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

October 19, 2004

Ms. Linda Bruemmer, Manager
Section of Asbestos, Indoor Air,
Lead, and Radiation
Division of Environmental Health
Department of Health
121 E. Seventh Place, Suite 220
P.O. Box 64975
St. Paul, Minnesota 55164-0975

Dear Ms. Bruemmer:

We have completed a review of the Minnesota application for an Agreement dated July 6, 2004. The review was conducted by an interoffice staff team identified in Enclosure 1. The review was based on a Commission Policy Statement that provides criteria for new agreements, and an Office of State and Tribal Programs (STP) Procedure SA-700 and Handbook, *Processing an Agreement*. A copy of the procedure and handbook is provided at: http://www.hsrd.ornl.gov/nrc/procedures/sa700.pdf.

The review was conducted to determine whether the State's program met the evaluation criteria for an Agreement Program that is adequate to protect public health and safety and compatible with the NRC materials program. The team found that the application provided information on all major program elements and reflected significant effort on the part of your staff. However, as reflected in the comments, the team identified a few areas where additional information or documentation is needed. We have provided early notification of our comments to Mr. George Johns of your staff. Mr. Johns has addressed most of our comments informally. However, in accordance with our procedures, we must request that a formal response from the State be submitted.

For your reference, the comments are correlated to the pertinent sections of your application and the pertinent sections of the STP Procedure SA-700 Handbook. Our comments are provided in Enclosure 2. The results of our review of Minnesota regulations were transmitted separately to the State in a letter dated September 17, 2004 from Ms. Josephine Piccone, Deputy Director, STP to Mr. George Johns, Supervisor, Environmental Monitoring.

After you have an opportunity to review our comments, we would welcome an opportunity to discuss our comments, and answer any questions. Please contact me at (301) 415-3340 or Cardelia Maupin at (301) 415-2312.

Sincerely,

Paul H. Lohaus

Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosures:
As stated

cc: George Johns

STATE OF MINNESOTA
REVIEW TEAM

Cardelia Maupin, Sr. Project Manager Office of State and Tribal Programs	Team Leader, Organization and Staffing\Training Elements
James Lynch, Regional State Agreements Officer, Region-III	Inspection & Enforcement Elements
Kathleen Kannler and Margaret Bupp Office of the General Counsel	Legal & Regulatory Elements
John Zabko Office of State and Tribal Programs	Regulatory Elements
Ujagar Bhachu Office of Nuclear Material Safety and Safeguards	Licensing Elements
Richard Jolliffe Office of Nuclear Security and Incident Response	Events & Allegations Elements

ENCLOSURE 1

STATE OF MINNESOTA
FINAL APPLICATION COMMENTS

Section 4. 1 Legal Elements

Section 4.1.1 Statutory Authority

Review Team Comments: The Minnesota rule 4731.3015, Exemption; Use of Radioactive Material Under Certain Federal Contracts, paragraph B.(2) states that the NRC will determine whether the conditions have been met for an exemption for a prime contractor or subcontractor of the Department of Energy or the NRC. In accordance with STP Procedure SA-700 Handbook, Section 4.1.1.2, Evaluation Criteria, paragraph (e)(iv.), the Minnesota rule should state that the NRC and Minnesota will jointly make the determinations.

Recommendation: The Review Team recommends that the Minnesota rule 4731.3015, Exemption; Use of Radioactive Material Under Certain Federal Contracts, paragraph B.(2) be revised to read: "the State and the NRC jointly determine that." Please see STP Procedure SA-700 Handbook, Section 4.1.1.2, Evaluation Criteria, paragraph (e)(iv).

4.1.2 Program Organization

Review Team Comments:

1. Section 4.1.2, "Program Organization," page 2. This section provides information on the Radiation Control Unit (RCU); however, the organizational charts do not include the RCU. The organization charts include the "Asbestos, Indoor Air, Lead and Radiation Section" and the "Radioactive Materials Group." In discussions with Minnesota staff, we understand that the RCU is divided into two Groups, the Radioactive Materials Group and the X-ray Group. The information in this section should be revised to reflect this organization. In addition, this section should be revised to ensure that the information provided on page 2 is consistent with the organizational charts (e.g., the organizational location of the RCU, the X-ray Group and the Asbestos, Indoor Air, Lead and Radiation Section).

2. Section 4.1.2, page 2, under the RCU. This section should be revised to clearly identify the organization that will carry out the day to day operations of the Agreement Program, (e.g., the Radioactive Materials Group). This information has been provided informally to NRC; however, the Minnesota application should be revised to include this information.

3. Section 4.1.2, page 2, under the RCU, in discussions with Minnesota staff, we understand that the State regulates PET and radium as the only forms naturally occurring or accelerator-produced radioactive material (NARM) regulated by the State. The radium is in the form of 45 radium gauge licensees and one PET licensee. The radium and PET licensees are inspected every four-years. In addition, we understand that the State requires NARM registration. Section 4.1.2, page 2, should be revised to reflect this information. This information has been provided informally to NRC; however,

the Minnesota application should be revised to include this information.

