

Protecting, maintaining and improving the health of all Minnesotans

August 13, 2007

Linda McLean Regional State Agreement Officer Division of Nuclear Safety US Nuclear Regulatory Commission, Region IV 611 Ryan Plaza Drive, Suite 400 Arlington, Texas 76011-4005

Dear Ms. McLean:

Subject: Integrated Materials Performance Evaluation Program (IMPEP) Questionnaire

Attached is the Minnesota Department of Health's response to the IMPEP Questionnaire. As indicated in the response, the only Non-Common Performance Indicator is Item I, which is Legislation and Program Elements Required for Compatibility.

Also, as requested, an appointment has been established with the John Linc Stine, Environmental Health Director. Mr. Stine is also the State Liaison Officer. That meeting is scheduled for 9:00 AM on October 19, 2007.

If you have any questions concerning Minnesota's response, please contact me at (651) 201-4602 or George F. Johns, Jr. at (651) 201-4530.

Sincerely,

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Thomas P. Hogan, Manager Indoor Environments and Radiation 625 Robert Street North PO Box 64975 St. Paul, Minnesota 55164-0975

George



UNITED STATES NUCLEAR REGULATORY COMMISSION REGION IV 611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TEXAS 76011-4005

July 19, 2007

Mr. Tom Hogan Minnesota Department of Health Division of Environmental Health Section of Indoor Environments & Radiation P.O. Box 64975 St. Paul. MN 55164-0975

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Dear Mr. Hogan:

As you are aware, NRC is using the Integrated Materials Performance Evaluation Program (IMPEP) for the evaluation of Agreement State Programs. Per my discussion with you, I will be the team leader for the IMPEP review of the Minnesota program scheduled for October 15-19, 2007. The team will also include Jim Lynch from NRC Region III, Elizabeth Ulrich from NRC Region I, and Tobias Lickerman from the State of New York.

Enclosed is the document, "Integrated Materials Performance Evaluation Program Questionnaire." The questionnaire was previously furnished to you electronically. I ask that you send your responses electronically to me at mlm1@nrc.gov by September 15, 2007. I am sending the document in advance of the IMPEP review in order to provide time for you to allocate the staff resources necessary to complete the document by the due date. Part A of the questionnaire contains questions on the common performance indicators. Part B contains questions on the non-common performance indicators for Agreement States.

Also included with the questionnaire is the document "Materials Requested to Be Available for the Onsite Portion of an IMPEP Review." We encourage States to have the items listed prepared prior to the IMPEP team's arrival.

I request that you set up an appointment with the appropriate State Senior Management Official(s) to discuss the results of the IMPEP review of the Minnesota program in the morning of October 19, 2007.

If you have any questions, please call me at (817) 860-8116. Thank you for your cooperation.

Sincerely,

Linda McLean

Linda McLean Regional State Agreements Officer Division of Nuclear Materials Safety

Enclosure: As stated

Approved by OMB¹ No. 3150-0183 Expires 8/31/07

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

QUESTIONNAIRE

State of Minnesota

Reporting Period: February 3, 2006 to October 12, 2007

Note: If there has been no change in the response to a specific question since the last IMPEP questionnaire, the State or Region may copy the previous answer if appropriate. Please note that previous IMPEP questionnaires responses can be found on the STP webpage.

A. COMMON PERFORMANCE INDICATORS

I. Technical Staffing and Training

- 1. Please provide the following organization charts, including names and positions:
 - (a) A chart showing positions from Governor down to Radiation Control Program Director;
 - (b) A chart showing positions of current radiation control program including management; and
 - (c) Equivalent charts for sealed source and device, low level radioactive waste and uranium recovery programs, if applicable
- 2. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) person-years of effort applied to the agreement or radioactive material program by individual. Include the name, position, and, for Agreement States, the fraction of time spent in the following areas: administration, materials licensing & compliance, emergency response, LLW, U-mills, other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program. Include all vacancies and identify all senior personnel assigned to monitor work of junior personnel. If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts. The table heading should be:

¹ Estimated burden per response to comply with this voluntary collection request: 53 hours. Forward comments regarding burden estimate to the Records Management Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0183), Office of Management and Budget, Washington, DC 20503. If an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection. At a minimum, the list should include the following information for each inspection that is overdue or conducted overdue during the review period:

- (1) Licensee Name
- (2) License Number
- (3) Priority
- (4) Last inspection date or license issued date if initial inspection
- (5) Date Due
- (6) Date Performed
- (7) Amount of Time Overdue
- (8) Date inspection findings issued
- 11. If you have any overdue inspections, do you have an action plan for completing them? If so, please describe the plan or provide a written copy with your response to this questionnaire.
- 12. Please provide the number of reciprocity licensees that were candidates for inspection per year as described in NRC IMC 1220 and the number of candidate reciprocity inspections that were completed each year during the review period.

III. Technical Quality of Inspections

- 13. What, if any, changes were made to your written inspection procedures during the reporting period?
- 14. Prepare a table showing the number and types of supervisory accompaniments made during the review period. Include:

	Inspector	<u>Supervisor</u>	License Category	Date
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- 15. Describe internal procedures for conducting supervisory accompaniments of inspectors in the field.
- 16. Describe or provide an update on your instrumentation, methods of calibration and laboratory capabilities. Are all instruments properly calibrated at the present time? Were there sufficient calibrated instruments available through the review period?
- IV. Technical Quality of Licensing Actions
 - 17. How many specific radioactive material licenses does the Program regulate at this time?

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26. Provide a brief description of your program's strengths and weaknesses. These strengths and weaknesses should be supported by examples of successes, new initiatives, problems or difficulties which occurred during this review period.

B. NON-COMMON PERFORMANCE INDICATORS

I. Legislation and Program Elements Required for Compatibility

- Please list all currently effective legislation that affects the radiation control program.
- 28. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.
- 29. Please review and verify that the information in the enclosed State Regulation Status sheet is correct. For those regulations that have not been adopted by the State, explain why they were not adopted, and discuss actions being taken to adopt them.

If legally binding requirements were used in lieu of regulations, please describe their use.

30. If you have not adopted all amendments within three years from the date of NRC rule promulgation, briefly describe your State's procedures for amending regulations in order to maintain compatibility with the NRC, showing the normal length of time anticipated to complete each step.

II. Sealed Source and Device Program

31. Prepare a table listing new and amended (including transfers to inactive status) SS&D registrations of sealed sources and devices issued during the review period. The table heading should be:

SS&D	Manufacturer,			
Registry	Distributor or	Product Type	Date	Type of
Number	Custom User	<u>or Use</u>	Issued	Action

- 32. What guides, standards and procedures are used to evaluate registry applications?
- 33. Please include information on the following questions in Section A, as they apply to the Sealed Source and Device Program:

MATERIALS REQUESTED TO BE AVAILABLE FOR THE ONSITE PORTION OF AN IMPEP REVIEW

Please have the following information available for use by the IMPEP review team when they arrive at your office:

- List of open license cases, with date of original request, and dates of follow up actions
- List of licenses terminated during review period.
- Copy of current log or other document used to track licensing actions
- Copy of current log or other document used to track inspections
- List of Inspection frequency by license type
- □ List of all allegations occurring during the review period. Show whether the allegation is open or closed and whether it was referred by NRC

ALSO, PLEASE HAVE THE FOLLOWING DOCUMENTS AVAILABLE:

	All State regulations
	Statutes affecting the regulatory
	authority of the state program
D	Standard license conditions
	Technical procedures for licensing,
. '	model licenses, review guides
D	SS&D review procedures
D	Instrument calibration records
	Inspection procedures and guides
	Inspection report forms

- Records of results of supervisory accompaniments of inspectors
 Emergency plan and communications list
 Procedures for investigating
- Procedures for investigating allegations
- Procedures for investigating incidents
- Enforcement procedures, including procedures for escalated enforcement, severity levels, civil penalties (as applicable)
- Job descriptions

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NRC Chronology Identification	-R Notice State Due Date)	D D	Proposed (P) Final (F) Rule / License Condition L(C) ML #	NRC Review / Y, N ⁸ / Date / ML # ⁰	Final State Regulation (Effective Date)
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 ML050140452	03/04/05° ML050690100	
Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for	59 FR 61767; 59 FR 65243; 60 FR 322: (1/1/98)	1995-1	F ML050140452	03/04/05° ML050690100	
Medical Use-Parts 30, 32, 35 Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2	F ML050140452	03/04/05 ⁶ ML050690100	
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983; (3/1/98)	1995-3	F ML050140452	03/04/05 ⁶ ML050690100	
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	F ML050140452	03/04/05 ⁶ ML050690100	
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F ML050140452	03/04/05 ⁶ ML050690100	
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F ML050140452	03/04/05 ⁶ ML050690100	
35	60 FR 48623; (10/20/98)	1995-7	F ML050140452	03/04/05 ⁶ ML050690100	
Medical Administration of Kadiation and Kadioacure materials and the second of the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28724; (4/1/99)	1996-1	F ML050140452	03/04/05° ML050690100	
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials	61 FR 1109; (none)	1996-2			Not required ³
Licenses-Parts 30, 40, 70 Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3	F ML050140452	03/04/05 ⁶ ML050690100	

NRC: Chronology Identification	FR Notice (State Due Date)	D RATS .	Proposed (P) / Final (F) Rule / License Condition (LC) ML#	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation (Effective Date)
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	F ML050140452	03/04/05 ⁶ ML050690100	
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; (2/22)	1999-3	F ML050140452	03/04/05 ⁶ ML050690100	
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	F ML050140452	03/04/05 ⁶ ML050690100	
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	F ML050140452	03/04/05 ⁶ ML 050690100	
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	F ML050140452	03/04/05 ⁶ ML050690100	
Revision of the Skin Dose Limit-Part 20	67 FR 16298 (4/5/05)	2002-1	F ML050140452	03/04/05 ⁶ ML050690100	
Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249 (10/24/05)	2002-2	F ML050140452	03/04/05 ⁶ ML050690100	
Financial Assurance for Materials Licensees - Parts 30, 40, 70	68 FR 56327 (12/3/06)	2003-1	P ML070240111	N 03/06/07 ML070650052	

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. ADAMS ML Number

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

By letter dated September 2, 2005, from Paul H. Lohaus, Director, Office of State and Tribal Programs, Agreement States were given 90 days to issue legally binding requirements satisfying the requirements of NRC Order EA-05-090.

A. COMMON PERFORMANCE INDICATORS

I. Technical Staffing and Training

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- 1. Organization Charts
 - (a) Minnesota Department of Health Organization Chart
 - (b) Environmental Health Division Organization Chart
 - (c) Indoor Environments and Radiation Organization Chart







11/06

	X-ray Unit	Kimberly Pappas Environmental Health Supervisor	Marge Shaw Radiation Specialist 2	Bryce Armstrong Radiation Specialist 1	Candance Brown Radiation Specialist 1	Michael Cimaglio Radiation Specialist 1 (M)	Kelly Daigle Radiation Specialist 1 (M)	Jolene Hoepner Radiation Specialist 1	Benjamin Sunderlin Radiation Specialist 1	Tou Xiong Radiation Specialist 1	Lisa Smith Office & Admin. Specialist Sr.	Lisa Shuck Office & Admin. Specialist
Hogan Health Manager	Radioactive Materials Unit	George Johns Environmental Health Supervisor	Sue McClanahan Radiation Specialist 3	Sherrie L. Flaherty Radiation Specialist 2	Craig Verke Radiation Specialist 2	Brandon Juran Radiation Specialist 1	Tim Donakowski Health Physicist 1	Norma Leiand Office & Admin. Specialist				
Tom H Environmental H	Indoor Air Unit	Dale Dorschner Environmental Health Supervisor	Kathy Norlien Environmental Research Scientist	John Olson Industrial Hygienist 2 (Enforcement Coordinator)	Daniel Tranter Research Scientist 2	Joshua Miller Research Scientist 2	Heather Kehn Planner Principal	Tina Leland Office & Admin. Specialist Sr.				
	Asbestos and Lead Compliance Unit	Dan Locher Environmental Health Supervisor	Nancy LaPlante Industrial Hygienist 3	Justine Greene Industrial Hyglenist 3	Greg Boole Industrial Hygienist 2	Daniel Miller Industrial Hygienist 2	Bruce Lange Industrial Hygienist 2	Bob Miles Public Health Sanitarian 2	Linda Nelson Office & Admin. Specialist Sr.	Glenda Tosh Office & Admin. Specialist		

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Indoor Environments and Radiation Division of Environmental Health Minnesota Department of Health

A. COMMON PERFORMANCE INDICATORS

I. Technical Staffing and Training

2. Staffing Plan

Radioactive Materials Staffing Plan					
Name	Position	Area of Effort		TE%	
		Administration	70		
George F. Johns, Jr.	Supervisor	Materials Licensing and Compliance		25	
U ·	^	Emergency Response			5
		Administration (Reciprocity)	10		
Sue M ^c Clanahan	Radiation Specialist 3	Materials Licensing and Compliance		10	
		Emergency Response			- 5
		Administration (Scheduling)	20		
Sherrie Flaherty	Radiation Specialist 2	Materials Licensing and Compliance		75	
-	^	Emergency Response			5
		Administration (Instruments & GLs)	10		
Craig Verke	Radiation Specialist 2	Materials Licensing and Compliance		85	
O		Emergency Response			5
		Administration (Rules)	10		
Brandon Juran	Radiation Specialist 1	Materials Licensing and Compliance		85	
	× .	Emergency Response			5
		Administration	0		an of statistics investigation
Timothy	Health Physicist 1	Materials Licensing and Compliance	nen de la	0	
Donakowski		Emergency Response			5
zzerowenie w zakale i dan da akterikani i interneti i zakale i interneti i interneti i interneti i interneti in		Administration	1.2		
Totals (FTE)		Materials Licensing and Compliance		2.8	
		Emergency Response			0.3

2. The following is a summary of the Radioactive Materials Unit's staffing plan.

3. Staffing in the Radioactive Materials Unit has changed from the staffing indicated in the application for an Agreement State. The plan that was submitted included the following staff:

Susan McClanahan, Radiation Specialist 3 Timothy Donakowski, Health Physicist John Goepferd, Radiation Specialist 2 Craig Verke, Radiation Specialist 2 Brandon Juran, Radiation Specialist 1

As the current Staffing Plan indicates, John Goepferd and Timothy Donakowski are not active in the materials program.

¹ Cyclotrons

Since the application submittal, Brandon Juran has attended all but one core course. He has also attended two specialized courses as indicated in the following table. (The request for the Root Cause/Incident Workshop was misplaced by the NRC. The training is now scheduled for January 2008.)

Core Courses – Brandon Juran	Date
Inspection Procedures (G-108)	03/21/05 - 03/25/05
Licensing Practicing and Procedures (G-109)	03/28/05 - 04/01/05
Applied Health Physics (H-109)	08/01/05 - 08/12/05
Root Cause/Incident Workshop (G-205)	
Inspecting for Performance - Materials Version (G-304)	06/13/06 - 06/15/06
Diagnostic and Therapeutic Nuclear Medicine (H-304)	08/22/05 - 08/26/05
Safety Aspects of Industrial Radiography (H-305)	04/24/06 - 04/28/06
Transportation of Radioactive Material (H-308)	10/24/05 - 10/28/05
Teletherapy and Brachytherapy (H-313)	10/16/05 - 10/20/06
Radiological Emergency Response Operations (RERO)	05/23/05 - 05/27/05
Increased Controls	02/13/06 - 02/17/06
Specialized Courses – Brandon Juran	DATE
Environmental Monitoring for Radioactivity (H-111)	06/13/05 - 06/17/05
Air Sampling for Radioactive Material (H-119)	06/06/05 - 06/10/05

The Radioactive Materials staff has added Sherrie Flaherty, DC. Dr. Flaherty has attended the training indicated below:

Core Courses - Dr. Sherrie Flaherty	Date
Inspection Procedures (G-108)	06/27/05 - 07/01/05
Licensing Practicing and Procedures (G-109)	09/12/05 - 09/16/05
Applied Health Physics (H-109)	08/01/05 - 08/12/05
Root Cause/Incident Workshop (G-205)	$09/17/07 - 09/21/07^2$
Inspecting for Performance – Materials Version (G-304)	06/13/06 - 06/15/06
Diagnostic and Therapeutic Nuclear Medicine (H-304)	08/22/05 - 08/26/05
Safety Aspects of Industrial Radiography (H-305)	04/24/06 - 04/28/06
Transportation of Radioactive Material (H-308)	10/24/05 - 10/28/05
Teletherapy and Brachytherapy (H-313)	10/16/05 - 10/20/06
Radiological Emergency Response Operations (RERO)	05/23/05 - 05/27/05
Increased Controls	10/30/06 - 11/03/06

² Request submitted to NRC on a pay basis.

