

September 9, 2004

George F. Johns, Jr, Manager
Environmental Health Supervisor
Minnesota Department of Health
Snelling Office Park
645 Energy Park Drive, Suite 300
St. Paul, MN 55108-2970

Dear Mr. Johns:

As requested, we have reviewed the final changes to Chapter 4731 of the Minnesota Regulations, received by this office, via disc, on July 21, 2004. Each regulatory change was reviewed against the equivalent NRC regulations 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 you on September 2, 2004.

As a result of our review, we have 12 comments and 12 editorial suggestions that have been identified in the enclosures. 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](#).

The SRS Data Sheet attached summarizes our knowledge of the status of the required amendments to the Minnesota regulations. With this regulation submission, you have submitted proposed regulations for all required amendments up to, and including RATS ID# 2002-2. When your Agreement becomes final with the NRC, please be aware that you will be required to adopt, and submit for review, rules covering any new amendments to the Code of Federal Regulations (CFR) Chapter 10 that are a matter of compatibility, from this date forward. 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.hsrd.ornl.gov/nrc/rulemaking.htm>.

If you have any questions regarding the comments, the compatibility and health categories, or any of the NRC regulations used in the review, please contact me or John Zabko at (301) 415-2308 or JGZ@NRC.GOV.

Sincerely,

IRA By KN Schneider For

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

Enclosures:
As stated

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

Enclosures: As stated

Distribution:

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OFFICE	STP		OGC		STP	
NAME	JZabko		STreby		KNS for JPiccone	
DATE	08/19/04*		08/31/04*		09/09/04*	

ML042530034

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Editorial Suggestions

1. 4731.0100 (20.1003 equivalent) in the definition for “Very High Radiation Area”, the word “generates” should be replaced by “penetrates”.
2. 4731.3040(2) (30.18(b)) should read as follows: “A person who possesses radioactive material received or acquired before September 25, 1971 under the general license then provided under Code of Federal Regulations, title 10, section **31.4**, is exempt from parts...”
3. 4731.3225, Subpart 1., Item B. Subitem 2 (31.7). The State should insert “, the NRC ” after the second instance of the phrase “commissioner” for consistency with the rest of the paragraph.
4. 4731.3240, Subpart 1., Item B.(31.10). The State should insert “the commissioner, the NRC, or ” before the last occurrence of the phrase “an agreement state” for consistency with the rest of the paragraph.
5. 4731.3320 (32.17 equivalent). The concentration of Sc-46 should be 1.4×10^{-3} mCi/ml.
6. 4731.4411, Item B. Subitem 2 (35.50). Remove the words “or agreement state” from the phrase “NRC or agreement state master material licensee.” Agreement States do not issue Master Material Licenses.
7. 4731.4433, Item C. Subitem 2 (35.190). The State incorrectly references their equivalent requirements to 10 CFR Part 35.100. The State lists 4731.4443 when it should be 4731.4432.
8. 4731.4475, Subpart 2., Item D. (35.647). Insert the word “tube” after the word “transfer” in the phrase “transfer-applicator interfaces” to provide clarity and accurately reflect the intent of the rule.
9. 4731.7070, Item B.(3) (39.35 equivalent). States that the report must “include any contamination”. The State should revise this sentence to state that the report should “describe any contamination”.
10. 4731.0100 (90) (40.4 equivalent). Should read as follows: “Government agency” means an executive department, commission, independent establishment, or corporation wholly or partly owned by the United States **or the State of Minnesota** and which is an instrumentality of the United States **or the State of Minnesota** or a board bureau, division, service, office, officer, authority, administration or other establishment in the executive branch of federal or state government.
11. 4731.0790 (5) (40.42(1)). Should read as follows: “Specific licenses for uranium and thorium milling are **exempt** from subpart 4, items...”.
12. 4731.0405 (71.4 equivalent). Uses the term “certification holder” instead of the legal term “certificate holder”. The State should revise their regulations to use the correct legal term “certificate holder”.

