

July 16, 2003

Ms. Patricia A. Bloomgren, Director
Environmental Health Division
P. O. Box 64975
St. Paul, Minnesota 55164-0975

Dear Ms. Bloomgren:

This letter is in response to a letter dated May 8, 2003 to me from Ms. Jennifer Beens Harper, Assistant Attorney General. Ms. Harper's letter responded to the seven comments identified during the Nuclear Regulatory Commission's (NRC) completeness review of Section 4.1, Legal Elements, of the Draft Minnesota application. In addition, this letter is to follow-up on items discussed in my November 18, 2002 letter to you.

The results of our review of the State's response to our seven comments are enclosed in Enclosure 1. We have determined that based upon the State's response, two of the seven comments have been resolved. For the remaining five comments, the State's response referenced proposed regulations as the legal mechanism for addressing these comments. If your proposed regulations are adopted as indicated in these responses, without significant change, our remaining five comments would be addressed.

In my November 18, 2002 letter, I indicated that it is important to the NRC budget planning process that the best projections are made regarding your schedule for becoming an Agreement State. NRC's resources are allocated and committed based upon your projected schedule. We would really appreciate the State's assistance in this area by providing us with a schedule for completion of the proposed Minnesota Agreement.

We have enclosed an outline of a draft schedule for completion of an Agreement application. The enclosed draft schedule incorporates guidance in Appendix C-1 of the State and Tribal Program (STP) Procedure SA-700, *Processing an Agreement*, which can be viewed at STP's Website: <http://www.hsrn.gov/nrc/procedures/sa700.pdf>.

We would appreciate your providing us with a completed draft schedule within 30 days of the date of this letter. If you have any questions, please contact me or Ms. Cardelia Maupin of my staff at 301-415-2312 or E-mail: chm1@nrc.gov on this matter.

Thank you for your attention to this matter.

Sincerely,

/RA/

Paul Lohaus, Director
Office of State and Tribal Programs

Enclosures:
As stated

Patricia A. Bloomgren

July 16, 2003

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COMPLETENESS REVIEW COMMENTS ON LEGAL ELEMENTS

ANALYSIS OF MINNESOTA MAY 8, 2003 RESPONSE TO SEPTEMBER 12, 2002

NRC Comment 1:

Although Minnesota statutes in Section 144.1205, Subd. 8., "Reciprocity Fee," provides authority for assessing a fee to a licensee submitting an application for reciprocal recognition of a materials license, it does not provide the general authority for the reciprocal recognition of these licensees. Please see SA-700 Handbook, Sections 4.1.1.1, Information Needed, paragraph (b)(3) and 4.1.1.2, Evaluation Criteria, paragraph (c).

Minnesota Response:

The proposed rule 4317.0316 states that the Commissioner of Health may reciprocally recognize radioactive materials licenses issued by the NRC or a state agency in another state under conditions set forth in the rule.

Comparable Standards/Criteria:

Model Legislation: Section 7, paragraph (d): Rules and regulations promulgated under this act may provide for recognition of other state or federal licenses as the agency may deem desirable, subject to such registration requirements as the agency may prescribe.

1981 Policy Statement on Criteria for entering Agreement, Criterion 27: Arrangements should be made for the reciprocal recognition of State licenses and Federal licenses in connection with out-of-the-jurisdiction operations by a State or Federal licensee.

Minnesota Statutes § 144.1205, subd. 8 provides: A licensee submitting an application for reciprocal recognition of a materials license issued by another agreement state or the United States Nuclear Regulatory Commission for a period of 180 days or less during a calendar year must pay one-half of the application fee specified under subdivision 4. For a period of 181 days or more, the licensee must pay the entire application fee under subdivision 4.

NRC Review: Contingent upon the adoption of the proposed rule referenced in the State's response, Minnesota would meet the comparable standard/criterion.

NRC Comment 2:

The Minnesota statutes do not provide general authority to make it unlawful to use, possess, transfer, dispose, or acquire material without a license, or that it is unlawful to violate a license condition. Please see SA-700 Handbook, Section 4.1.1.1, Information Needed, paragraph (b)(4).

Enclosure 1

Minnesota Response:

Minnesota Statutes § 144.12, subd. 1 states:

The commissioner may control, by rule, by requiring the taking out of licenses or permits, or by other appropriate means, any of the following matters:... Sources of radiation, and the handling, storage, transportation, use and disposal of radioactive isotopes and fissionable materials;

Minn. Stat. § 144.12, subd. 1 (15) (2002). In addition, proposed rule 4731.0300 provides for the licensing of radioactive materials, and prohibits persons from receiving, using, possessing, transferring, owning or acquiring radioactive material unless they have a license. Minn. R.4731.0300, subp. 1. Subpart 4 of the same proposed rule provides that any license may be revoked, suspended or modified in whole or in part because of conditions revealed by an application or a statement of fact.