Specialized Courses – Dr. Sherrie Flaherty	DATE
Environmental Monitoring for Radioactivity (H-111)	06/13/05 - 06/17/05
Air Sampling for Radioactive Material (H-119)	06/06/05 - 06/10/05
Health Physics in Radiation Accidents (REAC/TS)	$08/20/07 - 08/24/07^3$

4. All staff are qualified to conduct inspections and to function as license reviewers. MDH does have a formal training program for radioactive materials staff. The MDH *License Reviewer and Inspector Qualification Journal* follows this page.

5. As previously indicated, Messrs Donakowski and Goepferd have had no role in the radioactive materials program. Although included in the Agreement State application, John Goepferd was not included due to his pending retirement. Timothy Donakowski has been assigned to the Radioactive Materials Unit; however, he functions primarily in the X-ray Unit as an inspector of industrial xray applications. The format for industrial X-ray inspections is more consistent with radioactive materials inspections.

6. There are no vacancies in the Radioactive Materials program.

7. MDH has no oversight board or committee.

³ Training approved and scheduled.

MINNESOTA DEPARTMENT OF HEALTH



LICENSING AND INSPECTION QUALIFICATION JOURNAL



Division of Environmental Health Asbestos, Lead, Indoor Air & Radiation Section Radiation Control Unit

> 1645 Energy Park Drive, Suite 300 St. Paul, Minnesota 55108 (651) 643-2151

January 2005

MINNESOTA DEPARTMENT OF HEALTH LICENSING AND INSPECTION QUALIFICATION JOURNAL

INTRODUCTION

The combination of the Licensing Procedures Manual, Inspection Procedures Manual, Enforcement Applications Manual, and the Qualification Journal form the nucleus of the Unit's Licensing and Inspection program. They provide the basic information necessary to review applications, issue licenses, conduct inspections, and implement any enforcement actions.

POLICY STATEMENT

The Qualification Journal is the tool that documents the license reviewer's and the inspector's qualification progress as well as the steps taken to qualify that individual. This Journal contains an outline of the *minimum* activities expected by the Radiation Control Supervisor and the Section Manager. These activities are classified as the following:

- 1. Formal training
- 2. Self-study
- 3. Accompanied inspections
- 4. Licensing audits

Additional activities may be assigned to augment an employee's professional development.

With the concurrence of the Section Manager, the Radiation Control Unit Supervisor will schedule attendance at the job related NRC sponsored training courses. No person will be expected to attend all the courses in a twelve-month period. However, each employee will have the opportunity to attend all courses. The Section Manager reserves the right to waive the requirement for attendance at any course based on availability and program workload.

US Nuclear Regulatory Commission establishes the content of MDH staff training. The current policy states: "although Agreement States need not follow NRC Inspection Manual, Chapter 1246, they should have an equivalent program for training and qualification of personnel, and it should be present and adhered to in Agreement State programs.¹" Formal training consists of the "core courses" indicated in Sections I and II of the NRC Inspection Manual. These courses represent the minimum formal training requirements established for staff personnel who license and inspect radioactive materials programs.

In addition to the core courses, several "specialized training" courses may be scheduled to expand the staff's technical knowledge. Attendance, which is normally scheduled after employees have completed the core courses and functioned in the job position for a significant period, will be based on the availability of funds; the previous experience of personnel; and on the anticipated requirements of assigned work. The Section Manager will make the determination on an individual basis. For example, a staff member should attend the training if assigned activities in one of the areas for which a formal training course is available. As an alternative, management should ensure that the individual has had equivalent experience.

The self-study portion of this journal consists of a series of questions on each section of the Minnesota Department of Health's rules pertaining to the use of licensed material. These questions test the employee's knowledge of the rules and the thought process needed to effectively review licensing action requests and conduct inspections.

¹ Integrated Materials Performance Evaluation Program (IMPEP) Directive 5.6, Common Performance Indicator 3 – Technical Staff and Training

RADIOACTIVE MATERIAL LICENSE REVIEWER AND INSPECTOR QUALIFICATION JOURNAL

Webster's Collegiate Dictionary defines "journal" as, "A record of current transactions and an account of day-to-day events." Clearly, a journal should not be a massive reference manual. The Qualification Journal used by the State of Minnesota for its radioactive materials license reviewers and inspectors defines areas in which an individual must demonstrate competence. It also provides a record to show how and when this competence was measured or demonstrated. Although this Journal does not include reference material, in some cases it does describe various reference materials employees should study to satisfactorily complete the Journal.

The agreement between the State of Minnesota and the U.S. Nuclear Regulatory Commission (NRC) in accordance with the provisions of subsection 274b of the Atomic Energy Act of 1954 (Act), as amended, determines the minimum training requirements for a radioactive materials inspector. Under the provisions of the Act, the Minnesota Legislature must certify that the State has a program for the control of radiation hazards adequate to protect the public health and safety. The legislature must also affirm the desire to assume regulatory responsibility for those hazards (i.e., become an Agreement State). The Act also requires that the State's program must be adequate to protect the public health and safety with the NRC's program for the regulation of such material and the State's program must be adequate to protect the public health and safety with respect to the materials covered by the Agreement. To implement the requirements of the Act, the NRC routinely interacts with each Agreement State; verifies that compatibility is being maintained; and evaluates the State's program to determine that it is adequate to protect the public health and safety.

One of the important criteria reviewed by the NRC is the level of technical competence of each Agreement State radioactive materials license reviewer and inspector. Since technology and the uses of radioactive material are not static, it is necessary to continually evaluate the skills of Agreement State personnel based on current perceived hazards that exist throughout the radioactive material industry. Hazards exist now that did not exist ten years ago. Both the license reviewer and the inspector should recognize that as industry practices and activities change, there will be additions and revisions to this journal. These changes will require a corresponding update of skills.

PURPOSE

This Qualification Journal establishes the current minimum training requirements required to license and inspect radioactive material facilities in the State of Minnesota. The Journal also is a record that documents the training requirements of the individuals completing those tasks. It is important to note that subsequent training may be required to retain or update those skills.

FORMAT

The Journal documents that various administrative and technical tasks required of the license reviewer and the inspector have been accomplished. It shows that:

- 1. The license reviewer/inspector received an administrative orientation that explains administrative actions of the Department.
- 2. The license reviewer/inspector demonstrated a basic understanding of Information Notices issued by the U.S. Nuclear Regulatory Commission.
- The license reviewer/inspector completed required formal training courses.

TRAINING POLICY

An individual can be qualified to perform license and inspection functions for certain types of licenses while working toward full qualification of all types of licenses issued by MDH. When an individual has demonstrated competency in a particular training area, their training record will be updated to document that competency. An individual will not serve as lead inspector or senior license reviewer unless that individual has demonstrated competency in the program areas applicable to that type of license.

Normally, staff is expected to complete the Core Courses within the two years. Specialized training courses will be scheduled based on employee's schedules, program requirements, and availability of funds.

Because inspector training does not stop with initial qualification, refresher training will be provided as needed. Training will be made available for inspectors and reviewers on a basis of need and availability. Needs assessment should include training necessary to keep current with inspection and licensing program changes as well as changes in technology.

ACADEMIC QUALIFICATIONS

The usual criteria for evaluating technical personnel are academic qualifications. Most assume that more degrees equal greater ability to perform complex technical tasks. Unfortunately, most resumes and job interviewers focus almost entirely on academic qualifications. Little effort is made to evaluate the other areas listed above. This does not imply academic excellence is not important, it obviously is. However, academic excellence or experience without collateral skills (those listed above) will not result in a competent and effective radioactive materials license reviewer or inspector. The qualification objectives³ for entry-level license reviewers and inspectors are:

- Graduation from an accredited college or university with major coursework in a natural science; or
- An equivalent combination of the required education and experience, substituting one year of fulltime professional experience in a radiation or environmental control program for thirty semester hours of education; or
- An equivalent combination of education and full-time experience in radiological technology, nuclear medicine technology or radiation therapy, substituting thirty semester hours or equivalent or one year of full-time experience for one year or thirty semester hours of the required education or experience.

COMMUNICATION SKILLS

Communication is an essential element in the licensing and inspection processes. It is imperative that employees understand the licensee's policies and procedures. However, it is just as important that employees effectively communicate any issues identified during a review or inspection. The license reviewer and the inspector must be able to adequately converse with licensees and transfer information. Good communication skills are essential in the evaluation and assurance of radiological safety programs licensed by MDH.

³ The specific education and experience requirements for employees are included in the position descriptions.

issuing Information Notices. Each Notice describes a problem or concern that relates to equipment failure, design problems, loss of control over radioactive material, etc. More importantly, the Notices describe various solutions and corrective actions that were taken or can be taken to resolve identified problems.

During training, the license reviewers and inspectors may need to refer to some of these Notices. Employees are not expected to review every Notice. However, as a minimum, they should know where to look if a question or concern arises.

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CORE COURSE TRAINING LOG

	COURSE	DATE
1.	Inspection Procedures (G-108)	
2.	Licensing Practicing and Procedures (G-109)	
3.	Applied Health Physics (H-109)	
4.	Root Cause/Incident Workshop (G-205)	
5.	Inspecting for Performance – Materials Version (G-304)	
6.	Diagnostic and Therapeutic Nuclear Medicine (H-304)	
7.	Safety Aspects of Industrial Radiography (H-305)	
8.	Transportation of Radioactive Material (H-308)	
9.	Teletherapy and Brachytherapy (H-313)	
10.	Radiological Emergency Response Operations (RERO)	
11.	Increased Controls	

By signature, the Radiation Control Supervisor certifies that the requirements for Core Course Training have been satisfied.

Supervisor's Signature

Date

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RADIOLOGICAL SAFETY INSPECTION ACCOMPANIMENTS

As part of your on-the-job training, you will accompany other inspectors and observe how they conduct inspections. You will probably have an opportunity to accompany more than one inspector. In this way, you will be able to learn those techniques and methods that best suit your personality and technical skills.

After you have participated in inspections, principally as an observer, you will have an opportunity to prepare for, perform, and document the results of actual inspections while being observed by the Radiation Control Unit Supervisor or a qualified inspector. If it is determined that you are capable of performing a quality inspection for a particular type of licensed program, you will be granted approval for performing that type of inspection without accompaniment. The Inspector Fieldwork Evaluation Report (Appendix A) must be completed and a copy included in this Journal.

As you demonstrate the ability to perform additional types of inspections, these will be added to the types of inspections you can perform without accompaniment. The following kinds of inspections are included in this qualification program:

- 1. Measuring Systems Fixed and Portable Gauges (includes Self-Shielded Irradiators less than 10,000 Curies)
- 2. Medical Institution Diagnostic Only
- 3. Medical Institution Diagnostic & Therapy
- 4. Research and Development
- 5. Broadscope
- 6. Industrial Radiography

In addition to the accompaniments indicated above, the Radiation Control Unit Supervisor or another qualified inspector will make periodic evaluations. These evaluations are to assure consistency within the program. The Inspector Fieldwork Evaluation Report must be completed and a copy incorporated into this Journal.

RADIOLOGICAL SAFETY INSPECTION ACCOMPANIMENTS WITH PARTICIPATION

This log verifies that you have accompanied a qualified inspector on a series of inspections principally as an observer with some participation. This accompaniment included at least one of each type of licensed program described on the previous page.

Licensee	License or Registration Number	Inspection Date	Qualified Inspector
1.	· · · · · · · · · · · · · · · · · · ·		·
2.			· · · · · · · · · · · · · · · · · · ·
3.			
4.			
5.	· · · · · · · · · · · · · · · · · · ·		
6.			
7.			
8.			
9.	· ·		
10.			·
11.			
12.	•		
13.			
14.	•		

EVALUATED RADIOLOGICAL SAFETY INSPECTIONS - ANNUAL ACCOMPANIMENTS

This log documents accompaniments and subsequent evaluation by the Radiation Control Unit Supervisor. Your effort included a review of the license files while preparing for the inspection, the conduct of the inspection, written documentation of the inspection findings, and any enforcement correspondence of findings that resulted from your inspection. A copy of the Inspector Evaluation Form (included in Appendix A) has been completed and placed in this manual.

Licensee	License or Registration Number	Inspection Date	Supervisor's Signature
1.			
2.	· · · · · · · · · · · · · · · · · · ·		
3.			
4.			
5.	· ·		
6.			
7.			
8.			
9.			
10.	· ·	· ·	
11.			
12.			· ·
13.			
14.		<u>.</u>	

APPENDIX A INSPECTOR FIELDWORK EVALUATION REPORT

19

INSPECTOR'S PREPARATION

- 1. Has the inspector reviewed the license and prior compliance history?
- 2. Has the inspector planned the inspection
- 3. Does the inspector have the appropriate instruments?
- 4. Are the instruments in calibration?
- Does the inspector have the necessary supplemental materials? (Regulations, inspection forms, personal dosimetry, ID, wipe materials, smoke tubes and bombs, thermal anemometer, dose calibrator sources, instrument check sources, etc.)

Comments:

IV. OPENING

V.

Ш.

- 1. Was the opening interview conducted with management?
- 2. Were incidents or overexposures discussed?
- 3. Did licensee understand the purpose, scope and techniques?

Comments:

INSPECTION

- 1. Did the inspector use appropriate form or checklist?
- 2. Did the inspector perform a "walk through" at the beginning of the inspection?
- 3. Were licensee operations and use and handling of materials observed?
- 4. Were the facilities checked for proper posting?
- 5 Was security verified?
- 6. Were workers checked for personal dosimetry?
- 7 Were workers interviewed to verify their understanding of safety procedures?
- 8. Were ancillary workers also interviewed?
- 9. Were adequate wipes, surveys, and measurements taken?
- 10. Did inspector check for adherence to ALARA?
- 11. Were records verified against oral statements for
 - a. procurement and inventory
 - b. receipt and transfer of materials
 - c. internal audits
 - d. qualification and training of users
 - e. emergency plan and procedures .
 - f. committee meetings and minutes
 - g. authorized users
 - h. instrument calibration
 - i. dose calibrator tests
 - j. surveys and monitoring
 - k. personnel dosimetry and bioassay
 - I. leak tests
 - m. generator-assay, moly breakthrough and logs
 - n. release of effluents, sewer and air
 - o. management and disposal

		<u> </u>
Yes	L NO	
🗌 Yes	🔲 No	🗌 N/A
🗌 Yes	🗖 No	🗌 N/A
• Yes	🗌 No	🗌 N/A
T Yes	No	N/A

🗌 Yes	🗌 No	🗌 N/A
🗍 Yes	No No	🗌 N/A
🗌 Yes	No 🗌	N/A

🗌 Yes	🗌 No	🗌 N/A
[] Yes	🗌 No	N/A
Yes Yes Yes Yes	No No No No	□ N/A □ N/A □ N/A □ N/A
☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes	No No No No	N/A N/A N/A N/A
 ☐ Yes 	N 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	N/A

ΙX.

Follow-up review

Were all deficiencies addressed?
 Were the corrective actions adequate?

Was the inspection closed out in a timely manner? 3.

Comments:

Yes	🗌 No	🗋 N/A
] Yes	No No	🗌 N/A
Yes	No.	🗌 N/A

A. COMMON PERFORMANCE INDICATORS

II. Status of Materials Inspections

- 8. All MDH Radioactive Materials licenses are being inspected at the frequency listed in IMC 2800.
- 9. The following is a summary of the 2006 and 2007 inspections:

2006: Routine Inspections

Priority 1	4
Priority 2	5
Priority 3	. 5
Priority 5	5
TOTAL	19

Increased Controls Inspections

Priority 1	11
Priority 5	 4
TOTAL	15

Initial Inspections*

Priority 1	0
Priority 2	1 .
Priority 3	1
Priority 5	. 14
TOTAL	16

*All new licenses are inspected within 12 months.

2007: Routine Inspections

TOTAL	21
Priority 5	4
Priority 3	7
Priority 2	5
Priority 1	5

Increased Controls Inspections

Priority 1	2
Priority 5	6
TOTAL	8

Initial Inspections*

Priority 1	0
Priority 2	 0
Priority 3	0
Priority 5	 3
TOTAL	3
	. 1

*All new licenses are inspected within 12 months.

Overdue Inspections:

1.)

2.)