Please see STP Procedure SA-700 Handbook, Sections 4.1.1.1, Information Needed, and 4.1.1.2, Evaluation Criteria.

Recommendation: The Review Team recommends that Minnesota revise its Agreement application to address the comments on program organization.

4.1.3 Content of the Proposed Agreement

Review Team Comments:

1. On page 1, paragraph one, line three of the Proposed Agreement, the wording "any State" should be deleted and the wording "the State of Minnesota" should be inserted.

2. On page 1, paragraph one, line six, the wording "with respect to byproduct materials as defined in Sections 11e.(1) and (2) of the Act" is included in the proposed Minnesota Agreement. In the July 6, 2004 request from Governor Pawlenty to Chairman Diaz 11e.(2) byproduct material was not included. Since Minnesota is not requesting authority for 11e.(2) materials, which include uranium milling activities, the State should delete the wording "and (2)" from paragraph one of the Proposed Agreement. Please see STP Procedure SA-700 Handbook, Sections 4.1.3.1, Information Needed and 4.1.3.2, Evaluation Criteria, and Management Directive 5.8, *Proposed 274b Agreements with States.*

Recommendation: The Review Team recommends that Minnesota revise its Agreement application to address the comments on the content of the proposed agreement.

4.2 Regulatory Requirements Program Elements

Comments on these program elements were provided to Minnesota by letter dated September 17, 2004 from Josephine Piccone to George Johns.

4.3 Licensing Program Elements

Review Team Comments:

1. The Section 4.3.1 of the Minnesota application, includes an excerpt from the *Regulatory Guide for Diagnostic and Therapeutic Medical Procedures.* The excerpt includes a section entitled "Annotated Drawings." At bullet three, line four, a reference is made to 10 CFR 20.1003. Rather than referencing NRC regulations, the guide should reference Minnesota regulations (i.e., Section 4731 of the MDH regulations) or provide a rationale why this guide references NRC's regulation.

2. The Section 4.3.1 of the Minnesota application includes the *Regulatory Guide for Decommissioning.* The regulatory guide did not provide adequate guidance for termination of licenses. In addition, on page 2 of the regulatory guide a reference is made to NUREG/CR-5849, "Manual for Conducting Radiological Surveys and Supports

of Licensing Termination," which has been superseded by NUREG-1757, *Consolidated NMSS Decommissioning Guidance.* To ensure up-to-date and adequate decommissioning guidance, Minnesota may want to adopt by reference or commit to using NUREG-1757 or provide other appropriate regulatory guidance. Please see STP Procedure SA-700 Handbook, Section 4.3.1.2, Evaluation Criteria, which requires that procedures for evaluating decommissioning should address decontamination, disposal and any restrictions on the future use of the property.

3. The Minnesota rules have some provisions on actions to be taken in the event a licensee files for bankruptcy; however, supporting licensing procedures or guides are silent on this licensing related activity. Minnesota should submit a procedure for handling change of control and bankruptcy actions. The State may adopt by reference or commit to using model procedures in NUREG-1556 Vol. 15 or provide other appropriate regulatory guidance.

4. The *Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments,* Appendix *A, Model Program for Maintaining Occupational Radiation Exposure ALARA,* page 15, Table A-1 Investigational levels, provides dose investigational levels to serve as check points above which the Radiation Safety Officer would perform a review of occupational exposures. As noted in NUREG-1556, Vol. 9, Appendix M, pages M-3 and M-4, the ICRP recommended value for Investigational Level I is 10 percent of the annual limit for occupational exposure and 30 percent for Investigational Level II. The values presented in the Minnesota regulatory guide are much higher than those recommended. For example, the NRC guidance document provides an Investigational Level I of 500 mrem per year for the whole body, while, the Minnesota guide provides a value of 2400 mrem per year. The State should modify the information provided in Table A-1.

5. The *Regulatory Guide for Industrial Radiography*, Appendix C, *Model Annual Audit Checklist*, page 25, section on Transportation (10 CFR 49), does not include the requirement for checking whether the licensee has a valid Certificate of Compliance, issued by NRC, for the Type B package that may be used for transportation of devices. For further information see NUREG-1556, Vol. 2, *Program Specific Guidance About Industrial Radiography*, Appendix I, Transportation (10 CFR 71.5(a) and 49 CFR (170-185).

Please see STP Procedure SA-700 Handbook, Section 4.3.1.2, Evaluation Criteria.

Recommendation: The Review Team recommends that Minnesota revise its Agreement application to address the comments on licensing program elements.

4.4 Inspection Program Elements

Review Team Comments:

1. In Section 4.4.1 *Inspection Procedures,* of the Minnesota application, the State provided the Minnesota Instrument Inventory. The inventory does not address the State's neutron monitoring capabilities. Neutron sources are currently licensed in the State. Please see STP Procedure SA-700 Handbook, Sections 4.4.1.2 Evaluation Criteria.

2. In the *Inspection Procedures Manual*, the section "Determining Inspection Priorities," provides a listing of inspection priorities to which licensees can be assigned. The Manual discusses Priority 7 inspections; however, they are not included in the listing of inspection priorities. Thus, it is not clear whether Priority 6 or Priority 7 inspections are the longest inspection intervals. This information should be clarified.