Comparable Standards/Criteria:

Model Legislation: Section 19: It shall be unlawful for any person to use, manufacture, produce, distribute, sell, transport, transfer, install, repair, receive, acquire, own or possess any source of radiation unless licensed by or registered with the agency in conformance with rules and regulations, if any, promulgated in accordance with the provisions of this act.

1981 Policy Statement on Criteria for entering Agreement, Criterion 13: In the present state of knowledge it is necessary in regulating the possession and use of byproduct, source and special nuclear materials that the State regulatory authority requires the submission of information on, and evaluation of the potential hazards and the capability of the user or possessor prior to his receipt of materials.

NRC Review: Contingent upon the adoption of the proposed rule referenced in the State's response, Minnesota would meet the comparable standard/criterion.

NRC Comment 3:

Although Minnesota statutes in Section 144.99, Subd 9, provides for placing conditions on the license for certain violations, it is not clear whether the Minnesota statutes include authority to allow the use of license conditions to impose additional requirements when required to protect public health and safety. Please see SA-700 Handbook, Section 4.1.1.2, Evaluation Criteria, paragraph (d).

Minnesota Response:

The proposed rule, 4731.0300, subp. 5(D) includes the following language:
The commissioner may incorporate in any license at the time of issuance, or thereafter, by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive materials, including special nuclear materials, as the commissioner deems appropriate and necessary in order to: (1) promote health or to minimize danger to life or property; ...

Comparable Standards/Criteria:

Model Legislation: Section 7, paragraph (a)(4): The terms and conditions of all licenses shall be subject to amendment, revision, or modification by rules, regulations or orders issued in accordance with the provisions of this act.

1981 Policy Statement on Criteria for entering Agreement, Criterion 12: Consistent with the overall criteria here enumerated and to accommodate special cases or circumstances, the State regulatory authority shall be authorized in individual cases to impose additional requirements to protect health and safety, or to grant necessary exemptions which will not jeopardize health and safety.

NRC Review: Contingent upon the adoption of the proposed rule referenced in the State's response, Minnesota would meet the comparable standard/criterion.

NRC Comment 4:

The Minnesota statute should permit exemptions from licensing requirements if the exemptions do not adversely affect public health and safety and should include exemption from the requirement to obtain a license. Please see SA-700 Handbook, Sections 4.1.1.1, Information Needed, paragraph (b)(2); and 4.1.1.2, Evaluation Criteria, paragraph (e). In addition, SA-700 Handbook Section 4.1.1.2(e)(i - iv), provides four specific exemptions that should be addressed by an Agreement State either by statute or regulation. If these four exemptions are addressed in Minnesota regulations, it is not necessary to include them in Minnesota statutes.

Minnesota Response:

Proposed rule 4731.0300, subp. 7 allows for such exemptions. This rule would permit a variance from the requirement to obtain a license if the Commissioner determines that the variance is authorized by law and would not result in an undue hazard to life or property.

Comparable Standards/Criteria:

Model Legislation: Section 7, paragraph (c): The agency is authorized to exempt certain sources of radiation or kinds of uses or users from the licensing or registration requirements set forth in this section when the agency makes a finding that the exemption of such sources of radiation or kinds of uses or users will not constitute a significant risk to the health and safety of the public.

1981 Policy Statement on Criteria for entering Agreement, Criterion 12: Consistent with the overall criteria here enumerated and to accommodate special cases or circumstances, the State regulatory authority shall be authorized . . . or to grant necessary exemptions which will not jeopardize health and safety.

NRC Review: Contingent upon the adoption of the proposed rule referenced in the State's response, Minnesota would meet the comparable standard/criterion.

NRC Comment 5:

The Minnesota statutes authorizing the promulgation of rules [144.12 ,subd.1 and 144.1202, subd. 2] are very generic and fail to provide any sufficient procedures, requirements, or public participation. Please see SA-700 Handbook, Section 4.1.1.1, Information Needed, paragraph (c)(1).

Minnesota Response:

As referenced in Minn. Stat. § 144.12, subd. 1, any rules promulgated under these two statutes are done so pursuant to Minnesota Statutes, chapter 14, the Administrative Procedure Act ("the Act"). A copy of the Act is attached hereto as Exhibit 1. All rules in the state of Minnesota are promulgated pursuant to the Act. As you can see, the Act sets forth specific procedures and requirements for rulemaking, including specific provisions addressing procedure, requirements and public participation. See Minn. Stat. §§ 14.05-.47 (2002).

Comparable Standards/Criteria:

Model Legislation: Section 17, paragraph (a): In any proceeding for the issuance or modification of rules or regulations relating to control of sources of radiation, the agency shall provide an opportunity for public participation through written comments or public hearing.