Licensee Name	Acuren Inspection, Inc
License Number	1191-100-89
Priority	1
Last Inspection Date	April 5, 2005 (NRC)
Date Due	April 6, 2006
Date Performed	October 16, 2006
Amount of Time Overdue	3 months
Date Inspection Findings Issued	October 27, 2006

MDH failed to notice the program code provided by the NRC for this industrial radiography license was incorrect. It had been coded as a portable gauge license. Shortly after discovering the error, the facility was inspected. The Region III Agreement State Officer and Federal & State Materials & Environmental Management were informed of the issue.

Licensee Name	Medtronic
License Number	1166-101-27
Priority	5
Last Inspection Date	New License December 29, 2005
Date Due	December 29, 2006
Date Performed	January 31, 2007
Amount of Time Overdue	1 month
Date Inspection Findings Issued	February 6, 2007

On January 30, 2007, MDH identified another overdue inspection. MDH failed to recognize that the NRC had issued a new license to Medtronic, Inc. (License number 1166-101-27, priority 5) on December 29, 2005. An inspection was done January 31, 2007, one month overdue.

11. MDH currently has no overdue inspections.

12. **Reciprocity Inspections**

2006 Reciprocity

Priority 1, 2, and 3	9
Priority 5	20
TOTAL	29
Reciprocity Inspections	

corbroord mobelling		
Priority 1, 2, and 3	4	(44.4%)
Priority 5	4	(20.0%)
TOTAL	8	(27.6%)

10.

2007 Reciprocity (as of July 31, 2007) Reciprocity Licensees Entering Minnesota

proond and and and a second and a	
Priority 1, 2, and 3	5
Priority 5	18
TOTAL	23

4	(80.0%)
6	(33.3%)
10	(43.5%)
	4 6 10

A. COMMON PERFORMANCE INDICATORS

III. Technical Quality of Inspections

In addition to creating inspection reports for the initial inspections for Increased Controls and an inspection report for Cyclotrons, virtually all inspection reports have been modified for format and/or content within the past year. Inspection reports are frequently modified to address issues identified during inspections. For example, to address concerns that inspection staff were not correctly identifying the postings at temporary industrial radiography jobsites, the report was modified to require a sketch of the setup.

Industrial radiography and Gamma Knife inspection reports were modified to incorporate Increased Controls. The Fixed Gauge inspection report is currently being modified to address Increased Controls for Pu:Be gauges that exceed the Quantities of Concern.

Medical inspection reports were modified to match current rules.

Because the staff has had limited experience in inspecting radioactive materials 14. programs, the majority of the supervisory accompaniments were conducted for training. As such, they were informal and the MDH Inspector Evaluation Forms were not completed. In addition, several of the unevaluated accompaniments were to audit the Increased Controls inspections during the inspection development process.

The following table summarizes the supervisory accompaniments completed since becoming an Agreement State. Note: Included in the accompaniments are several team inspections. The accompaniments were intended to evaluate staff interaction during inspections of larger radiological programs.

Supervisory Accompaniments by George F. Johns, Jr.				
License Number	Licensee Name	Type of License or Inspection	Date	
	Brandon Juran			
1001	North Valley	Portable Gauge	07/10/06	
1030	Valley Paving	Portable Gauge	07/10/06	
1047	Mayo Clinic IC	Increased Control	11/16/06	
1007	Abbott Northwestern Hospital	Medical – Diagnostic and Therapy	01/10/07	
1069	Stork Twin Cities Testing	Industrial Radiography	01/13/07	
1049	University of Minnesota - Gamma Knife IC	Increased Control	01/29/07	

13.

1164	Hennepin County Medical Center	Medical – Diagnostic and Therapy	02/06/07
1042	HealthEast Woodwinds Hospital ¹	Medical - Diagnostic	07/11/07
	Sherrie F	laherty, DC	
 Martin L. Sandari, A. Sandari, S. Sandari, Sandari, S. Sandari, S. Sandari, S. Sandari, S. Sandari, S			
1052	Park Nicollet- Methodist	Decommissioning	06/07/06
1055	North Memorial	Medical – Diagnostic and Therapy	06/05/06
1009	Mobile Imaging	Mobile Medical	06/29/06
1002	Northern Shared Medical	Mobile Medical	07/12/06
1075	Chart Industries	Industrial Radiography	07/13/06
1186	Midwest Industrial X-ray	Industrial Radiography	07/20/06
1047	Mayo Clinic IC	Increased Controls	11/16/06
1048	SMDC	Medical – Diagnostic and Therapy	12/6-7/06
1025	Immanuel St. Joseph's	Medical – Diagnostic and Therapy	12/19/06
1007	Abbott Northwestern Hospital	Medical – Diagnostic and Therapy	01/10/07
1164	Hennepin County Medical Center	Medical – Diagnostic and Therapy	02/06/07
1023	Mallinckrodt ²	Nuclear Pharmacy	08/09/07
	Crai	g Verke	
1070	Stork Twin Cities Testing	Portable Gauge	06/22/06
1015	City of Minneapolis	Portable Gauge	07/14/06
1082	Braun Intertec	Industrial Radiography	10/16/06
1191	Acuren	IC and Industrial Radiography	10/17/06
1047	Mayo Clinic IC	Increased Controls	11/16/06
1025	Immanuel St. Joseph's Hospital	Medical – Diagnostic and Therapy	12/19/06
1007	Abbott Northwestern Hospital	Medical – Diagnostic and Therapy	01/10/07
1164	Hennepin County Medical Center	Medical – Diagnostic and Therapy	02/06/07
1037	Cardinal Health ³	Nuclear Pharmacy	07/25/07

- 15. Supervisory accompaniments are conducted similar to NRC accompaniments during the Integrated Materials Performance Evaluation Program. The supervisor has no role in the inspection except to audit the inspector. At the conclusion of the inspection, the inspector is provided feedback on his or her performance. Further feedback is provided when the inspection report has been completed and peer reviewed.
- 16. MDH maintains a sufficient number of detectors and dosimeters to meet the normal activities of the Unit as well as any potential emergency response requirements. Included in the inventory are a neutron detector, two alpha
- ¹ Formal evaluation completed
- ² Formal evaluation completed
- ³ Formal evaluation completed
detectors, and two 2" NaI scintillation detectors. MDH has four hand-held instruments for gamma spectrometry. Two of the instruments have a medical library. The other two have an industrial library of radionuclides. To facilitate the identification of low activity radionuclides, an InSpector 1000 was purchased. In addition, MDH recently purchased two NDS instruments so that inspectors could more accurately complete side-by-side comparisons to the instruments used by most industrial radiographers.

MDH has implemented a program that provides Emergency Response Kits to state responders. The loan program ensures that the MnDOT Hazardous Materials Inspectors and the State Patrol Commercial Vehicle Inspection Section staff have up-to-date equipment to assess radiological hazards. Included in the Response Kits are a Ludium 2241-2 scaler, a pancake probe, and a 1" NaI scintillation detector.

			Last
Instrument	Model	Serial Number	Calibration
Manufacturer		254600	11/14/2006
ICN	DMC2000A	254090	11/14/2000
ICN	DMC2000X	267295	11/14/2006
ICN	DMC2000X	258846	8/21/2006
ICN	DMC2000X	258862	8/21/2006
Exploranium	GR-135 Minispect	2595	11/27/2006
Exploranium	GR-135 Minispect	2596	4/6/2007
Exploranium	GR-130 Minispect	9612	11/27/2006
Exploranium	GR-130 Minispect	9913	4/9/2007
NDS Products	RA-500	44036	4/6/2007
NDS Products	RA-500	44037	4/6/2007
NDS Products	RA-500	44038	9/5/2006
NDS Products	RA-500	44039	9/5/2006
NDS Products	ND-2200	55872	4/17/2007
NDS Products	ND-2200	55873	4/17/2007
Victoreen	190	107367	5/8/2007
Victoreen	190	107737	8/17/2006
Victoreen	190	107738	11/15/2006
Victoreen	450P	1126	8/17/2006
Victoreen	450P	2363	8/17/2006
Victoreen	450P	2378	5/5/2007
Victoreen	450P	2381	4/6/2007
Ludlum	2241-2	217968	2/23/2007
Ludlum	2241-2	217822	2/23/2007
Ludlum	2241-2	217896	4/6/2007

The following table summarized the Radioactive Materials Unit's instrumentation.

н. Талана (1997)	Ludlum	· 22/1 2	217853	8/22/2006
\mathcal{L}	Ludium	2241.2	217805	11/15/2006
	Luuluin	2241-2	217021	11/1/2006
	Ludium	2241-2	220410	11/1/2006
	Lucium	2241-2	220293	0/10/2006
		2241-2	232001	9/19/2000
	Lucium	2241-2	232007	9/19/2000
	Lualum	2241-2	232708	9/19/2000
	Lucium	2241-2 2019 - 2019 - 2019 - 2019 - 2019 - 2019 - 2019 - 2019 - 2019 - 2019 - 2019 - 2019 - 2019 - 2019 - 2019 - 2019	241180	5/20/2007
· .	Lucium	2241-3	228168	11/1/2006
		2241-3	220224	2/23/2007
	Ludium	2241-3	220176	4/9/2007
	Ludium	2241-3	220152	8/22/2006
	Lucium	2241-3	220193	11/15/2006
· ·	Ludium	2241-2 w/ AC-3 probe (457975) and NaI probe model SPA-4 (159)	228381	11/14/2006
	Ludlum	2241-2 w/ AC-3 probe (457979) and NaI probe model SPA-4 (160)	228391	11/14/2006
	Radiation Alert	Inspector	5588	8/18/2006
	Radiation Alert	Monitor 5	2561	11/14/2006
	Radiation Alert	Monitor 4/4EC	-31663	11/14/2006
2	Radiation Alert	Monitor 4/4EC	31784	11/14/2006
н. Табрата (1997)	Radiation Alert	Monitor 4/4EC	31896	11/14/2006
	Radiation Alert	Monitor 4/4EC	38564	11/14/2006
	Canberra	InSpector 1000	11063990	11/01/06
	Reuter-Stokes	100 mR/hr HPIC	N-4510	11/10/2000
	Reuter-Stokes	100 mR/hr HPIC	N-4518	2/1/1999
ан сайтаан ал айсан а Айсан айсан айс	Eberline	NRD with	RN 014279	11/30/2006
		Ludlum 2241-2	232688	
	Dosimeter Corp.	611	9124754	11/14/2006
	Dosimeter Corp.	611	9124767	11/14/2006
	Dosimeter Corp.	611	9124783	11/14/2006
	Dosimeter Corp.	611	9124781	4/9/2007
	Dosimeter Corp.	611	9124787	4/9/2007
	Dosimeter Corp.	611	9124795	4/9/2007
	Dosimeter Corp.	862	4010818	11/14/2006
	Dosimeter Corp.	862	4010820	11/14/2006
	Dosimeter Corp.	862	4010831	11/14/2006
	Dosimeter Corp.	862	4010832	11/14/2006
	Dosimeter Corp.	862	4010833	11/14/2006
	Dosimeter Corp.	862	4010835	11/14/2006
	Dosimeter Corp.	862	4010838	11/14/2006
	u			

Dosimeter Corp.	862	8101121	4/9/2007
Dosimeter Corp.	862	8101122	4/9/2007
Dosimeter Corp.	862	8101123	4/9/2007
Dosimeter Corp.	862	8101124	4/9/2007
Dosimeter Corp.	862	8101125	4/9/2007
Dosimeter Corp.	862	8101126	4/9/2007
Dosimeter Corp.	862	8101127	4/9/2007
Dosimeter Corp.	862	8101128	4/9/2007
Dosimeter Corp.	862	8101130	4/9/2007
Dosimeter Corp.	862	8101131	4/9/2007
Dosimeter Corp.	862	8101132	4/9/2007
Dosimeter Corp.	862	8101133	4/9/2007
Dosimeter Corp.	862	8101134	4/9/2007
Dosimeter Corp.	862	8101135	4/9/2007
Dosimeter Corp.	862	8101136	4/9/2007
Dosimeter Corp.	862	8101137	4/9/2007
Dosimeter Corp.	862	8101138	4/9/2007
Dosimeter Corp.	862	8101139	4/9/2007
Dosimeter Corp.	862	8101140	4/9/2007
Dosimeter Corp.	862	9101882	4/9/2007
Eberline	E-520 w/ HP 270 probe	4115	Reserve
Eberline en e	E-520 w/ HP 270 probe	2242	Reserve
Eberline	E-520 w/ HP 270 probe	4112	Reserve
Eberline	E-520 w/ HP 270 probe	2233	Reserve
Eberline	E-520 w/ HP 270 probe	2245	Reserve

The majority of the instruments are calibrated by the Iowa Calibration Facility, which is a part of the Iowa Homeland and Emergency Management Division. Some instruments are calibrated by the manufacturer.

A. COMMON PERFORMANCE INDICATORS

IV. Technical Quality of Licensing Actions

- 17. At the present time, the Radiation Control Unit has 187 active licenses.
- 18. Since assuming authority for radioactive materials, MDH has not issued any major, unusual, or complex licenses or amendments. The initial licensing effort was directed at facilities using Radium-226. That was followed by the effort to convert NRC licenses. In addition to license amendments, subsequent licensing efforts have been to make the licenses more consistent.

MDH has not terminated any licenses of significance; has not completed a major decommissioning action; processed a license requiring bankruptcy notification; or completed a license renewal.

MDH did, however, expend considerable time attempting to resolve the list of registered general licensees. The NRC provided a list of 108 general licensees. Of that number, MDH was able to determine that 65 facilities currently have generally licensed devices. Because five facilities and their licensed devices could not be located, MDH has sent letter to all suppliers and manufacturer's of generally licensed devices in a last ditch attempt to locate the material that cannot be located. The disposal of gauges for three of the five facilities has been documented based on the response to that letter.

- 19. MDH has issued one variance. The Minnesota Department of Health (MDH) reviewed and approved a request from the University of Minnesota deviate from License Condition 17 of the MDH Radioactive Materials License, which prohibits opening, sealed sources or removing sealed sources from the source holders. The purpose of this variance was to allow the University of Minnesota to remove sources in density/moisture testing gauges in storage for pickup and final disposal by the Los Alamos National Lab, Office of Source Recovery Program (OSR). The variance only covered sources scheduled to be picked up by OSR on December 5, 2006. The University of Minnesota was required to follow the procedures outlined in the variance request dated November 16, 2006, including the attached manufacturer's procedures. Specifically:
 - For the 503 DR probe assembly the licensee was prohibited from removing or attempting to remove the source from the carbide cup.
 - For CPN gauges with a Cesium-137 source or a combination Cesium-137 and Americium-241/ Beryllium source at the end of the source rod, the licensee was prohibited from cutting the rod at or below the rod tip weld.
 - For CPN gauges with an Americium-241/ Beryllium source in the gauge bottom pan the licensee was prohibited from removing or attempting to remove the source from the carbide cup.

The variance expired on December 8, 2006, at which time source removal was again prohibited under License Condition 17 of MDH Radioactive Materials License 1049-201-27.

20. During the reporting period, MDH incorporated by license condition the transportation changes implemented by the NRC, the security requirements for portable gauges equivalent to 10 CFR 30.34, the requirements in 10 CFR Part 35, and, of course, the conditions concerning Increased Control.

MDH has revised the medical use regulatory guides as well as the nuclear pharmacy guide to reflect the changes in the NRC's corresponding guidance documents. In addition, MDH has developed a regulatory guide for cyclotrons using NUREG-1556 Volume 21 as a resource. In addition, MDH created and updated as appropriate the following documents:

- Preceptor Statements (Form 313),
- Registration of Generally Licensed Devices (Form11), and
- In Vitro Testing under General License (Form 483).

MDH implemented the *Checklist to Ensure That Radioactive Materials Will Be Used as Intended* for all licensing actions.

21. MDH has not received any renewal applications.

A. COMMON PERFORMANCE INDICATORS

V. Responses to Incidents and Allegations

- 22. MDH has reported all reportable incidents.
- 23. All of the seven incidents submitted for inclusion in the Nuclear Materials Event Database (NMED) were related to procedural issues. None involved equipment failure.

To ensure that problems have been communicated to the NRC and other Agreement States, the incidents have been entered into the Nuclear Materials Event Database (NMED). The following table lists the NMED entries. Full reports of each event are appended to this section.

NMED	License	Licensee
Item Number	Number	
060428	1035	University of Minnesota Fairview Riverside
060638	1066	3M
060711	GL	Seagate Technology
060752	1066	3M
070178	1112	Sappi Fine Paper
070179	1047	Mayo Clinic
070230	1025	Immanuel St. Joseph's Hospital

24. The Radioactive Materials Unit has received no allegations and has made no changes to the procedure for handling those issues.

