September 17, 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:

In response to the phone conversation of September 14, 2004 between you and the Office of State and Tribal Programs staff, we have revised our comments reflected in the September 9, 2004 letter regarding the review of the final changes to Chapter 4731 of the Minnesota Regulations. The additional discussion and information you provided allowed us to eliminate several of our initial comments.

As a result of our revision, we have 5 comments and 13 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,

/RA By J.M. Piccone/

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

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/RA By J.M. Piccone/

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

Enclosures: As s	tated					
Distribution:						
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NAME	JZabko		STreby		JMPiccone	
DATE	09/16/04*		09/14/04*		09/17/04*	

ML042650007

- 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 X 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) equivalent). 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".
- 13. 4731.0405 (71.11equivalent). **Deliberate Misconduct.** The proposed regulations use 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" rather than "certification holder".

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

STA	TE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	4731.0100	20.1004		А	Definitions: Sievert
					The State has incorrectly shown the conversion from Sievert to REM
					To meet compatibility the State needs to change its regulations to read: "1 Sievert = 100 rem."
2	4731.2950	Part 20		В	Definitions:
		Appendix G			The following definition is missing: "High integrity container"
					The State needs to adopt this NRC definition to achieve compatibility.
3	4731.3220	Part 31.6		[B]	General License to Install Devices Generally Licensed in 31.5
					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 provide reciprocal recognition of licenses.
					The State needs to revise the language in 4731.3220 to read: Any person who holds a specific license issued by the NRC or by an Agreement State authorizing the holder to manufacture, install, or service a device described in 10 CFR 31.5 within areas of NRC or Agreement State jurisdiction is hereby granted a general license to install or service such devices in areas subject to the commissioner's authority.

STA	TE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
4	4731.0100	Part 32.2		[A]	Dose Commitment This definition is missing. The State needs to adopt the NRC definition to achieve compatibility.
5	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	Conducting Industrial Radiographic Operations

STATE REGULATION STATUS

STATE REGULA State: Minnesota All amendments reviewed	Tracking Ticket Number: 4-264 Date: September 17, 2004						
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 (Effective Date)		
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1	F ML041960593	09/09/04 ⁶ ML042530034 09/17/04 ⁶ ML042650007			
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 09/17/04 ⁶ ML042650007			
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 09/17/04 ⁶ ML042650007			
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1	F ML041960593	09/09/04 ⁶ ML042530034 09/17/04 ⁶ ML042650007			
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 09/17/04 ⁶ ML042650007			
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2	F ML041960593	09/09/04 ⁶ ML042530034 09/17/04 ⁶ ML042650007			
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		

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)	н
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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
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3	F ML041960593	09/09/04 ⁶ ML042530034 09/17/04 ⁶ ML042650007	
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 09/17/04 ⁶ ML042650007	
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 09/17/04 ⁶ ML042650007	
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 09/17/04 ⁶ ML042650007	
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	F ML041960593	09/09/04 ⁶ ML042530034 09/17/04 ⁶ ML042650007	
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 09/17/04 ⁶ ML042650007	
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F ML041960593	09/09/04 ⁶ ML042530034 09/17/04 ⁶ ML042650007	
	60 FR 48623; (10/20/98)	1995-7	F	09/092/04 ⁶	

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F) ¹	NRC Review / Y, N ² / Date /	Final State Regulation ¹
			Rule / ML #⁵	ML #⁵	(Effective Date)
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35			ML041960593	ML042530034 09/17/04 ⁶ ML042650007	
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 09/17/04 ⁶ ML042650007	
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 09/17/04 ⁶ ML042650007	
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 09/17/04 ⁶ ML042650007	
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 ML041960593	09/09/04 ⁶ ML042530034 09/17/04 ⁶ ML042650007	
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 09/17/04 ⁶ ML042650007	
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 09/17/04 ⁶ ML042650007	
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 09/17/04 ⁶ ML042650007	

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)
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 09/17/04 ⁶ ML042650007	
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 09/17/04 ⁶ ML042650007	
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 09/17/04 ⁶ ML042650007	
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 09/17/04 ⁶ ML042650007	
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 09/17/04 ⁶ ML042650007	
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1			Not applicable SECY-95- 112⁴
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	

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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 09/17/04 ⁶ ML042650007	
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	F ML041960593	09/09/04 ⁶ ML042530034 09/17/04 ⁶ ML042650007	
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 09/17/04 ⁶ ML042650007	
Revision of the Skin Dose Limit-Part 20	67 FR 16298 (4/5/05)	2002-1	F ML041960593	09/09/04 ⁶ ML042530034 09/17/04 ⁶ ML042650007	
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 09/17/04 ⁶ ML042650007	
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.