patrick on February 6, 2018.

As a result of our review, we have four 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 Nuclear Material Safety and Safeguards (NMSS) Procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements."

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 NMSS Procedure SA-201, "Review of State Regulatory Requirements," please highlight the location of any changes made by North Dakota, in response to our comments, and provide a copy to Division of Materials Safety, Security, State, and Tribal Programs, NMSS. 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 NMSS State Communication Portal: <https://scp.nrc.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 Michelle Beardsley, State Regulation Review Coordinator, at (267) 884-2305, (Michelle.Beardsley@nrc.gov) or Joe O'Hara at (301) 415-6854, (Joe.OHara@nrc.gov).

Sincerely,

/RA Paul Michalak for/

Linda Howell, Acting Deputy Director
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosures:

1. Compatibility Comments
2. North Dakota SRS Data Sheet

COMPATIBILITY COMMENTS ON NORTH DAKOTA FINAL REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	33-10-13.1-01	§71.20	N/A	N/A	<p>[Removed]</p> <p>North Dakota includes 10 CFR 71.20 in the list of regulations adopted by reference. This regulation has been removed.</p> <p>North Dakota needs to remove 10 CFR 71.20 from the list of regulations that are adopted by reference.</p>
2	33-10-13.1-01.3	§71.101(c)(1)	2015-3	C	<p>Quality assurance requirements</p> <p>Subsequent to the review of North Dakota's proposed regulations, it was discovered that the general licensee's quality assurance program (QAP) needs to be sent to North Dakota for review and approval. Therefore, North Dakota needs to delete 71.101(c)(1) from 33-10-13.1-01 paragraph 3 to designate that the QAP should go to North Dakota. Additionally, North Dakota needs to supply their contact information.</p> <p>North Dakota needs to make the changes indicated above in order to meet the Compatibility Category C designation assigned to 10 CFR 71.101(c)(1).</p>
3	33-10-13.1-01.1	§71.91(b)	2015-3	NRC	<p>Records</p> <p>In 33-10-13.1-01.1, North Dakota adopts 10 CFR 71.91 by reference in its entirety. However, § 71.91(b) has a Compatibility Category NRC designation and should not be adopted by reference.</p> <p>North Dakota needs to make the change indicated above in order to meet the Compatibility Category NRC designation assigned to 10 CFR 71.91(b).</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
4	33-10-13.1-01	§ 71.91(c)&(d) § 71.101(a) § 71.101(b)&(c) § 71.103(a) § 71.135	2015-3	C	<p>Quality assurance requirements</p> <p>Quality assurance organization</p> <p>North Dakota needs to add a paragraph in 33.10-13.1-01 to indicate that the terms “certificate of compliance, compliance holder or applicant” apply to the NRC because the NRC is the sole authority for issuing a package’s Certificate of Compliance.</p> <p>North Dakota needs to make the change indicated above in order to meet the Compatibility Category C designation assigned to 10 CFR 71.91(c)&(d), 71.101(a), 71.101(b)&(c), 71.103(a), and 71.135.</p>

STATE REGULATION STATUS

State: North Dakota

Tracking Ticket Number: 18-15

Date: February 8, 2018

[# 3 amendment(s) reviewed identified by a *at the beginning of the equivalent NRC requirement.]

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1991-1	Safety Requirements for Radiographic Equipment Part 34 55 FR 843 (Superseded 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 (Superseded 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, and 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 (Superseded 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 and 35 57 FR 45566	none	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1993-1	Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites] Parts 30 and 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 ⁱ	Not Applicable	North Dakota does not have any licensees subject to these regulations. (See SECY-95-112)
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, and 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, and 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, and 35 59 FR 61767; 59 FR 65243; 60 FR 322	01/01/1998	Final ML031010635	No Comments 04/28/2003 ML031220151	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment Part 20 60 FR 7900	03/13/1998	Final ML031010635	No Comments 04/28/2003 ML031220151	
1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20 and 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 and 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, and 70 60 FR 38235	11/24/1998	Final ML031010635	No Comments 04/28/2003 ML031220151	
1995-7	Medical Administration of Radiation and Radioactive Materials Parts 20 and 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.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
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, and 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: Recordkeeping Requirements Parts 20, 30, 40, 61, and 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 and 35 62 FR 4120	05/29/2000	Final ML031010635	No Comments 04/28/2003 ML031220151	

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1997-4	Fissile Material Shipments and Exemptions Part 71 62 FR 5907 (Superseded 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)
1997-5	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations Parts 30, 34, 71, and 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, and 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 Microcurie 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, and 150 63 FR 1890; 63 FR 13773	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, and 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.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
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, 32, 35, 36, and 39 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	
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.