NMED Item Number: 060428

Narrative:

Last Updated: 09/06/2006

The licensee reported the loss of 10 (and recovery of 3) Best Industries Pd-103 brachytherapy seeds (model 2335), each containing an activity of 46.25 MBq (1.25 mCi). At the end of a patient implant procedure, the Mick applicator with a Mick cartridge attached that contained 10 seeds was placed on a scrub table. The Mick cartridge was incorrectly removed from the applicator. The top portion of the cartridge was unscrewed and removed, rather than being removed as a single unit. As a result, the bottom portion of the cartridge was inadvertently left in the applicator. The top portion was placed in the lead pig and handed to the physicist. Ten seeds were left in the bottom portion of the cartridge, still in the applicator. The proper seed count within the lead pig was not verified. The room and patient were surveyed and documentation completed, although the seed count was incorrect. The physician's equipment, including the applicator, was removed for cleaning. The lead pig was checked into Nuclear Medicine and a log of the number of seeds returned was recorded. Approximately one hour later, the nuclear medicine technologist noticed that ten seeds were missing. She contacted the physician and physicist. The physician's clean equipment was checked and the bottom half of the cartridge was found without any seeds. Three seeds were recovered from the operating room sink. The sink drain was disassembled, but no more seeds were recovered.

Event Date:	Discovery Date:	Report Date:
06/30/2006	06/30/2006	07/28/2006

Licensee/Reporting Party Information:

Regulated By:	AGREEMENT STATE	Reciprocity:	NONE
License Number:	MN-1035-200-37	Name:	UNIVERSITY OF MINNESOTA FAIRVIEW RIVERSIDE
Docket Number:	NA	City:	MINNEAPOLIS
Program Code:	NA	State:	MN
Responsible NRC Region:	3 `		

Site of Event:

Site Name: MINNEAPOLIS State: MN

Additional Involved Party:

License Number:	NA	City:	NA	
Name:	NA	State:	NA	

Other Information:

NRC Reportable Event:	Y	Abnormal Occurrence:	Ν
Agreement State Reportable Event:	Y	Investigation:	Y
Atomic Energy Act Material:	Y	Record Complete:	Y
Consultant Hired:	Ν	Event Closed by Region/State	:: Y

Event Cause:

LAS - LOST/ABANDONED/STOLEN Cause: MANAGEMENT DEFICIENCY

Corrective Actions Information:

LAS Number: Corrective Action:

1 NEW PROCEDURE WRITTEN

Source/Radioactive Material Information:

Source Number:	1	
Source/Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide:
Manufacturer:	BEST INDUSTRIES	Activity (Ci):

PD-103 0.0125

Leak Test Results (uCi):

NA

Model Number:2335Serial Number:AGGREGATE

Reporting Requirement Information:

LAS

Reporting Requirement: 20.2201(a)(1)(ii) - Lost, stolen, or missing licensed material in a quantity greater than 10 times the Appendix C quantities.

Keywords:

LAS

Keyword: MATERIAL LOST AND PARTIALLY FOUND

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN42679	07/05/2006		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
MN060003	09/06/2006		AGREEMENT STATE EVENT REPORT

NMED Item Number: 060638

Narrative:

Last Updated: 10/17/2006

The licensee reported the loss of an H-3 foil source with an activity of 22.2 GBq (600 mCi). The source was part of a 3M static electricity measuring meter (model H-3 Static Meter), but was separated from the device at some time. The source was determined missing in the afternoon of 9/5/2006. Swabs taken that day and analyzed in a liquid scintillation detector revealed low levels of contamination. Clean-up of the contaminated area commenced the day of discovery and was complete within 24 hours. Contamination was not severe and only a portion of the facility was affected. Wipe tests of the meter revealed maximum readings of 2.59 kBq (70 nCi). The meter did not require leak testing and was inventoried at six month intervals. However, it is not known when the source was lost. The licensee believes that the source separated from the wand, was picked up during routine cleaning, and was disposed of in regular trash. Dose estimates conducted by the licensee projected internal exposure(s) to any individual of less than 10 uSv (1 mrem). Corrective actions taken by the licensee included completion of a visual inspection of all 50 static meters to determine all sources are present, returning all static meters to 3M Corporate Health Physics to ensure H-3 sources are strongly adhered to their mountings, and modifying procedures to visually inspect the presence of the foil source following reassembly of the source cone (source holder). The Minnesota Department of Health investigated the incident on 9/7/2006.

Event Date:	Discovery Date:	Report Date:
09/05/2006	09/05/2006	09/06/2006

Licensee/Reporting Party Information:

Regulated By:	AGREEMENT STATE	Reciprocity:	NONE
License Number:	MN-1066-100-62	Name:	3M CO.
Docket Number:	NA	City:	SAINT PAUL
Program Code:	NA	State:	MN
Responsible NRC Region	: 3		

Site of Event:

Site Name: SAINT PAUL State: MN

Additional Involved Party:

License Number: NA City: NA Name: NA State: NA

Other Information:

NRC Reportable Event:	Y	Abnormal Occurrence:	Ν
Agreement State Reportable Event:	Y	Investigation:	Y
Atomic Energy Act Material:	Y	Record Complete:	Y
Consultant Hired:	N	Event Closed by Region/State:	Y

Event Cause:

1

EOP - EQUIPMENT Cause: DEFECTIVE OR FAILED PART LAS - LOST/ABANDONED/STOLEN Cause: DEFECTIVE OR FAILED PART

Contributing Factors Information: EOP Number: Contributing Factor: LOSS OF ADMINISTRATIVE CONTROL LAS Number: Contributing Factor:

LOSS OF ADMINISTRATIVE CONTROL 1

Corrective Actions Information: EOP

https://nmed.inl.gov/show item.asp?item no=060638

Number: Corrective Action:

1 PROCEDURE MODIFIED

2 ENGINEERING CHANGE TO SYSTEM

LAS

Number: Corrective Action:

1 PROCEDURE MODIFIED

2 ENGINEERING CHANGE TO SYSTEM

Source/Radioactive Material Information: EOP

Source Number: 1 Source/Material: SEALED SOURCE GAUGE Radionuclide: H-3 Manufacturer: SAFETY LIGHT CORP. Activity (Ci): 0.6 Model Number: LAB-508-3 Leak Test Results (uCi): NA Serial Number: NR LAS Source Number: 1 Source/Material: H-3 SEALED SOURCE GAUGE Radionuclide: Manufacturer: SAFETY LIGHT CORP. Activity (Ci): 0.6 Model Number: LAB-508-3 Leak Test Results (uCi): NA Serial Number: NR

Device/Associated Equipment Information:

EQP			
Device Number:	1		
Device/Equipment:	GAUGE PORTABLE	Model Number:	H-3 STATIC METER
Manufacturer:	3M CO.	Serial Number:	NR

LAS

Device Number:	1	,	
Device/Equipmemt:	GAUGE PORTABLE	Model Number:	H-3 STATIC METER
Manufacturer:	3M CO.	Serial Number:	NR

Reporting Requirement Information:

Reporting Requirement: 30.50(b)(2) - Equipment is disabled or fails to function as designed.

LAS

Reporting Requirement: 20.2201(a)(1)(ii) - Lost, stolen, or missing licensed material in a quantity greater than 10 times the Appendix C quantities.

Keywords:

LAS Keyword: MATERIAL LOST AND NOT FOUND

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
MN060004	10/17/2006		AGREEMENT STATE EVENT REPORT

https://nmed.inl.gov/show item.asp?item no=060638

EQP

Page 1 of 4

NMED Item Number: 060711

Narrative:

Last Updated: 03/29/2007

The licensee reported the loss and recovery of nine NRD nuclear ionizer fan elements (model P-2063, serial numbers A2ER777 through A2ER785) that contained Po-210 sources (model P-001) with activities of 1.17 GBq (31.5 mCi), each. The nuclear ionizing devices were due for return to the vendor, but could not be found after an extensive search. The licensee also generated a written communication requesting assistance from associated work areas across their site. The devices were manufactured on 9/22/2005. They were located on 12/7/2006 in a locked storage cabinet. The sources have been returned to the distributor. Corrective actions taken by the licensee included generating a new procedure.

Event Date:	Discovery Date:	Report Date:
10/10/2006	10/10/2006	11/13/2006

Licensee/Reporting Party Information:

Regulated By:	AGREEMENT STATE	Reciprocity:	NONE
License Number:	GENERAL LICENS	Name:	SEAGATE TECHNOLOGY
Docket Number:	NA	City:	BLOOMINGTON
Program Code:	NA	State:	MN
Responsible NRC Region	: 3		

Site of Event:

Site Name: BLOOMINGTON State: MN

Additional Involved Party:

License Number:	NA	City:	NA
Name:	NA	State:	NA

Other Information:

NRC Reportable Event:	Υ	Abnormal Occurrence:	N
Agreement State Reportable Event:	Y	Investigation:	Y
Atomic Energy Act Material:	Y	Record Complete:	Y
Consultant Hired:	Ν	Event Closed by Region/Stat	e: Y

Event Cause:

LAS - LOST/ABANDONED/STOLEN Cause: MANAGEMENT DEFICIENCY

Corrective Actions Information:

LAS

1

Number: Corrective Action:

EQUIPMENT RETURNED TO MANUFACTURER FOR REPAIR OR DISPOSAL

2 NEW PROCEDURE WRITTEN

Source/Radioactive Material Information:

LAS			
Source Number:	1		
Source/Material:	SEALED SOURCE IONIZING	Radionuclide:	PO-210
Manufacturer:	NRD, INC.	Activity (Ci):	0.0315
Model Number:	P-001	Leak Test Results (uCi):	NA
Serial Number:	NR		•
LAS			
Source Number:	2		
Source/Material:	SEALED SOURCE IONIZING	Radionuclide:	PO-210
Manufacturer:	NRD, INC.	Activity (Ci):	0.0315

https://nmed.inl.gov/show_item.asp?item_no=060711

7/31/2007

NMED Event 060/1	1		Page 2 of 2
Model Number:	P-001	Leak Test Results (uCi):	NA
Serial Number:	NR		
LAS			
Source Number:	3		
Source/Material:	SEALED SOURCE IONIZING	Radionuclide:	PO-210
Manufacturer:	NRD. INC.	Activity (Ci):	0.0315
Model Number:	P-001	Leak Test Results (uCi):	NA
Serial Number:	NR		
LAS			
Source Number	4		
Source/Material	SEALED SOURCE IONIZING	Padionuslide	BO 210
Source/Material.	NPD DIC		PO-210
Madel Number	P_001	Look Test Peoults (uCi):	0.0315
Serial Number:	NP	Leak Test Results (uCI).	NA
	1 1 1 1		
	2		
Source Number:			
Source/Material:	SEALED SOURCE IONIZING	Radionuclide:	PO-210
Manufacturer:	NKD, INC.	Activity (Ci):	0.0315
Model Number:	P-001	Leak Test Results (uC1):	NA
Serial Number:	NK		
LAS			
Source Number:	6		
Source/Material:	SEALED SOURCE IONIZING	Radionuclide:	PO-210
Manufacturer:	NRD, INC.	Activity (Ci):	0.0315
Model Number:	P-001	Leak Test Results (uCi):	NA
Serial Number:	NR		
LAS			
Source Number:	7		
Source/Material:	SEALED SOURCE IONIZING	Radionuclide:	PO-210
Manufacturer:	NRD, INC.	Activity (Ci):	0.0315
Model Number:	P-001	Leak Test Results (uCi):	NA
Serial Number:	NR		
LAS			
Source Number:	8		•
Source/Material:	SEALED SOURCE IONIZING	Radionuclide:	PO-210
Manufacturer:	NRD, INC.	Activity (Ci):	0.0315
Model Number:	P-001	Leak Test Results (uCi):	NA
Serial Number:	NR		
LAS	· · · ·		
Source Number	9		
Source/Material	SFALED SOURCE IONIZING	Padionuclide	PO 210
Manufacturer:	NRD. INC.	Activity (Ci).	0.0215
Model Number	P-001	Leak Test Results (uCi).	NIA
Serial Number	NR	Loan Tost Rosults (UCI).	1873
			. "
Device/Associated I	Equipment Information:		
LAS			•
Device Number:	1		
Device/Equipmemt:	STATIC ELIMINATOR	Model Number:	P-2063

https://nmed.inl.gov/show_item.asp?item_no=060711

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NMED Event 060711		· ·	Page 3 of 4
Manufacturer:	NRD, INC.	Serial Number:	A2ER777
LAS			
Device Number:	2		
Device/Equipment:	STATIC ELIMINATOR	Model Number:	P-2063
Manufacturer:	NRD, INC.	Serial Number:	A2ER778
LAS			
Device Number:	3		
Device/Equipmemt:	STATIC ELIMINATOR	Model Number:	P-2063
Manufacturer:	NRD, INC.	Serial Number:	A2ER779
LAS			·
Device Number:	4		
Device/Equipment:	STATIC ELIMINATOR	Model Number:	P-2063
Manufacturer:	NRD, INC.	Serial Number:	A2ER780
			· · ·
LAS			
Device Number:	5		
Device/Equipmemt:	STATIC ELIMINATOR	Model Number:	P-2063
Manufacturer:	NRD, INC.	Serial Number:	A2ER781
LAS	• • • • •		
Device Number:	6		
Device/Equipment:	STATIC ELIMINATOR	Model Number:	P-2063
Manufacturer:	NRD, INC.	Serial Number:	A2ER782
LAS			
Device Number:	7		
Device/Equipmemt:	STATIC ELIMINATOR	Model Number:	P-2063
Manufacturer:	NRD, INC.	Serial Number:	A2ER783
LAS		· · · · ·	
Device Number:	8		
Device/Equipment:	STATIC ELIMINATOR	Model Number:	P-2063
Manufacturer:	NRD, INC.	Serial Number:	A2ER784
LAS			
Device Number:	9		
Device/Equipmemt:	STATIC ELIMINATOR	Model Number:	P-2063
Manufacturer:	NRD, INC.	Serial Number:	A2ER785

Reporting Requirement Information:

LAS

Reporting Requirement: 20.2201(a)(1)(i) - Lost, stolen, or missing licensed material in a quantity greater than or equal to 1,000 times the Appendix C quantities.

Keywords:

LAS Keyword: MATERIAL LOST AND FOUND

Reference Documents:

https://nmed.inl.gov/show_item.asp?item_no=060711

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:	
EN43003	11/27/200	6	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE	
MN060005	12/13/200	6	AGREEMENT STATE EVENT REPORT	
MN060005A	01/04/200	7	AGREEMENT STATE EVENT REPORT	
MN060005B	03/29/200	7	AGREEMENT STATE EVENT REPORT	

NMED Item Number: 060752

Narrative:

Last Updated: 03/29/2007

The licensee reported the loss of an NRD static eliminator (model P-2042 Nucleospot, serial #A2ER211) that contained 18.5 MBq (0.5 mCi) of Po-210. The device was determined missing during replacement operations on 11/13/2006. The device was manufactured in September 2005 and the original source activity was 185 MBq (5 mCi). The device was in use at the licensee's laboratories in Saint Paul, Minnesota, and the lease on the device ended in November 2006. Licensee Corporate Health Physics (CHP) attempted to replace the device with a new one, but it was not in the balance where it was normally used. The licensee determined that the RSO had taken a different position at the company and had not been in the laboratory since the last semiannual physical inventory conducted in July 2006. CHP was not notified of the RSO's job transfer. Therefore, there was a period of several months when there was no individual specifically responsible for the device. The licensee believes that during that time the device was moved to a different facility, stolen, or disposed of in the trash. Wipe tests performed in January 2006 revealed no removable activity. The licensee has taken actions to recover the device through personnel interviews, e-mail contacts, and searches of various laboratories. Corrective actions taken by the licensee included reminders to RSOs and management to notify CHP of personnel changes and reminders to personnel of the need to leave the static eliminators in their assigned locations.