**COMMENTS ON PROPOSED MINNESOTA REGULATIONS
AGAINST COMPATIBILITY & HEALTH AND SAFETY CATEGORIES**

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	4731.0100	20.1003		A	<p>Definitions: Limits</p> <p>This definition is missing.</p> <p>The State needs to adopt the NRC definition to meet compatibility.</p>
2	4731.0100	20.1003		[C]	<p>Definitions: Person</p> <p>“Federal Agencies” is missing from this definition.</p> <p>The State needs to adopt the NRC definition as written in 20.1003 to meet compatibility.</p>
3	4731.0100	20.1004		A	<p>Definitions: Sievert</p> <p>The State has incorrectly shown the conversion from Sievert to REM</p> <p>To meet compatibility the State needs to change its conversion to “1 Sievert = 100 rem”</p>
4	4731.2950	Part 20 Appendix G		B	<p>Definitions:</p> <p>The following definitions are missing: “Chelating agent”, “High integrity container” and “Land disposal facility”.</p> <p>The State needs to adopt the NRC definitions to achieve compatibility.</p>
5	4731.3065	Part 30.32		C	<p>Applications For Specific Licenses</p> <p>The State did not include provisions under 10 CFR §30.32(g)(2).</p> <p>The State needs to adopt this section to achieve compatibility.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
6	4731.3220	Part 31.6		[B]	<p>General License to Install Devices Generally Licensed in 31.5</p> <p>The State's rule as currently written provides the State authority to grant specific licensees of the State, NRC, or other Agreement States general licenses to install and service such devices in areas of NRC jurisdiction. The intention of 10 CFR 31.6 is to allow specific licensees of Agreement States to work in areas of NRC jurisdiction under a general license granted by the NRC.</p> <p>The State needs to revise the language in 4731.3220 to reflect that a person that holds a specific license issued by the NRC or another Agreement State authorizing the holder to manufacture, install, or service a device described in 10 CFR 31.5 or equivalent State regulations should be issued a general license by the State's commissioner to install or service such devices in areas subject to the commissioner's authority.</p>
7	4731.0100	Part 32.2		[A]	<p>Dose Commitment</p> <p>This definition is missing.</p> <p>The State needs to adopt the NRC definition to achieve compatibility.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
8	4371.4120	Part 34.41		B, except paragraph (c) is B for States which authorize offshore platform or under-water radiography or D- for other States and paragraph (d) is D	<p>Conducting Industrial Radiographic Operations</p> <p>In Subp. 3, "Offshore Water Operations," the State requires that procedures for lay-barge, off shore platform, and underwater radiography be approved by the Commissioner (MN) prior to these operations being conducted in the State. 10 CFR 34.41 (c) allows the operations listed above to be conducted in areas of NRC jurisdiction as long as the procedures have been approved by the NRC or any Agreement State.</p> <p>To meet the compatibility category for this requirement, the State should revise the language of 4731.4120 Subpart 3 to allow procedures for the operations listed above approved by the NRC or other Agreement States to be used in the State.</p>
9	4371.4320	Part 34.87		C	<p>Form of Records</p> <p>The State has omitted the requirements of 34.87.</p> <p>The State needs to include this section to achieve compatibility.</p>
10	4731.0402	71.5		[B]	<p>Transportation of Licensed Material</p> <p>Page 75, line 8 states that "licensees should particularly note" 49 CFR 173. Licensees are required to adhere to pertinent parts of 49 CFR 173.</p> <p>The State should revise their regulations to adopt the NRC definition that "licensees must adhere to" 49 CFR 173.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
11	4731.0405	71.11		[C]	<p>Deliberate Misconduct</p> <p>The proposed regulations use the term “certification holder” instead of the legal term, “certificate holder.”</p> <p>The State should revise their regulations to use the correct legal term “certificate holder.”</p>
12	4731.0420	71.101		<p>D- Paragraphs (a), (b), and c) are designated D’s for those States which have no licensees that use Type B packages.</p> <p>or</p> <p>C- Paragraphs (a), (b) and c) are designated C’s for those States which have licensees that use Type B packages.</p> <p>D- paragraph (f)</p> <p>C- paragraph (g)</p> <p>NRC- paragraphs (d) and (e)</p>	<p>Quality Assurance Requirement</p> <p>Proposed regulations state that Quality Assurance requirements are required “prior to the time a package approval is issued.” However, these requirements are in force at all times.</p> <p>The State should revise their regulations to require quality assurance requirements at all times</p>