3. The *Inspection Procedures Manual*, page 7, in the section,"Scheduling Inspections," provides a discussion on follow-up inspections. The discussion is not clear as to the length of time between escalated enforcement actions and follow-up inspections. For example, the section "Follow-up Inspections" indicates that these inspections will occur within six months; whereas, the section "Intervals between Inspections," indicates that an inspection will occur within one year. The State should clarify this information.

4. The *Inspection Procedures Manual*, page 36, Section IV, "Processing Inspection Reports," subsection, "Peer Review Process," refers to licensing actions as opposed to inspection activities. This section should be rewritten to correctly address the inspection process.

5. The *Licensing and Inspection Qualification Journal* indicates that the Radiation Control Unit Supervisor or another qualified inspector will make periodic evaluations of inspectors. NRC Manual Chapter 2800 requires that an inspection supervisor evaluate the performance of each inspector, during actual inspections, at least once per year. The Journal should be revised to indicate that these evaluations will be made by the Minnesota inspection supervisor.

Please see STP Procedure SA-700 Handbook, Section 4.4.1.2, Evaluation Criteria.

Recommendation: The Review Team recommends that Minnesota revise its Agreement application to address the comments on inspection program elements.

4.5 Enforcement Program Elements

Review Team Comments: No comments were provided on this section.

4.6 Technical Staffing and Training Program Elements

Review Team Comments:

1. Section 4.6.1 of the Minnesota application provides information on the Minnesota staff and their training. Subsequent to this submittal, we were informed that the Radiation Specialist 1 (Johnson), left the program. Section 4.6 of the Minnesota application should be revised to reflect that Ms. Johnson is no longer with the Minnesota Program and that there is a vacant position (e.g., revise the organizational chart for the Radioactive Materials Group and the Professional Staff Assignments). Please provide further information on the status of this newly vacant position. For example, has a vacancy announcement been prepared for this position.

2. In Section 4.6.1 of the Minnesota application, the "Professional Staff Assignments" and the organization chart, indicated that five professional staff are assigned to the proposed Agreement Program along with one supervisor. However, the "Staff Needs Analysis" provides staffing support from only three individuals, who will be providing a 2.4 staff effort (0.8x3) to the Agreement Program. Please provide information on the overall FTE allocated to the Minnesota Agreement Program. This information should include a breakdown of the individual FTE effort provided by the Radiation Specialist 3 (McClanahan), and the Environmental Health Supervisor (Johns). In addition, please clarify the FTE for administrative support provided to the proposed Agreement program. Although this information has been provided informally to the NRC, the Minnesota application should be revised to include this information.

3. Section 4.6.2 of the Minnesota application provided the *MDH Licensing and Inspection Qualification Journal.* The journal does not provide any time frames for completion of staff training. The STP Procedure SA-700 Handbook, Sections 4.6.2.2 Evaluation Criteria indicates that the qualification journal should specify the time frame for completing requirements. Although this information has been provided informally to the NRC, the Minnesota application should be revised to include this information.

4. Section 4.6.3 of the application provided Current Technical Staff Qualification. This section should be updated to reflect the "on-the-job" training of Minnesota staff who accompanied State of Iowa and NRC inspectors. Although this information has been provided informally to the NRC, the Minnesota application should be revised to include this information.

5. Section 4.6.3 of the application should be updated to reflect the State's request to the NRC Region III Office for practical licensing training of their material licensing reviewers. Any updates on the status of this training should be included in the State's revisions.

Please see STP Procedure SA-700 Handbook, Sections 4.6.2.1, Information Needed and 4.6.2.2, Evaluation Criteria.

Recommendation: The Review Team recommends that Minnesota revise its Agreement application to address the comments on the technical staffing and training program elements.

4.7 Event and Allegation Response Program Elements

Review Team Comments:

1. Section 4.7.1 of the application did not reference nor did it include a copy of the Minnesota procedure "*Response Manual for Allegations.*" Section 4.7.1 should be revised to include a copy of the procedure and references to the procedure.

Recommendation: The Review Team recommends that Minnesota revise its Agreement application to include a copy of its allegations procedure.

From: Marc Dapas
To: Cardelia Maupin
Date: 10/8/04 3:36PM
Subject: Review of Minnesota Application for an Agreement

Per our discussion this afternoon of the changes you made to the subject document to address my comments, you have my concurrence on the document. Thanks.

Ms. Linda Bruemmer, Manager
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After you have an opportunity to review our comments, we would welcome an opportunity to discuss our comments, and answer any questions. Please contact me at (301) 415-3340 or Cardelia Maupin at (301) 415-2312.

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Office of State and Tribal Programs

Enclosures:
As stated

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Distribution:

DIR RF	DCD (SP08) PDR (YES)
BUsilton, STP	JZabko, STP
JLynch, RSAO-III	MDapas, R-III
RJolliffe, NSIR IRD	UBhachu, NMSS
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Response to Incoming Document: ML041960496

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