Event Date:	Discovery Date:	Report Date:
07/01/2006	11/13/2006	12/11/2006

Licensee/Reporting Party Information:

Regulated By:	AGREEMENT STATE	Reciprocity:	NONE
License Number:	MN-1066-101-62	Name:	3M CO.
Docket Number:	NA	City:	SAINT PAUL
Program Code:	NA	State:	MN
Responsible NRC Region:	3		

Site of Event:

Site Name: SAINT PAUL State: MN

Additional Involved Party:

License Number: NA City: NA Name: NA State: NA

Other Information:

NRC Reportable Event:	Y	Abnormal Occurrence:	Ν
Agreement State Reportable Event:	Y	Investigation:	Y
Atomic Energy Act Material:	Y	Record Complete:	Y
Consultant Hired:	N	Event Closed by Region/State:	Y

Event Cause:

LAS - LOST/ABANDONED/STOLEN Cause: MANAGEMENT DEFICIENCY

Corrective Actions Information:

LAS

LAS

Ao

Number: Corrective Action:

1 PERSONNEL RECEIVED ADDITIONAL TRAINING

Source/Radioactive Material Information:

Source Number:	1		
Source/Material:	SEALED SOURCE IONIZING	Radionuclide:	PO-210
Manufacturer:	NR	Activity (Ci):	0.0005
Model Number:	NR	Leak Test Results (uCi):	NA
Serial Number:	NR		

https://nmed.inl.gov/show_item.asp?item_no=060752

7/31/2007

Device/Associated Equipment Information:

LAS

Device Number:	1		
Device/Equipment:	STATIC ELIMINATOR	Model Number:	P-2042
Manufacturer:	NRD, INC.	Serial Number:	A2ER211

Reporting Requirement Information:

LAS

Reporting Requirement: 20.2201(a)(1)(i) - Lost, stolen, or missing licensed material in a quantity greater than or equal to 1,000 times the Appendix C quantities.

Keywords:

LAS Keyword: MATERIAL LOST AND NOT FOUND

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:	
EN43043	12/14/2006		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE	
MN060006	01/04/2007		AGREEMENT STATE EVENT REPORT	
LTR070104	01/04/2007		AGREEMENT STATE LETTER	
MN060006A 03/29/2007)7	AGREEMENT STATE EVENT REPORT	

NMED Item Number: 070178

Narrative:

Last Updated: 03/29/2007

Page 1 of 2

The licensee reported that three shutters on a Berthold fixed gauge (model LB-300-L, serial #223/02-99 5386) were inoperable. The gauge contained a Co-60 source (Laboratorium Prof, model P 2608-100) with an activity of 70.3 MBq (1.9 mCi). Technicians using penetrating oil were unsuccessful in restoring movement to the shutters. Berthold was contacted on 10/27/2006 and recommended additional actions to free the shutters. The shutters could not be freed. Berthold sent a representative on 12/5/2006. Three bearings (two top and one bottom) were replaced and the representative recommended that a top plate be installed to better secure the sources and prevent vibration. Specific process changes were also performed to decrease vibration. In addition, the licensee will secure the gauge to prevent vibration from wearing the bearings and conduct shutter inspections during each equipment down day. The licensee will re-evaluate the effectiveness of the changes in one year.

Event Date:	Discovery Date:	Report Date:
10/18/2006	10/18/2006	12/07/2006

Licensee/Reporting Party Information:

Regulated By:	AGREEMENT STATE	Reciprocity:	NONE
License Number:	MN-1112-101-09	Name:	SAPPI FINE PAPER
Docket Number:	NA	City:	CLOQUET
Program Code:	NA	State:	MN
Responsible NRC Region	: 3		

Site of Event:

Site Name: CLOQUET State: MN

Additional Involved Party:

License Number:	ŇA	City:	NA
Name:	NA	State:	NA

Other Information:

NRC Reportable Event:	Y	Abnormal Occurrence:	Ν
Agreement State Reportable Event:	Υ	Investigation:	Y
Atomic Energy Act Material:	Y	Record Complete:	Y
Consultant Hired:	Ν	Event Closed by Region/State	e: Y

Event Cause:

EQP - EQUIPMENT Cause: DEFECTIVE OR FAILED PART

Corrective Actions Information:

EQP

Number: Corrective Action:

- 1 REPAIRS MADE WITHOUT ENGINEERING CHANGE TO SYSTEM
- 2 PROCEDURE MODIFIED

Source/Radioactive Material Information:

EQP

Source Number:	1		
Source/Material:	SEALED SOURCE GAUGE	Radionuclide:	CO-60
Manufacturer:	LABORATORIUM PROF.	Activity (Ci):	0.0019
Model Number:	P 2608-100	Leak Test Results (uCi):	NA
Serial Number:	NR	·	

Device/Associated Equipment Information:

https://nmed.inl.gov/show item.asp?item no=070178

NMED Event 070178	-			Page 2 of 2
EQP Device Number: Device/Equipmemt: Manufacturer:	1 GAUGE FIXED BERTHOLD	Model Number: Serial Number:	LB-300-L 223/02-99 538	6
EQP Device Number: Device/Equipmemt: Manufacturer:	2 SHUTTER, GAUGE BERTHOLD	Moo Seri	lel Number: al Number:	NR NA

Reporting Requirement Information:

EQP

Reporting Requirement: 30.50(b)(2) - Equipment is disabled or fails to function as designed.

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report
MN060007	03/29/2007		AGREEMENT

ype of Report: GREEMENT STATE EVENT REPORT

NMED Item Number: 070179

Narrative:

Last Updated: 07/10/2007

The licensee reported the loss of an I-125 brachytherapy seed with an activity of 4.65 MBq (125.7 uCi) that was used as a temporary implant for a patient with a non-palpable breast lesion. The seed was implanted in the patient on 12/5/2006 and removed on 12/6/2006. The Nuclear Medicine Pharmacy was not contacted to retrieve the seed from Pathology following the surgical removal. On 12/13/2006, a nuclear medicine technologist discovered that one seed was missing when preparing to transfer I-125 seeds for disposal. The technician returned to the pathology suite, conducted a radiation survey of the suite, sink, drain traps, and waste baskets, but was unable to find the missing seed. A survey of the operating room and janitor's closet was also negative. It was determined that the seed was most likely lost while within the pathology laboratory. The licensee believes that the seed was either washed down the drain during cleaning of the area or was discarded as medical waste. The licensee stated that there were no radiation levels above background in any of the incineration ash. Corrective actions taken by the licensee included modifying procedures.

Event Date:	Discovery Date:	Report Date:
12/06/2006	12/13/2006	01/10/2007

Licensee/Reporting Party Information:

Regulated By:	AGREEMENT STATE	Reciprocity:	NONE
License Number:	MN-1047-201-55	Name:	MAYO CLINIC
Docket Number:	NA	City:	ROCHESTER
Program Code:	NA	State:	MN
Responsible NRC Region:	3		

Site of Event:

Site Name: ROCHESTER State: MN

Additional Involved Party:

License Number: NA City: NA Name: NA State: NA

Other Information:

NRC Reportable Event:	Y	Abnormal Occurrence:	Ν
Agreement State Reportable Event:	Y	Investigation:	Y
Atomic Energy Act Material:	Y	Record Complete:	Y
Consultant Hired:	Ν	Event Closed by Region/State:	Y

Event Cause:

LAS

LAS - LOST/ABANDONED/STOLEN Cause: MANAGEMENT DEFICIENCY

Corrective Actions Information: LAS

Number: Corrective Action:

1 PROCEDURE MODIFIED

Source/Radioactive Material Information:

Source Number:	1		
Source/Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide:	I-125
Manufacturer:	NR	Activity (Ci):	0.0001257
Model Number:	NR	Leak Test Results (uCi):	NA
Serial Number:	NA		

Reporting Requirement Information:

https://nmed.inl.gov/show_item.asp?item_no=070179

Page 2 of 2

LAS

Reporting Requirement: 20.2

20.2201(a)(1)(ii) - Lost, stolen, or missing licensed material in a quantity greater than 10 times the Appendix C quantities.

Keywords:

LAS

Keyword: MATERIAL LOST AND NOT FOUND

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
MN070001	03/29/2007		AGREEMENT STATE EVENT REPORT
MD070001A	07/10/2007		AGREEMENT STATE EVENT REPORT

https://nmed.inl.gov/show_item.asp?item_no=070179

NMED Item Number: 070320

Narrative:

Last Updated: 07/10/2007

The licensee reported the loss of an I-125 seed (Oncura model 6711) that contained an activity of 18.46 MBq (0.499 mCi). The licensee received 101 seeds at their Nuclear Medicine hot laboratory on 4/23/2007, which were then transported to Radiation Oncology for assay on 4/24/2007. There were 10 strands, each containing 10 seeds, and one calibration seed. All seeds were account for. One of the strands was dismantled and all ten seeds were assayed and stored in a lead pig. The area was surveyed at the end of the assay process and the seeds were maintained under lock until the next morning when they were retrieved for a procedure. The 10 loose seeds were loaded into a Mick cartridge and then all the seeds were transported to the operating room. After the procedure, the nine seed strands and the cartridge as a whole were accounted for. All strands were stored in a lead pig and the cartridge was stored in a second pig. The package containing both pigs was transported to Radiation Oncology and stored under lock at all times. On 5/23/2007, a re-count of the seeds was completed prior to sending them back to the manufacturer. The calibration seed and the strands were accounted for. However, the cartridge only contained nine of the 10 seeds. The area where the cartridge was loaded and unloaded was surveyed, as well as the two units that were used to sterilize the seeds. The seed was not located. Surveys of other areas where the package was transported are in progress. The cause of the incident was determined to be inadequate procedures. Corrective actions taken by the licensee included generating new procedures.

Event Date:	Discovery Date:	Report Date:
04/24/2007	05/23/2007	05/24/2007

Licensee/Reporting Party Information:

Regulated By:	AGREEMENT STATE	Reciprocity:	NONE
License Number:	MN-1025-200-07	Name:	IMMANUEL-SAINT JOSEPH'S HOSPITAL
Docket Number:	NA	City:	MANKATO
Program Code:	NA	State:	MN
Responsible NRC Region	: 3		

Site of Event:

Site Name: MANKATO State: MN

Additional Involved Party:

License Number:	NA	City:	NA
Name:	NA	State:	NA

Other Information:

NRC Reportable Event:	Y	Abnormal Occurrence:	Ν
Agreement State Reportable Event:	Y	Investigation:	Y
Atomic Energy Act Material:	Ŷ	Record Complete:	Y
Consultant Hired:	Ν	Event Closed by Region/State:	Ν

Event Cause:

LAS - LOST/ABANDONED/STOLEN Cause: DEFECTIVE OR INADEOUATE PROCEDURE

Corrective Actions Information:

LAS

LAS

Number: Corrective Action:

1 NEW PROCEDURE WRITTEN

Source/Radioactive Material Information:

Source Number:	Y			
Source/Material:	SEALED SOURCE BRA	CHYTHERAPY	Radionuclide:	I-125
Manufacturer:	ONCURA	4	Activity (Ci):	0.000499
Model Number:	6711		Leak Test Results (uCi):	NA

https://nmed.inl.gov/show_item.asp?item_no=070320

7/31/2007

Reporting Requirement Information:

LAS

Reporting Requirement: 20.2201(a)(1)(ii) - Lost, stolen, or missing licensed material in a quantity greater than 10 times the Appendix C quantities.

Keywords:

LAS Keyword: MATERIAL LOST AND NOT FOUND

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43388	05/29/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
MN070002	07/10/2007		AGREEMENT STATE EVENT REPORT

A. COMMON PERFORMANCE INDICATORS

VI. General

- 25. Appended to this section are the annual audits conducted for the 2005 and 2006 program years. These audits provide a synopsis of the program's activities.
- 26. The following is a summary of the strengths and weaknesses of the Radioactive Materials program:
 - The Radioactive Materials Unit has a very diversified and competent staff.
 - Sue McClanahan has extensive supervisory experience and technical background in radiation via the X-ray program.
 - In addition to her extensive medical training. Dr. Sherrie Flaherty has a significant amount of teaching experience.
 - Brandon Juran's education in Chemistry and Chemical Engineering as well as in Materials Science and Engineering has provided a significant technical component to the program.
 - Craig Verke's experience as an X-ray inspector has ensured success in the Radioactive Materials enforcement program.
 - The Radioactive Materials staff is cross-trained as inspectors and license reviewers. The ability to function in both endeavors is an invaluable asset to both activities.
 - Because the Radioactive Materials program is relatively small, there are minimal communications issues. In addition, the requirement for peer review of inspections and licensing actions promotes communication as well as consistency.
 - As a neighboring State has found, the problem with a small staff is that changes in personnel can have a significantly impact. In addition, the fact that the Radioactive Materials employees are in the same job classification as the X-ray employees could negatively impact the ability maintain a qualified staff. (Currently, the Radioactive Materials Supervisor and Sue McClanahan are retirement eligible.)
 - The fees established to support the program are adequate to cover operational costs (e.g., salaries, training, travel, and equipment costs). The only financial impediment is that the funding appropriation has been established at a level that impedes the ability to access approximately onethird of the fees. MDH is committed to addressing that issue.
 - The Radioactive Materials Unit has initiated an extensive outreach program. Examples of this program includes:
 - Purchasing and loaning emergency response kits to MnDOT and the State Patrol Commercial Vehicle Section;
 - Training for HAZMAT teams and other emergency response organizations in the state; and

- o Semi-annual meetings with Medical Physicists.
- Finally, the Radioactive Materials program is able to change its policies and procedures in a very short time. The ability to modify and disseminate guidance documents based on the responses received from the regulated community is an invaluable asset. This capability is also conducive to one of the Radioactive Materials Unit's goals, which is to refrain from being a static entity by embracing change.

MINNESOTA DEPARTMENT OF HEALTH



AUDIT OF THE 2005 RADIOACTIVE MATERIALS PROGRAM

1



Radiation Control Unit Indoor Environments & Radiation Section Department of Environmental Health Minnesota Department of Health

INTRODUCTION

Scope of the Radiation Control Unit

X-ray Group

The X-ray Group registers and inspects all x-ray machines at medical, dental, veterinary, industrial and educational facilities on a four-year cycle. Currently, there are 4283 active facilities. Annually, Radiation Control staff inspect mammography facilities for compliance with the Federal Mammographic Quality Standards Act and approximately three dozen facilities for Level II inspections.

Radioactive Materials Group

The Radioactive Materials Group conducts environmental sampling statewide and near the state's two nuclear power plants. It regulates Radium-226, which is a naturally occurring isotope, and accelerator produced radioactive materials (NARM) within Minnesota. There are approximately 45 facilities that use Radium-226 in fixed and portable gauges. Staff in the Radioactive Materials Group continues to conduct routine inspections of these facilities. In addition, the Radioactive Materials Group is tasked with inspecting the nuclear pharmacy¹ with cyclotrons, which produce short-lived isotopes for medical applications, as well as the ten facilities that only use accelerator-produced materials². This group will be responsible for the day-to-day operations of the Agreement Program.

Radiation Control Unit staff (staff in the X-ray and Radioactive Materials Groups) respond to accidents and emergencies involving radiation. In addition, both staffs provide technical assistance to the general public, answering consumer concerns about radiation.

A historical perspective of the Radiation Control Program in Minnesota is included as Appendix A.

Outreach Training

A significant amount of the training activities provided by MDH in 2005 centered around rulemaking efforts. The following summarizes the various training forums.

DATE	TRAINING	ATTENDEES	LOCATION
January 19	Industrial X-ray	Minnesota Section of the American Society of Non Destructive Testing	Plymouth, MN
January 26	PET/CT Shielding	AAPM, Vendors, RSOs and Nuclear Medicine staff	St. Paul, MN

¹ A second cyclotron is expected to be operational in November of 2004.

² The NRC does not license these facilities.

Mileage in State Vehicles



Exposures (Doses)

All Radiation Control staff are monitored for exposure using thermoluminescent dosimeters (TLDs). In 2005, MDH changed vendors from Landauer® to Global Dosimetry®. Only two staff received any measurable dose in the past year. The highest recorded exposure was 34 mrem.

Staffing

The Final Agreement State Application dated July 6, 2004, lists Timothy Donakowski, John Goepferd, Brandon Juran and Craig Verke as the staff committed to the Radioactive Materials Program. Early in 2005, Sherrie Flaherty, DC, was hired to augment staffing in the materials program. Also, the Agreement State Application indicated that a support staff would be available to support the radioactive materials program. That position remains open due to funding concerns.

Inspector Accompaniments

To ensure quality and consistency in inspections of licensees, the following inspector accompaniments were completed during this year by the staff:

DATE	MDH STAFF	INSPECTOR	LICENSEE
01/11 - 12	Brandon Juran	Tony Go (NRC)	Abbott Northwestern Hospital
02/01 - 03	Brandon Juran	John Goepferd	North Memorial Medical Center
04/18	Brandon Juran	George Parker (NRC)	St. Luke's Hospital

prepares licenses and another staff member reviews that license. The Radiation Control Supervisor completes another review prior to having the document signed by the Section Manager.