1981 Policy Statement on Criteria for entering Agreement, Criterion 23: State practices for assuring fair and impartial administration of regulatory law, including provision for public participation where appropriate, should be incorporated in procedures for:

- a. Formulation of rules of general applicability;

NRC Review: The State's statute meets the criterion.

NRC Comment 6:

While inspections of property are provided for in Section 144.99, subd. 2, 2), it does not clarify that such inspections may take place at **all reasonable times**. Please see SA-700 Handbook, Section 4.1.1.2, Evaluation Criteria, paragraph (g).

Minnesota Response:

Proposed rule 4731.0106, specifically dealing with inspections of radiation sources, including source material, special nuclear material, and radiation producing equipment including x-ray, states that inspections may take place at "all reasonable times."

Comparable Standards/Criteria:

Model Legislation: Section 12: The agency or its duly authorized representatives shall have the power to enter at all reasonable times upon any . . .

1981 Policy Statement on Criteria for entering Agreement, Criterion 17: Licensees shall be under obligation by law to provide access to inspectors.

NRC Review: Contingent upon the adoption of the proposed rule referenced in the State's response, Minnesota would meet the comparable standard/criterion.

NRC Comment 7:

The statutes do not provide for an immediate suspension of the license without prior hearing in the event of an emergency which poses a risk to public health and safety. Section 144.99, subd. 6 provides for a cease and desist order that would be effective for 72 hours, but this is not the same as immediate suspension in cases of an emergency. Please see SA-700 Handbook, Section 4.1.1.2, Evaluation Criteria, paragraph (h).

Minnesota Response:

Minnesota Statutes § 144.99, subd. 6 authorizes the Department of Health to issue a cease and desist order if the continuation of the activity would result in an immediate risk to public health. The cease and desist order would be issued without a hearing. Although the statute provides that a cease and desist order is only effective for a maximum of 72 hours, it also specifically provides that the Commissioner may seek an injunction in District Court to restrain activities beyond 72 hours. Under Minnesota law, the Commissioner could also pursue a temporary restraining order without notice to the opposing party if it clearly appears from specific facts shown by affidavit or by the verified complaint that immediate and irreparable injury, loss, or damage will result. Minn. R. Civ. P. 65.01.

Comparable Standards/Criteria:

Model Legislation: Section 18: Whenever, in the judgement of the agency, any person has engaged in or is about to engage in any acts or practices which constitute or will constitute a violation of any provision of this act, or any rule, regulation or order issued thereunder, and at the request of the agency, may make application to the appropriate court for an order enjoining such acts or practices, . . . a permanent or temporary injunction, restraining order, or other order may be granted.

1981 Policy Statement on Criteria for entering Agreement, Criterion 19: Possession and use of radioactive materials should be amenable to enforcement through legal sanctions, and the regulatory authority shall be equipped or assisted by law with the necessary powers for prompt enforcement . . .

NRC Review: The State's statute meets the criterion.

PROCESSING SCHEDULE FOR MINNESOTA AGREEMENT

EVENT	EVENT TIME (weeks)	ELAPSED TIME (weeks)	DATE
Part 1 - Review of the Request for an Agreement			
Minnesota Program notifies the Office of State and Tribal Programs (STP) that a Draft Request will be submitted (2 months prior to submittal)			5/16/02
STP establishes NRC Review Team (Team established between notification and receipt of draft request)			6/14/02
STP receives draft request from Minnesota Program	0	0	7/22/02
NRC Review Team concludes completeness review	3	3	8/12/02
NRC Review Team provides any comments resulting from the completeness review to Minnesota Program	3	6	9/12/02
NRC Chairman receives formal request from Governor of Minnesota ¹			
NRC Review Team completes review of formal request	8		
NRC Review Team completes negative consent Commission Paper, including draft staff assessment and FR notice	2		
Part 2 - FR publication & public comment period (16 weeks)			
NRC Offices concur on Commission Paper	3		
EDO sends Paper to Commission	2		
Commission gives negative consent	2		
First publication in FR	1		
Minnesota staff submits Agreement for State Legislature's approval			
Public comment period ends	4		
Minnesota staff receives approval from Legislature			

¹ Significant comments for resolution were provided during the completeness review.

EVENT	EVENT TIME (weeks)	ELAPSED TIME (weeks)	DATE
NRC Review Team analyzes comments; completes final assessment and Commission paper	4		
Part 3 - Final processing and Commission approval (13 weeks)			
NRC Offices concur on final assessment and paper	3		
EDO signs paper	2		
Commission SRM approving Agreement (includes arrangements for signing Agreement)	4		
Effective date of Agreement	4		