STATE REGULATION STATUS

State: Minnesota
All amendments reviewed

Tracking Ticket Number: 4-182 thru 4-187
Date: September 9, 2004

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)
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1	F ML041960593	09/09/04 ⁶ ML042530034	
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 ML041960593	09/09/04 ⁶ ML042530034	
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	F ML041960593	09/09/04 ⁶ ML042530034	
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1	F ML041960593	09/09/04 ⁶ ML042530034	
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 ML041960593	09/09/04 ⁶ ML042530034	
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2	F ML041960593	09/09/04 ⁶ ML042530034	
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			Not applicable SECY-95-112 ⁴
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

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Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3	F ML041960593	09/09/04 ⁶ ML042530034	
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 ML041960593	09/09/04 ⁶ ML042530034	
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2	F ML041960593	09/09/04 ⁶ ML042530034	
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983; (3/1/98)	1995-3	F ML041960593	09/09/04 ⁶ ML042530034	
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	F ML041960593	09/09/04 ⁶ ML042530034	
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F ML041960593	09/09/04 ⁶ ML042530034	
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F ML041960593	09/09/04 ⁶ ML042530034	
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7	F ML041960593	09/09/04 ⁶ ML042530034	
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 ML041960593	09/09/04 ⁶ ML042530034	
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 ML041960593	09/09/04 ⁶ ML042530034	
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65120; (1/9/00)	1997-1	F ML041960593	09/09/04 ⁶ ML042530034	
Recognition of Agreement State Licenses in Areas Under Exclusive Federal	62 FR 1662; (2/27/00)	1997-2	F ML041960593	09/09/04 ⁶ ML04253003404 2530034	

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)
Jurisdiction Within an Agreement State-Part 150					
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F ML041960593	09/09/04 ⁶ ML042530034	
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 ML041960593	09/09/04 ⁶ ML042530034	
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6	F ML041960593	09/09/04 ⁶ ML042530034	
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea-Part 30	62 FR 63634; (1/02/01)	1997-7	F ML041960593	09/09/04 ⁶ ML042530034	
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773; (2/12/01)	1998-1		09/09/04 ⁶ ML042530034	
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	F ML041960593	09/09/04 ⁶ ML042530034	
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20	63 FR 39477; 63 FR 45393; (10/26/01)	1998-5	F ML041960593	09/09/04 ⁶ ML042530034	

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Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	F ML041960593	09/09/04 ⁶ ML042530034	
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1			Not applicable SECY-95-112 ⁴
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 ML041960593	11/21/03 ⁶ ML033280512	
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	F ML041960593	09/09/04 ⁶ ML042530034	
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	F ML041960593	09/09/04 ⁶ ML042530034	
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	F ML041960593	09/09/04 ⁶ ML042530034	
Revision of the Skin Dose Limit-Part 20	67 FR 16298 (4/5/05)	2002-1	F ML041960593	09/09/04 ⁶ ML042530034	
Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249 (10/24/05)	2002-2	F ML041960593	09/09/04 ⁶ ML042530034	
Financial Assurance for Materials Licensees - Parts 30, 40, 70	68 FR 56327 (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

6. The Minnesota proposed final regulations were submitted and reviewed on this date as part of their Agreement State application package.