Revised Licenses

Unlike a license amendment, which is a change required by Minnesota rules and requested by the licensee, a license revision is a change to a license due to an MDH error or oversight. In most cases, the licensee has identified these errors when they receive the newly issued licensing document. Because the licensing process is new to MDH staff, revisions were anticipated. No attempt to determine the specific errors was made.

Standard License Conditions

The standard license conditions used by the US Nuclear Regulatory Commission have been made MDH Standard Licensing Conditions.

MDH generated a license condition for approximately 21 licenses that require increased controls. The Office of State and Tribal Programs approved that condition. In addition, on December 20, 2005, MDH submitted three license conditions to the NRC for approval. These conditions were generated to ensure that legally binding requirements were in place during the period that MDH was updating its rules. Appendix D contains the license conditions.

Incidents

Two PET related incidents were identified in 2005.

- On July 8, 2005, MDH received a call from Cardinal Health, a major supplier of radiopharmaceuticals. The facility manufactures Fluorine-18 (F-18) for diagnostic studies. One of the staff at the facility had exceeded the annual limit for extremity exposure. Ultimately, the total extremity dose was determined to be 52,800 mrem, which exceeds the 50,000 mrem per year limit.
- On December 1, 2005 a facility notified MDH of radiation doses for individual members of the public in excess of the 100 mR/year limit at their PET imaging center.³ Based on occupancy factors and surveys performed, elevated annual exposures to three individuals occupying the adjacent spaces for 2001 to 2005 were identified. Their estimated exposures ranged from 100 330 mR/year. A possible fourth individual may have received excessive exposure but as of this date, this person's identity and exposure levels were unknown.

Time Study

MDH has initiated a time study to track the time associated with licensing actions. However, the data is extremely limited and will not accurately reflect the effort needed to complete licenses

³ This incident is remains open; therefore, it is not for public disclosure. The facility name has been omitted.

Rules

In January of 2005, the rules governing the use of radioactive materials were adopted and the obsolete portions of Chapter 4730 were rescinded.

On November 22, 2005, MDH submitted proposed rules to address changes in 10 CFR 30.34, changes in the training and experience for medical users (Part 35) and transportation changes (Part 71). Brandon Juran and Sue McClanahan worked on the proposed changes. Brandon has been assigned to this rulemaking effort.

Revenues

The Radioactive Materials Program will continue to run in a deficit mode until it is authorized to collect revenues for by-product materials. Although minuscule, for the first time since its inception, the program did receive revenues in 2005. The following table summarizes those revenues.

REVENUE SOURCE CODE	2005 REVENUE
Administrative Penalties	\$8,000
License Amendment Fees	
Reciprocity Fees	
License Application Fees	12,860
General License Annual Fees	·
Specific License Annual Fees	
Total	\$20,860

Equipment

Brandon Juran has been assigned the task of ensuring that all radiation detection equipment is calibrated annually. The Iowa Calibration Facility, which is part of the Iowa Department of Homeland Security and Emergency Management, calibrates the majority of the equipment. However, the neutron detector and the Exploranium® spectrum analyzers are calibrated by the manufacturers. Appendix E lists the instruments currently in the Radioactive Materials Group inventory.

In addition to what is listed in Appendix D, MDH also has seven Eberline E-520s. These detectors have been replaced by the Ludlum kits and are expected to be sent for surplus in 2006. It should also be noted that four response kits have been loaned to Minnesota Department of Transportation Hazardous Materials personnel to enhance their response capabilities.

There are four older devices remaining in the inventory that were manufactured by Eberline®. Repair costs for these devices are significant and Eberline continues to systematically terminate

RADIOLOGICAL EMERGENCY PREPAREDNESS (REP) PROGRAM

Radiation Control staff participated in a nuclear power generating plant drill and an evaluated exercise in 2005. Both activities were for the Monticello facility. No deficiencies associated with MDH participation were identified during the evaluated exercise.

Staffing

MDH has increased the number of staff associated with the REP program. The following table summarizes the current goals for staff assignments within the State Emergency Operations Center during a nuclear power plant event.

SEOC FUNCTION	STAFF
PAC	John Goepferd
· · · · · · · · · · · · · · · · · · ·	Brandon Juran
	Marge Shaw
	Craig Verke
Dose Assessment	Timothy Donakowski
	Dan Locher
Operations Table	Sue McClanahan
·	Sherrie Flaherty

Training

MDH staff participated in several emergency response training events conducted by Minnesota Department of Homeland Security and Emergency Management. All but one of the staff assigned to the REP Program have attended Emergency Operation Training Operations (RERO), which is a Federal Management Agency training course. Marge Shaw is scheduled for RERO training in February of 2006. The following table summarizes the Radiation Control participation in 2005 training activities.

DATE	TYPE OF ACTIVITY	STAFF
04 Jan-05	Quarterly REP Meeting	George Johns
13-Jan-05	Monticello Form Training	Tim Donakowski John Goepferd George Johns Marge Shaw
24-Feb-05	IPTF	George Johns Brandon Juran Dan Locher Sue McClanahan
28-Apr-05	Prairie Island Training Center	Tim Donakowski Daniel Locher
5-May-05	Meeting at HSEM	George Johns

5-Oct-05	REP Quarterly Meeting	George Johns
		Sue McClanahan
8-Oct-05	Monticello Mini Drill	John Goepferd
		Dan Locher
		Craig Verke
6-Dec-05	Monticello Health Physics Drill	Kelly Daigle
		Tim Donakowski
		Brandon Juran
	•	Jennifer Miller
9-Dec-05	REP Quarterly Meeting	Dan Locher
		George Johns
15-Dec-05	PI PAC Tour and Training	Kelly Daigle
		Tim Donakowski
		Sherrie Flaherty
	· · ·	Brandon Juran
	ł	Dan Locher
		Jennifer Miller
	- -	Marge Shaw
		Craig Verke

contracted with Global Dosimetry to provide and process TLDs. The first group of dosimeters will be placed in the first quarter of 2006.

15 -

Appendix A

History

1938	٠	The Minnesota State Board of Health granted federal funds to begin the Industrial Health Division.
1939	•	The Legislature authorized creation of the Industrial Health Division. At this time, medical and industrial use of radium was just becoming common. Immediate concerns included radium dial painters' exposure and the medical use of radium in therapy. The Industrial Health Division, in order to detect exposure, used ultraviolet light to determine whether or not radium dial painters were using proper hand washing techniques. The National Council of Radiation Protection and Measurements established a maximum permissible body burden (MPBB) for radium. Radiation protection measures for patients, staff, and the public were established.
Early 1940s	.	The Industrial Health Division conducted surveys of hospitals, clinics, and private offices to ensure proper radiation protection procedures were being followed in the handling and disposal of radium plaques and needles.
Late 1940s	•	Foot fluoroscopes in shoe fitting became widespread. Consequently, the Industrial Health Division began frequent surveys and adjustments of foot fluoroscopes. The Industrial Health Division also began surveying x-ray equipment in hospitals and medical and dental offices, which necessitated the purchase of radiation detection and measurement instruments.
1950 1951		By 1950, 200 foot-operated fluoroscopes had been inspected and adjusted. Mobile x-ray units began operating throughout the state to test the public for tuberculosis. The Industrial Health Division began surveying these machines. A study began in Minnesota to determine the exposure of personnel operating x-ray machines.
1952	•	The Industrial Health Division began assessing new medical buildings or additions to determine the effectiveness of radiation shielding construction. The Industrial Health Division also began accompanying the U.S. Atomic Energy Commission on inspections of isotope users in Minnesota. An organized effort was begun to survey every x-ray unit in hospitals and medical and dental facilities in Minnesota.
1953	•	The Minnesota State Board of Health became aware of nuclear fallout and its dangers and began participation in the National Air Sampling Network A staff member of the Industrial Health Division participated as an off-site monitor for the Nevada Test Site. The State Board of Health participated in the U.S. Public Health Service National Radiation Surveillance Network for air, milk, and water. The Section of Radiation and Occupational Health (formerly the Industrial Health Division) began to collect and analyze environmental samples from western Minnesota after concerns arose about illness and unusual environmental findings.
In August and September of 1962, Iodine-131 levels in milk had risen a significant amount. After meetings with representatives from the dairy industry, the Minnesota Department of Agriculture, and other concerned parties, an aged feeding program for fluid milk dairy herds was implemented to reduce the I-131 levels. Samples were collected on a 24-hour basis and verified that the technique was effective.

1966

Because of the extreme hazards related to leaking radium from a sealed source, the Section of Radiation and Occupational Health increased the frequency of its leak testing to every six months.

• Concern about radiation emission from color televisions prompted the Section of Radiation and Occupational Health to conduct surveys of television receivers to determine radiation levels. The results did not indicate a need for further corrective action.

• At this point in time, environmental monitoring and x-ray surveys took up most of the Section's staff time.

• In June of 1966, Iodine in eight milk-sampling locations rose slightly following Chinese nuclear weapons testing in the previous month. The levels were found to be within established limits. The general trend for Strontium-90 and Cesium-137 in milk continued downward, but remained within the detectable range.

• Daily sampling of air particulates continued by the Public Health Service Radiation Surveillance Network. The results were published in "Radiological Health Data and Reports," a monthly bulletin distributed by the Public Health Service.

 The Rural Cooperative Power Association of Elk River and the Minnesota Department of Health began their biennial release of the "Survey of Environmental Radioactivity."

• A demonstration nuclear power plant was built near Elk River, and operated for the next two years. Pre-operational and operational environmental monitoring was performed by the University of Minnesota School of Public Health under the direction of the Governor's Committee on Atomic Problems. Various structural and radiation problems were discovered during operational period. Due to these problems, the company expected to purchase the plant declined the offer.

• In April of 1966, due to increasing demands, the Section of Radiation and Occupational Health divided into two sections—the Section of Radiation Control and the Section of Industrial Hygiene.

• After investigations to determine the safety of building a nuclear reactor near Red Wing, the State Board of Health submitted their approval on May 21st to a hearing board for the Prairie Island nuclear power plant.

• Radiation Control had hired three additional staff members.

• The Atomic Energy Commission commissioned the Elk River Cooperative Power Association to dismantle & decontaminate the Elk River reactor. (This was one of first reactors in the country to be dismantled.)

1970

1969

• The Elk River Cooperative Power Association met with Radiation Control to discuss plans for decommissioning the reactor. Also discussed were the responsibilities of the State Board of Health for conducting environmental monitoring.

• At this time, 7000 x-ray and radioactive material sources were used in approximately 2500 facilities.

• Because of the widespread use of x-ray and radioactive material sources, schools

198	0	• By 1980, all Minnesota facilities owning x-ray machines or radioactive materials had been inspected.
198	5	• Some Cobalt-60 was included as scrap metal that was used to make table legs sold all over country. When MDH was notified, dozens of restaurants and other facilities were already using the tables and many more were in storage. Radiation Control staff inspected each table.
		• The same year, some Polonium-210 discs became dislodged from 3M anti-static devices, creating potentially contaminated areas. Many of these devices were located in manufacturing or processing facilities, but some were in food-processing establishments. NRC sent its staff to inspect these facilities, and Radiation Control assisted by conducting inspections in places like Hormel Meats in Austin and Baldinger Bakery in West St. Paul.
198	6	 The Chernobyl accident in the Soviet Union (now Ukraine) required additional environmental monitoring. Radiation Control maintained contact with the U.S. Department of Energy the Environmental Protection Agency to get updates on the content and amount of the release. Some radioactivity was found in Minnesota environmental samples, but none were high enough to warrant special action. Fees for the registration of x-ray machines and radium increased for the first time in ten years.
		• Minnesota became one of first states to initiate mammography inspections. Later, MDH collaborated with Medicare, the lead organization for mammography inspections.
198	37	• Another radioactive source mixed with scrap metal was made into chain link fencing. Radiation Control staff was dispatched to inspect the fencing.
198	38	• Staggered biennial renewal was initiated to make Radiation Control's workload more manageable.
199	00	• The registration fees were increased to make Radiation Control self-supporting by 1995.
199)]	 The Legislature gave Radiation Control the authority to issue Cease & Desist orders and Administrative Penalties; rules were drafted following the authorization. The Health Enforcement act was adopted to give MDH the ability to fine facilities and individuals for rule violations and noncompliance. The fine maximum was \$10,000 per inspection. In September, the Ionizing Radiation Rules were revised to incorporate Federal Performance requirements for x-ray systems, requirements for Quality Assurance, increased registrant responsibilities, and revised shielding rules for new buildings or major reconstruction projects. In August, 34 seminars on the new rules were held for vendors. The seminars were held September through November for registrants. Enforcement of the regulations on Quality Assurance was delayed to allow facilities to write their procedures and obtain necessary equipment. By 1991, there were 4500 facilities with over 12,000 x-ray systems operating in
		 By 1991, there were 4500 facilities with over 12,000 x-ray systems operating in Minnesota.

- The Legislature approved submittal of the application for Agreement State status and removed the August 2006 deadline for completion of the application.
- In June, Governor Pawlenty signed the cover letter that authorized submittal of the full application package.

- Minnesota Rules for Radiation Safety, Chapter 4731, were adopted without a hearing in and became effective on January 2, 2005.
- Notice of the intent to make Minnesota an Agreement State was published in the Federal Register for four consecutive weeks for public comment. No comments were received.

2006

e

The Chairman of the US Nuclear Regulatory Commission signed the Minnesota Agreement on February 3rd.

Option 2⁸

The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71 "Packaging and Transportation of Radioactive Material." Nothing in this license condition applies to the extent that the person is subject to regulations of the NRC.

⁸ This option is presented to address STP concerns about federal jurisdiction.

Ludlum	2241-3	220224	6/14/2005
Ludlum	2241-3	220176	6/14/2005
Ludlum	2241-3	220152	6/14/2005
Ludlum	2241-3	220193	10/25/2005
Dosimeter Corp.	862	4010818	10/24/2005
Dosimeter Corp.	862	4010820	10/24/2005
Dosimeter Corp.	862	4010831	10/24/2005
Dosimeter Corp.	862	4010832	10/24/2005
Dosimeter Corp.	862	4010833	10/24/2005
Dosimeter Corp.	862	4010835	10/24/2005
Dosimeter Corp.	862	4010838	10/24/2005
Dosimeter Corp.	611	9124754	10/24/2005
Dosimeter Corp.	611	9124767	10/24/2005
Dosimeter Corp.	611	9124783	10/24/2005
Dosimeter Corp.	611	9124781	5/12/2005
Dosimeter Corp.	611	9124787	5/12/2005
Dosimeter Corp.	611	9124795	5/12/2005
Dosimeter Corp.	862	8101121	5/12/2005
Dosimeter Corp.	862	8101122	5/12/2005
Dosimeter Corp.	862	8101123	5/12/2005
Dosimeter Corp.	862	8101124	5/12/2005
Dosimeter Corp.	862 .	8101125	5/12/2005
Dosimeter Corp.	862	8101126	5/12/2005
Dosimeter Corp.	862	8101127	5/12/2005
Dosimeter Corp.	862	8101128	5/12/2005
Dosimeter Corp.	862	8101130	5/12/2005
Dosimeter Corp.	. 862	8101131	5/12/2005
Dosimeter Corp.	862	8101132	5/12/2005
Dosimeter Corp.	862	8101133	5/12/2005
Dosimeter Corp.	862	8101134	5/12/2005
Dosimeter Corp.	862	8101135	5/12/2005
Dosimeter Corp.	862	8101136	5/12/2005
Dosimeter Corp.	862	8101137	5/12/2005
Dosimeter Corp.	862	8101138	5/12/2005
Dosimeter Corp.	862	8101139	5/12/2005
Dosimeter Corp.	862	8101140	5/12/2005
Dosimeter Corp.	862	9101882	5/12/2005

MINNESOTA DEPARTMENT OF HEALTH



AUDIT OF THE 2006 RADIOACTIVE MATERIALS PROGRAM



INTRODUCTION

Scope of the Radioactive Materials Group

The Radioactive Materials Group conducts environmental sampling statewide and near the state's two nuclear power plants. It regulates Radium-226, which is a naturally occurring isotope, and accelerator produced radioactive materials (NARM) within Minnesota. In addition, on March 31, 2006, MDH assumed regulatory authority for by-product material as part of the Agreement Program.