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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, and 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 Parts 30, 31, and 32 65 FR 79162	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, and 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, and 70 68 FR 57327	12/03/2006	Final ML110420074	No Comments 03/15/2011 ML110590610	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	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 ML110420074	No Comments 03/15/2011 ML110590610	
2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	Final ML110420074	No Comments 03/15/2011 ML110590610	
2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35 70 FR 16336; 71 FR 1926	04/29/2008	Final ML110420074	No Comments 03/15/2011 ML110590610	
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) 70 FR 72128	12/01/2005	License Condition ML052620195	No Comments 09/26/2005 ML052690322	
2006-1	Minor Amendments Parts 20, 30, 32, 35, 40, and 70 71 FR 15005	03/27/2009	Final ML110420074	No Comments 03/15/2011 ML110590610	
2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	Final ML110420074 Revised Final ML15237A398	Comments 03/15/2011 ML110590610 No Comments 10/08/2015 ML15237A396	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2006-3	National Source Tracking System Part 20 71 FR 65685, 72 FR 59162	01/31/2009	Final ML110420074 License Condition ML083430028	No Comments 03/15/2011 ML110590610 No Comments 12/18/2008 ML083440096	
2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010	Final ML110420074	No Comments 03/15/2011 ML110590610	
2007-2	Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements Parts 30, 31, 32, and 150 72 FR 58473	12/17/2010	Final ML110420074	No Comments 03/15/2011 ML110590610	
2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61, and 150 72 FR 55864	11/30/2010	Final ML15314A101 Final ML15314A101	Comments 03/15/2011 ML110590610 No Comments 12/10/2015 ML15313A416	
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 Letter	Outgoing Package	Notes
2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19 and 20 72 FR 68043	02/15/2011	Final ML110420074	No Comments 03/15/2011 ML110590610	
2009-1	Medical Use of Byproduct Material – Authorized User Clarification Part 35 74 FR 33901	09/28/2012	Final ML110420074	No Comments 03/15/2011 ML110590610	
2011-1	Decommissioning Planning Parts 20, 30, 40, and 70 76 FR 35512	12/17/2015	Proposed ML15314A104 Final ML17209A376	No Comments 12/10/2015 ML15313A416 No Comments 08/11/2017 ML17209A375	
2011-2	Licenses, Certifications, and Approvals for Materials Licensees Parts 30, 36, 39, 40, 70, and 150 76 FR 56951	11/14/2014	Proposed ML15314A107 Final ML16280A186	Comments 12/10/2015 ML15313A416 No Comments 10/25/2016 ML16280A170	
2012-1	Change of Compatibility Parts 31.5 and 31.6 (See RATS ID: 2001-1 for Rule text) 77 FR 3640	01/25/2015	Proposed ML15314A110 Final ML16280A186	Comment 12/10/2015 ML15313A416 No Comments 10/25/2016 ML16280A170	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2012-2	Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste Part 71 77 FR 34194	08/10/2015	Proposed ML15314112 Final ML17209A376	No Comments 12/10/2015 ML15313A416 No Comments 08/11/2017 ML17209A375	
2012-3	Technical Corrections Parts 30, 34, 40, and 71 77 FR 39899	08/06/2015	Proposed ML15314A113 Final ML17209A376	No Comments 12/10/2015 ML15313A416 No Comments 08/11/2017 ML17209A375	
2012-4	Requirements for Distribution of Byproduct Material Parts 30, 31, 32, 40, and 70 77 FR 43666	10/23/2015	Proposed ML15314A114 Final ML16280A186	Comments 12/10/2015 ML15313A416 No Comments 10/25/2016 ML16280A170	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2013-1	Physical Protection of Byproduct Material, Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, and 71 78 FR 16922	03/19/2016	Proposed ML15314A116 License Condition ML16060A156 Final ML16280A186	No Comments 12/10/2015 ML15313A416 Comments 03/01/2016 ML16060A064 No Comments 10/25/2016 ML16280A170	Part 37 only
2013-2	Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions, Parts 30, 40, and 70 78 FR 32310	08/27/2016	Proposed ML15314A117 Final ML16280A186	Comments 12/10/2015 ML15313A416 No Comments 10/25/2016 ML16280A170	
*2015-1	Domestic Licensing of Special Nuclear Material – Written Reports and Clarifying Amendments Part 70 79 FR 57721, 80 FR 143	01/26/2018	Proposed ML17227A178 Final ML18003B246	No Comments 09/18/2017 ML17227A193 No Comments 02/08/2018 ML18003B232	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2015-2	Safeguards Information - Modified Handling Categorization, Change for Materials Facilities Parts 30, 37, 73, and 150 79 FR 58664, 80 FR 3865	01/28/2018	Proposed ML15314A119 Final ML17209A376	No Comments 12/10/2015 ML15313A416 No Comments 08/11/2017 ML17209A375	
*2015-3	Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements Part 71 80 FR 33987	07/13/2018 *extended to 08/15/2020 See STC 17-060	Proposed ML17227A178 Final ML18003B246	Comments 09/18/2017 ML17227A193 Comments 02/08/2018 ML18003B232	
2015-4	Miscellaneous Corrections, Parts 37 and 40 80 FR 45841	09/02/2018	Proposed ML15314A121 Final ML17209A376	No Comments 12/10/2015 ML15313A416 No Comments 08/11/2017 ML17209A375	
*2015-5	Miscellaneous Corrections, Parts 19, 20, 30, 32, 37, 40, 61, 70, 71, and 150 80 FR 74974	12/31/2018	Proposed ML17227A178 Final ML18003B246	Comments 09/18/2017 ML17227A193 No Comments 02/08/2018 ML18003B232	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
N/A	Part 20, Requirements for Vacating Premises	N/A	Final ML14150A078	No Comments 07/15/2014 ML14149A400	

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