Radiation Control Unit (staff in the X-ray and Radioactive Materials Groups) are trained to respond to accidents and emergencies involving radiation. In addition, both staffs provide technical assistance to the general public, answering consumer concerns about radiation.

A historical perspective of the Radioactive Materials Program in Minnesota is included as Appendix A.

Department of Transportation Special Permits

Shipments of scrap metal that alarm detectors at processing plants or scrap yards in Minnesota are required to have authorization for their return to the point of origin. Upon return, the responsible state radiological program must assist the shipper in identifying the cause of the alarm if requested.

MDH issued four Department of Transportation (DOT) Special Permits (formerly called "exemptions") in 2006. Three of the shipments were within the state and the fourth was to a North Dakota facility.

Equipment

Brandon Juran transferred the task of ensuring that all radiation detection equipment is calibrated annually to Craig Verke. The Iowa Calibration Facility, which is part of the Iowa Department of Homeland Security and Emergency Management, calibrates the majority of the equipment.

The older devices that were manufactured by Eberline® have been replaced. Repair costs for these devices were significant because Eberline terminated its support for equipment. The counter for the neutron detector has been changed to a Ludlum 2241-2; Ludlum has calibrated that equipment. The detector, a "rem ball" that contains boron tri-fluoride, should be replaced prior to the next calibration. Ludlum will install a detector that is filled with helium and calibrate the device. That will eliminate the need to ship the device as hazardous material and will save approximately \$100.00 in shipping.

In 2005, MDH purchased and loaned four response kits to Minnesota Department of Transportation Hazardous Materials personnel to enhance their response capabilities. Additional kits were purchased and loaned to the Minnesota Department of Public Safety Commercial Vehicle Section in 2006.

1066-100-62	MN-06-004	3M Company	09/05/06	Missing Tritium foil source (600 mCi)	Missing
1112-101-19	MN-06-007	Sappi Fine Paper in Cloquet	10/18/06	Inoperable shutters on Berthold Model LB300L gauges	Repaired
General License	MN-06-005	Seagate Technology	11/06/06	Loss of 9 Polonium-210 static eliminators (31.5 mCi each)	Found
1066-100-62	MN-06-006	3M Company	12/07/06	Missing Polonium- 210 static eliminator (0.5 millicuries)	Missing

Increased Controls

MDH generated a license condition for 23¹ licenses that require increased controls. The Office of State and Tribal Programs approved that condition. In addition, on December 20, 2006, MDH submitted three license conditions to the NRC for approval. These conditions were generated to ensure that legally binding requirements were in place during the period that MDH was updating its rules. Appendix C contains the license conditions.

MDH has been tasked with inspecting the Increased Control licenses in accordance with the NRC schedule. All Priority 1 licensees must be inspected within a year of the implementation date, which was May 16, 2006. The following is a breakdown of the IC licensees and the 2006 inspections by priority.

INSPECTION	INSPECTED	REMAINING TO	TOTAL
PRIORITY	IN 2006	BE INSPECTED	
Priority 1	11	2^{2}	13
Priority 3	0	0	0
Priority 5	4	6	10
Total	15	· 8	23

Twelve of the IC inspections were closed by in 2006. Two more were closed as of January 8, 2007.

MDH inspection staff assigned to complete the IC inspections previously attended the NRC Materials Control and Security Systems and Principles Course; however, eight IC inspections were completed without the MDH staff being formally approved for independent inspections those types of licenses. The Radiation Control supervisor deemed the inspectors qualified to

¹ MDH terminated the University of Minnesota License Number 1085-100-27 after removal of the teletherapy unit at the College of Veterinary Medicine in October of 2006.

² MDH completed an additional Priority 1 inspection on January 3, 2007.

07/10/06	Brandon Juran	George Johns	Valley Paving, Inc. ³
07/12/06	Sherrie Flaherty	George Johns	Northern Shared Medical ⁴
07/13/06	Sherrie Flaherty	George Johns	Chart Industries
07/14/06	Craig Verke	George Johns	City of Minneapolis ⁵
07/20/06	Sherrie Flaherty	George Johns	Midwest Industrial X-ray ⁶
07/26/06	Craig Verke	Sherrie Flaherty	Life Scan
08/23/06	Sherrie Flaherty	Sue McClanahan	Cardinal Health (Cyclotron)
08/29/06	Craig Verke	Sherrie Flaherty	Avera McKennan Hospital
08/30/06	Sherrie Flaherty	Craig Verke	Midwest Asphalt
09/07/06	Sherrie Flaherty	Craig Verke	Bituminous Material ⁷
09/27/06	Craig Verke	Sherrie Flaherty	Health Partners - Riverside
10/18/06	Craig Verke	George Johns	Acuren Inspections, Inc.
10/25/06	Craig Verke	Sherrie Flaherty	Braun Intertec Corp. ⁸
12/06 - 12/07/06	Sherrie Flaherty	George Johns	SMDC
12/19/06	Sherrie Flaherty	George Johns	Immanuel – St. Joseph's ⁹

License Inspections

With one exception, all licensees have been inspected in accordance with NRC Inspection Manual 2800. Acuren Inspection, Inc. (License Number 1191-100-89) was inspected by the NRC on April 5, 2005; however, MDH failed to notice that the program code provided by the NRC for this industrial radiography license was incorrect. (It was listed as a portable gauge license.) MDH inspected the facility on October 16, 2006, which was shortly after discovering the error. The Region III Agreement State Officer and Federal & State Materials & Environmental Management (formerly The Office of State and Tribal Programs) was informed of the issue.

On January 30, 2007, MDH identified another overdue inspection. MDH failed to recognize that the NRC has issued a new license to Medtronic, Inc. (License Number 1169-101-27) on December 29, 2005. An inspection is scheduled for January 31, 2007.

On an average, inspection reports were issued in less than 15 days from the date of the inspection. Four of the 58 inspection reports issued in 2006 were issued later than the 30 day objective. One report was delayed while the IC Working Group re-evaluate the requirements for personnel reference checks at MDH's request.

³ Qualifying Evaluated Radiological Safety Inspection Accompaniment of Gauges for Brandon Juran.

⁴ Qualifying Evaluated Radiological Safety Inspection Accompaniment of Diagnostic Nuclear Medicine for Sherrie Flaherty.

⁵ Qualifying Evaluated Radiological Safety Inspection Accompaniment of Gauges for Craig Verke.

⁶ Qualifying Evaluated Radiological Safety Inspection Accompaniment of Industrial Radiography for Sherrie Flaherty.

⁷ Qualifying Evaluated Radiological Safety Inspection Accompaniment of Gauges for Sherrie Flaherty.

⁸ Qualifying Evaluated Radiological Safety Inspection Accompaniment of Industrial Radiography for Craig Verke.

⁹ Qualifying Evaluated Radiological Safety Inspection Accompaniment of Radiation Therapy for Sherrie Flaherty.

MDH staff processed 67 license amendments in 2006. As part of the established procedures, all licenses and amendments receive a three-party review. For example, a staff member prepares licenses and another staff member reviews that licensing action. The Radiation Control Supervisor completes another review prior to having the document signed by the Section Manager.

MDH encountered two problems with the licenses issued by the NRC and subsequently converted to MDH licenses:

- One license had possession limits that exceeded those for a Type C Broad Scope. The licensee has agreed to change their license to a Type A Broad Scope when their Research and Development license is renewed, which will occur in the fall of 2007. In addition, the licensee currently has a separate license for gauges. Only the licensee can identify which license authorizes the devices. MDH will consolidate the gauge and the research license during the R&D renewal. That will also afford the licensee time to revise their policies and procedures so that they are more uniform.
- Two Nuclear Medical Van licenses have fixed locations. Prior to becoming an Agreement State, MDH required a NARM user to obtain separate licenses for the mobile and fixed sites. To be consistent, MDH has requested the two companies formerly licensed by the NRC to obtain a separate license for the fixed sites or to commit to removing of all radioactive material at the end of each day. That process will be completed in 2007.

Reciprocity

Licensees from outside of Minnesota can operate in anywhere that the Minnesota Department of Health maintains jurisdiction under a reciprocal recognition of their license. The fee for that process is \$1200.00 for a year, which begins the date the reciprocity is approved by Radioactive Materials staff. MDH had 28 active reciprocity licenses on December 31, 2006. All of the licenses have been for service providers, which are required to be inspected on a five-year cycle. MDH staff completed eight reciprocity inspections in 2006.

Revenues

The Radioactive Materials Program continues to run in a deficit mode until it is authorized to collect revenues for by-product materials. Although minuscule, for the first time since its inception, the program did receive revenues in 2006. The following table summarizes those revenues.

Because the billing dates for the registered generally licensed material could not be determined, MDH has elected to bill the General Licensees in February of each year. The first billing to the 106 registered facilities will generate \$15,900 in additional revenues in FY07.

McClanahan have duties related to the X-ray Program, they do have RAM related responsibilities and serve as back up to the other staff. For example, Timothy Donakowski is responsible for the Environmental Analysis Report. Sue McClanahan is coordinating reciprocity activities and inspects the PET manufacturing (cyclotron) facilities.

The Agreement State Application also indicated that a support staff would be available to support the radioactive materials program. That position remains open due to management concerns. The lack of support staff has aided staff in becoming familiar with the format and style of letters as well as technical documents; however, it continues to divert professional staff and supervisor resources.

Outreach Training

A significant amount of the training activities provided by MDH in 2006 focused on the Agreement State process. The following summarizes the various training forums.

DATE	TRAINING	ATTENDEES	LOCATION
01/19/06	American Society For Non-	Minnesota Chapter	St. Louis Park
	Destructive Testing (ASNT)	Members	
01/26/06	Physicist Meeting	Health and Medical	Snelling Office
		Physicists	Park
01/31/06	HAZMAT Training	Grand Rapids Fire	Grand Rapids
		Department	
04/13/06	HAZMAT Training	Mankato CAT Team	Mankato
04/14/06	North Central Chapter of the	Health Physicists	St. Paul
	Health Physics Society		
05/25/06	HAZMAT Training	Hopkins Fire Department	Hopkins
11/06/06	Physicist Meeting	Health and Medical	Snelling Office
-		Physicists	Park
11/16/06	American Society For Non-	Minnesota Chapter	St. Louis Park
	Destructive Testing (ASNT)	Members	

Staff Training

Radiation Control staff attended the following courses:

DATE (2006)	TRAINING	ATTENDEE
02/13 - 02/17	NRC Materials Control and Security Systems and Principles Course	George Johns Brandon Juran Craig Verke

RADIOLOGICAL EMERGENCY PREPAREDNESS (REP) PROGRAM

Radiation Control staff participated in a nuclear power generating plant drill and an evaluated exercise in 2006. Both activities were for the Monticello facility. No deficiencies associated with MDH participation were identified during the evaluated exercise.

Staffing

MDH has increased the number of staff associated with the REP program. The expansion efforts involve staff assigned to other units within the Indoor Environments and Radiation Section. The following table summarizes the current goals for staff REP assignments during a nuclear power plant drill or exercise. These staff will, of course, be available for nuclear power plant incidents.

SEOC FUNCTION	- STAFF
PAC	John Goepferd
	Brandon Juran
· ·	Marge Shaw
	Craig Verke
	Ben Sunderlin
Dose Analyst and PAC Liaison	Dan Locher
Dose Assessment	Timothy Donakowski
Operations Table	George Johns
_	Sue McClanahan
	Sherrie Flaherty
Field Team Controllers	Dan Miller
· · · · · · · · · · · · · · · · · · ·	Bruce Lange

Training

MDH staff participated in several emergency response-training events conducted by Minnesota Department of Homeland Security and Emergency Management. All of the staff assigned to the REP Program have attended Emergency Operation Training Operations (RERO), which is a Federal Emergency Management Agency training course. Mike Cimaglio (X-ray staff) is scheduled for RERO training in February of 2007 and three additional X-ray staff will be attending RERO in FY08. The following table summarizes MDH's participation in 2006 Radiological Emergency Preparedness program for nuclear power generating plants.

		77
07/18/06	Prairie Island Exercise	Daniel Locher
		Sherrie Flaherty
		Tim Donakowski
		John Goepferd
· ·		Sue McClanahan
		Craig Verke
		John Stine
,		Linda Bruemmer
· ·		George Johns
		Brandon Juran
07/01/06	RAAC Pre-course Workbook	Brandon Juran
		Sherrie Flaherty
07/31 - 08/04/06	RAAC Training	Brandon Juran
		Sherrie Flaherty
08/14 - 8/18/06	Nuclear Power Plant Training	Daniel Locher
		Brandon Juran
10/19/06	Ingestion Pathway Training	Timothy Donakowski
		Brandon Juran
		Daniel Locher
		Sherrie Flaherty
		Craig Verke
10/20/06	Ingestion Pathway Training	Timothy Donakowski
		Daniel Locher
		Sherrie Flaherty
· .		Sue McClanahan
10/29 - 11/03/06	RERO Training	Ben Sunderlin

INDEPENDENT SPENT FUEL STORAGE FACILITY (ISFSI)

The Prairie Island Dry Cask Storage Facility (also known as ISFSI) was created in 1994 to store spent fuel outside the plant but within the boundaries of the nuclear generating plant property. This was the third such facility to be constructed the US. The Public Utilities Commission ordered Prairie Island Nuclear Power Plant to install two radiation monitors so that MDH could routinely assess the radiation levels from the casks.

Timothy Donakowski, Sherrie Flaherty, George Johns, Brandon Juran, Sue McClanahan and Craig Verke receive radiation level update twice a day. Two high-pressure ion chambers at the Prairie Island ISFSI are used to monitor those levels. In addition, alarms are reported via cell phone to Tim and George.

Equipment

As mentioned, the two high-pressure ion chambers have been in place since the 1994. No maintenance had been done on either unit since 1999. To facilitate a maintenance schedule, a new Reuter Stokes High Pressure Ion Chamber was ordered in 2006. A lightning strike damaged one of the units in August. Although originally scheduled to replace the other HPIC, the new unit was deployed as a replacement for the damaged system. A summary of the issues surrounding the replacement of the damaged unit is included as Appendix E.

An additional unit was ordered in the second half of 2006. That unit was returned to the manufacturer because it arrived without a modern. It is scheduled for placement in 2007.

ability in fields related to the utilization or development of nuclear energy.

- Legislature amended Statute 144.12 to include the handling, storage, transportation, use, and disposal of x-ray machines and radioactive materials. The Legislature also authorized the State Board of Health to adopt regulations for the control of sources of ionizing radiation.
- The State Board of Health adopted the Ionizing Radiation Rules on December 4. (Minnesota was one of the first states to have such regulations.)
- The Section of Radiation and Occupational Health initiated a detailed environmental radiation study program. A low background anticoincidence counter was purchased to assist in the sample analysis.
- Water surveillance expanded to monthly sampling and analysis of 40 surface waters and 20 ground water supplies.
- The environmental radiation study revealed the presence of Strontium-90 in milk. In a study supported by the U.S. Public Health Service, monthly milk samples were taken from five areas in Minnesota. The results indicated the amounts were well within the maximum permissible concentration levels.
- Additional environmental monitoring was conducted around the Elk River reactor site in accordance with the preoperational monitoring program.
- The Section of Radiation and Occupational Health staff expanded to include a radiochemist, a chemical engineer, two chemist aids, and a radiological health physicist on loan from U.S. Public Health Service.
- The Radiological Health Program expanded to include medical and industrial sources of radiation.
- The Legislature appropriated \$25,000 per year for the development of the State Board of Health Radiological Health Program. Three additional technical staff were hired, as was a radiation physicist. The State Board of Health appointed a Radiation Safety Advisory Committee to advise the Board on matters related to the field of radiation. In addition, a radiochemical lab was constructed and equipped.
- In August and September of 1962, Iodine-131 levels in milk had increased significantly. After meetings with representatives from the dairy industry, the Minnesota Department of Agriculture, and other concerned parties, an aged feeding program for fluid milk dairy herds was implemented to reduce the I-131 levels. Samples were collected on a 24-hour basis and verified that the technique was effective.
- Because of the extreme hazards related to leaking radium from a sealed source, the Section of Radiation and Occupational Health increased the frequency of its leak testing to every six months.
- At this point in time, environmental monitoring and x-ray surveys took up most of the Section's staff time.
- 1966

1965

1959

1962

- In June of 1966, Iodine in eight milk-sampling locations rose slightly following Chinese nuclear weapons testing in the previous month. The levels were found to be within established limits. The general trend for Strontium-90 and Cesium-137 in milk continued downward, but remained within the detectable range.
- Daily sampling of air particulates continued by the Public Health Service Radiation Surveillance Network. The results were published in "Radiological Health Data and

1977

1978

1979

1985

- The registration fee was incorporated.
- China & India conducted aboveground nuclear bomb tests. Environmental monitoring detected additional radioactivity in Minnesota milk and air, but not in sufficient quantities to recommend protective actions.
- Environmental monitoring was conducted following the nuclear accident at Three Mile Island. No related contamination was found in Minnesota.
 - Prairie Island had a loss of coolant accident caused by a rupture in the re-circulating water pipe. The accident was controlled within a couple hours; nonetheless, MDH followed through with its emergency response plan. Environmental monitoring and samples were taken and the two-mile area surrounding the plant was evacuated. Tests showed that the release consisted mostly of krypton, xenon, and a small amount of Iodine-131 that did not extend much beyond plant boundary.
 - Some Cobalt-60 was included as scrap metal that was used to make table legs sold all over country. When MDH was notified, dozens of restaurants and other facilities were already using the tables and many more were in storage. Radiation Control staff inspected each table.
 - The same year, some Polonium-210 discs became dislodged from 3M anti-static devices, creating potentially contaminated areas. Many of these devices were located in manufacturing or processing facilities, but some were in food-processing establishments. NRC sent its staff to inspect these facilities, and Radiation Control assisted by conducting inspections in places like Hormel Meats in Austin and Baldinger Bakery in West St. Paul.
 - The Chernobyl accident in the Soviet Union (now Ukraine) required additional environmental monitoring. Radiation Control maintained contact with the U.S. Department of Energy the Environmental Protection Agency to get updates on the content and amount of the release. Some radioactivity was found in Minnesota environmental samples, but none were high enough to warrant special action.
 - Fees for the registration of x-ray machines and radium increased for the first time in ten years.
 - Another radioactive source mixed with scrap metal was made into chain link fencing. Radiation Control staff was dispatched to inspect the fencing.
 - The registration fees were increased to make Radiation Control self-supporting by 1995.
 - The Legislature gave Radiation Control the authority to issue Cease & Desist orders and Administrative Penalties; rules were drafted following the authorization.
 - The Health Enforcement act was adopted to give MDH the ability to fine facilities and individuals for rule violations and noncompliance. The fine maximum was \$10,000 per inspection.

1987

1986

1990

• The Chairman of the US Nuclear Regulatory Commission signed the Minnesota Agreement on February 3.

• MDH implemented Increased Controls for 24 licensees.

• Governor Pawlenty certified that MDH was capable of assuming responsibility for NARM and John Stine, State Liaison Officer, provided assurance that the certification would be in effect the day the law was passed.

Ludlum	2241-2 w/ AC-3 probe (457979) and NaI probe model SPA-4 (160)	228391	8/22/2006
Radiation Alert	Monitor 5	2561	11/14/2006
Radiation Alert	Monitor 4/4EC	31663	11/14/2006
Radiation Alert	Monitor 4/4EC	31784	11/14/2006
Radiation Alert	Monitor 4/4EC	31896	11/14/2006
Radiation Alert	Monitor 4/4EC	38564	11/14/2006
Ludlum	2241-3	228168	11/1/2006
Ludlum	2241-3	228418	11/1/2006
Ludlum	2241-3	228295	11/1/2006
Ludlum	2241-2	232681	9/19/2006
Ludlum	2241-2	232667	9/19/2006
Ludlum	2241-2	232708	9/19/2006
Dosimeter Corp.	862	4010818	11/14/2006
Dosimeter Corp.	862	4010820	11/14/2006
Dosimeter Corp.	862	4010831	11/14/2006
Dosimeter Corp.	862	4010832	11/14/2006
Dosimeter Corp.	. 862	4010833	11/14/2006
Dosimeter Corp.	862	4010835	11/14/2006
Dosimeter Corp.	862	4010838	11/14/2006
Dosimeter Corp.	611	9124754	11/14/2006
Dosimeter Corp.	611	9124767	11/14/2006
Dosimeter Corp.	611	9124783	11/14/2006
Dosimeter Corp.	611	9124781	4/21/2006
Dosimeter Corp.	611	9124787	4/21/2006
Dosimeter Corp.	611	9124795	4/21/2006
Dosimeter Corp.	862	8101121	4/21/2006
Dosimeter Corp.	862	8101122	4/21/2006
Dosimeter Corp.	862	8101123	4/21/2006
Dosimeter Corp.	862	8101124	4/21/2006
Dosimeter Corp.	862	8101125	4/21/2006
Dosimeter Corp.	862	8101126	4/21/2006
Dosimeter Corp.	862	8101127	4/21/2006
Dosimeter Corp.	862	8101128	4/21/2006
Dosimeter Corp.	862	8101130	4/21/2006
Dosimeter Corp.	862	8101131	4/21/2006
Dosimeter Corp.	862	8101132	4/21/2006
Dosimeter Corp.	862	8101133	4/21/2006
Dosimeter Corp.	862	8101134	4/21/2006
Dosimeter Corp.	862	8101135	4/21/2006

Appendix C

License Conditions

Increased Controls

The licensee must comply with the requirements described in the Minnesota Department of Health letter dated **[insert date of letter]**¹¹ and the attached document entitled "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern." The licensee must complete implementation of said requirements by May 14, 2006 or the first day that radionuclides in quantities of concern are possessed at or above the limits specified in Table 1 of the attachment, whichever is later.

Part 30.34

Each portable gauge licensee must use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

Training and Experience Requirements for Medical Uses (Part 35)

Authorized users of radioactive material in medical applications must meet the training and experience in 10 CFR 35 subparts D, E, F, G and H, and the recentness of experience requirements in Minnesota Rules, part 4731.4415. In addition, the requirements for the following users (as defined in 10 CFR 35.2) apply:

A. 10 CFR 35.50 for Radiation Safety Officer (RSO)

B. 10 CFR 35.51 for Authorized Medical Physicists

C. 10 CFR 35.55 for Authorized Nuclear Pharmacists

Transportation

The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71 "Packaging and Transportation of Radioactive Material." Nothing in this license condition applies to the extent that the person is subject to regulations of the NRC.

¹¹ The date of the MDH letter should be the effective date of the Agreement with the NRC.

Appendix E

August 2006 PIC No. 1 Issues

On the morning of Wednesday, August 2, 2006 PIC No. 1 (North Unit) stopped sending data when polled by our monitoring computers. There were lightning storms in the area at that time and previous storms had effected the modem so that it would not answer. This time, the modem would answer but send no data.

On or about August 8, Prairie Island staff attempted to re-boot the modem. The displayed appeared to be corrupted, but came back after the re-boot. However, the modem would still not transmit data. A photograph of the display, showing the correct radiation level (90.1 μ R/h—see attached photo) was taken on August 10.

Based on the information from Prairie Island, the modem was assumed to have been damaged. GE Reuter Stokes staff agreed and suggested purchasing a new modem from Radio Shack®, or returning the unit to them for diagnosis.

On August 15, PI completed the following trouble-shooting:

- North radiation monitor modem was removed from North radiation monitor. The South radiation monitor modem was temporarily removed from the South radiation monitor and was re-installed in the North radiation monitor location. Attempts to retrieve data from the North radiation monitor (via dial-up) but were not successful. The modem connects but no data transmitted.
- The South modem was removed from North radiation monitor and was re-installed in the South radiation monitor. Retrieval of data from the South radiation monitor was successful.

Based on the information, the judgment was that the modem is not the problem. From observations of the North radiation monitor components it appears that the internal heater strip may have mal-functioned at some point in time, which resulted in excessive heat. The reasons for this conclusion are:

- The heater strip appears to be charred.
- The personnel barrier "card" is discolored.
- The plastic box for the associated temperature controller shows evidence of warping from melting.
- The plastic box for the modem shows evidence of warping from melting.

Prairie Island staff saw no visible evidence of damage to the computer card and associated electrical components on the other side of the panel from the heater strip but indicated that damage was highly likely. In addition, there was evidence of battery leakage from the back-up battery within the panel. The battery contacts were also corroded.

B. NON-COMMON PERFORMANCE INDICATORS

I. Legislation and Program Elements Required for Compatibility Authority for Minnesota's radiation control unit and proposed Agreement State activities is primarily found in Minnesota Statutes, Sections 144.12-144.121, and in the Minnesota Rules Chapter 4731. Below is a brief description of all statutes included in this section. Minnesota's statutes and rules are also accessible on the Internet at http://www.revisor.leg.state.mn.us/stats/. The NRC's Statute Compliance Letter is also included in this section. Finally, the initial version of Minnesota Statute 144.1205 and The Act, which was approved by the 2004 Legislature, are found here also. The Act became Minnesota Statute 144.1205 as amended.

Statute Subject

13.02 Collection, security and dissemination of records; definitions.

- 13.39 Civil investigation. Covers the requirements the Commissioner follows in a pending civil legal action.
- 13.41 Licensing data. Covers the requirements that the Commissioner must follow to ensure that data collected for licenses is kept within the statutory guidelines of data privacy.
- 144.05 General duties of Commissioner; reports.
- 144.12 Regulations, enforcement, licenses, fees. Overall commissioner authority to regulate, adopt rules, enforce, license and collect fees.
- 144.99 Enforcement. Outlines the authority that the Commissioner has to access information and issue correction orders, administrative penalty orders, injunctive relief, cease and desist orders, suspension or revocation of permits, licenses, registration or certificates. Allows for hearing, misdemeanor penalties, and the authority to impound radioactive materials and associate shielding.
- 144.121 X-ray machine and facilities using other sources of ionizing radiation. Indicates that machines and materials must be registered and that the Commissioner can collect fees and perform inspections.
- 144.989 Title; citation. This legislation is the title for the enforcement. Parts 144.989 to 144.993 are referred to as the Health Enforcement Consolidation Act of 1993.
- 144.991 Administrative penalty order procedure. Outlines the administrative penalty order procedure that must be followed.

144.992 False information. Asserts that a person cannot make false material statements, representation or certification in any of the commissioner's areas or they are subject to actions listed in section 144.99, subdivision 1.

27.

- 144.993 Recovery of litigation costs and expenses. Allows the Commissioner to recover any costs brought on my any litigation.
- 144.1201 Definitions. For agreement state program. Provides clarification for 144.1202.
- 144.1202 U.S. NRC agreement. Gives the responsibility and authority for an agreement state program to the Department of Health.
- 144.1203 Training; rulemaking. Authority given to the Commissioner to adopt rules to ensure that individuals handling or utilizing radioactive materials are properly trained and have the qualifications to do so.
- 144.1204 Surety requirement. Gives the Commissioner authority to require financial assurance for radioactive materials licensees.
- 144.1205 Radioactive material; source and special nuclear material; fees; inspection. Gives the Commissioner authority to collect fees and penalties, and to conduct inspections.
- 181.931 Definitions. Definitions used in the sections 181.931 to 181.935. This section covers employee rights.
- 181.932 Disclosure of information by employees. Actions prohibited by an employer whose employee files a complaint against the employer.
- 181.933 Notice of termination. Addresses employee who has been involuntarily terminated, and that any defamation action is prohibited.
- 181.934 Employee notice. The Department of Labor and Industry will have rules for the notification of employees by employers of an employee's rights.
- 181.935 Individual remedies; penalty. Refers to the ability of the employee to bring civil action to recover costs and damages caused by violation of 181.932.
- 28. There are no regulations subject to a "Sunset" or equivalent law.
- 29. The *State Regulation Status* has been reviewed. With the exception of the Nation Source Tracking requirements, MDH's current rulemaking effort will address all the items identified in the *State Regulation Status*. MDH anticipates the rule to become final by October 1, 2007.

The only amendment that was not adopted within three years from the NRC rule promulgation address Financial Assurance for Materials Licensees – Parts 30, 40, 70 (RATS ID 2003-1). Those rules were not identified during the Agreement State application process or review. Consequently, they were overlooked. They are, however, included in the Department's current rulemaking and should become final by October 1, 2007.

30.

STATE REGULATION STATUS

State: Minnesota

Regulation¹ (Effective Date) **Final State** applicable SECY-95-112⁴ required³ required³ required³ Sot Not Not Not 03/04/05⁶ ML050690100 03/04/05⁶ ML050690100 03/04/05⁶ ML050690100 03/04/05⁶ ML050690100 03/04/05⁶ ML050690100 Tracking Ticket Number: Revised 7-11 NRG Review / Y, N² / Date / ML #⁵ ML050690100 03/04/05⁶ Date: March 20, 2007 F ML050140452 F ML050140452 F ML050140452 Proposed (P) / Final (F) Rule / License ML050140452 ML050140452 ML050140452 Condition (FC) ML #5 Щ LL. ĽL. 1991-3 1991-4 1992-1 1992-2 1993-2 1991-1 1991-2 1993-1 1993-3 1994-1 RATS ID 56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183; (1/1/94) 58 FR 68726; 59 FR 1618; (none) 56 FR 64980; (10/15/94) 58 FR 39628; (10/25/96) 56 FR 34104; (1/27/95) 58 FR 33886; (7/22/96) 57 FR 45566; (none) 55 FR 843; (1/10/94) 56 FR 11504; (none) 58 FR 7715; (7/1/96) State Due Date) **FR** Notice Decommissioning Recordkeeping and License Termination: Documentation Additions Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35 Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70 Licensing and Radiation Safety Requirements for Irradiators-Part 36 Definition of Land Disposal and Waste Site QA Program-Part 61 [# amendments reviewed identified by a ★ at the beginning of the equivalent NRC requirement.] Quality Management Program and Misadministrations-Part 35 Safety Requirements for Radiographic Equipment-Part 34 Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70 Standards for Protection Against Radiation-Part 20 [Restricted areas and spill sites]-Parts 30, 40 ASNT Certification of Radiographers-Part 34 NRC Chronology Identification

NRC Chronology Identification	FR Notice (State Due Date)	RATS 10	Proposed (P) / Final (F) ¹ Rule / License Condition (LC) ML #	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation (Effective Date)
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61.FR 65120; (1/9/00)	1997-1	F ML050140452	03/04/05 ⁶ ML050690100	
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Arreement State-Part 150	62 FR 1662; (2/27/00)	1997-2	F ML050140452	03/04/05 ⁶ ML050690100	
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F ML050140452	03/04/05 ⁶ ML050690100	
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 Padiography Operations-Parts 30, 34, 71, 150	62 FR 28947; (6/27/00)	1997-5	F ML050140452	03/04/05 ⁶ ML050690100	ľ
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6	F ML050140452	03/04/05 ⁶ ML.050690100	
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14	62 FR 63634; (1/02/01)	1997-7	F ML050140452	03/04/05 ⁶ ML050690100	
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773; (2/12/01)	1998-1	F ML050140452	03/04/05 ⁶ ML_050690100	
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 ML050140452	03/04/05 ⁶ ML050690100	
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20	63 FR 39477; 63 FR 45393; (10/26/01)	1998-5	F ML050140452	03/04/05 ⁶ ML050690100	· · · · · · · · · · · · · · · · · · ·

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F) ¹ Rule / License Condition (LC) ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation (Effective Date)
Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71.	69 FR 3697; (10/01/07)	2004-1	P ML070240111 LC	X 03/06/07 ML070650052 N 1/20/06 ML060200281	
Security Requirements for Portable Gauges Containing Byproduct Material - Part 30	70 FR 2001; (7/11/08)	2005-1	P ML070240111 LC	N 03/06/07 ML070650052 N 1/20/06 ML060200281	
Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35	70 FR 16336; 71 FR 1926 (4/29/08)	2005-2	P ML070240111 LC	N 03/06/07 ML070650052 N 1/20/06 ML060200281	
Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090)7	70 FR 72128; (12/1/05)	2005-3	LC ML053220236	11/18/2005 ML053220444	
Minor Amendments - Parts 20, 30, 32, 35, 40, and 70	71 FR 15005 (03/27/09)	2006-1	P ML070240111	N 03/06/07 ML070650052	
National Source Tracking System - Serialization Requirements - Part 32 with reference to Part 20 Appendix E	71 FR 65685 (2/6/07)	2006-2			
National Source Tracking System - Part 20	71 FR 65865 (11/15/07) & (11/30/07)	2006-3			

Or other generic Legally Binding Requirements.

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 (γ/N) γ 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. ц М

Not required means these regulations are not required for purposes of compatibility.

3

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 4

B. NON-COMMON PERFORMANCE INDICATORS

II. Sealed Source and Device Program

Not Applicable

III. Low-Level Radioactive Waste Disposal Program

Not Applicable

IV. Uranium Recovery Program

Not Applicable