

January 31, 2012

MEMORANDUM TO: Michael F. Weber
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

Bradley W. Jones, Assistant General Counsel
for Reactor and Materials Rulemaking
Office of the General Counsel

Mark A. Satorius Director
Office of Federal and State Materials
and Environmental Management Programs

Elmo Collins, Regional Administrator
Region IV

FROM: Duncan White, Chief */RA/*
Agreement State Programs Branch
Division of Materials Safety
and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION
PROGRAM REVIEW OF THE MINNESOTA AGREEMENT STATE
PROGRAM

This memorandum transmits to the Management Review Board (MRB) a proposed final report (Enclosure 1) documenting the Integrated Materials Performance Evaluation Program (IMPEP) review of the Minnesota Agreement State Program. The review was conducted by an interoffice team during the period of November 14-18, 2011. The review team issued a draft report to Minnesota on December 12, 2011, for factual comment. The State responded by letter dated January 17, 2012 from Dale Dorschner, Manager, Indoor Environments and Radiation Section, Minnesota Department of Health noting a few minor edits which were incorporated in the proposed final report. Minnesota's response letter can be found in ADAMS (ML120240123) and is attached to the proposed final report.

The review team is recommending that Minnesota's performance be found satisfactory for all indicators reviewed. Accordingly, the review team is recommending that the Minnesota Agreement State Program be found adequate to protect public health and safety, and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommends that the next IMPEP review take place in approximately 5 years from the date of the current IMPEP with a Periodic meeting in 2.5 years. The Minnesota Agreement State Program meets the criteria for a one year extension of its next IMPEP review.

The MRB meeting to consider the Minnesota IMPEP report is scheduled for **Tuesday, February 14, 2012, from 1:00 p.m. to 3:00 p.m. (EST), in OWFN-3B4**. In accordance with NRC Management Directive 5.6, the meeting is open to the public. The agenda for the meeting is enclosed (Enclosure 2).

Enclosures: As stated

cc w/encl: Jennifer Opila, Colorado
Organization of Agreement States
Liaison to the MRB

Aggie Leitheiser, Assistant Commissioner
Health Protection Bureau
Minnesota Department of Health

Dale Dorschner, Environmental Health Manager
Indoor Environments and Radiation Section

Sherrie Flaherty, Supervisor
Radioactive Materials Unit

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
REVIEW OF THE MINNESOTA AGREEMENT STATE PROGRAM

NOVEMBER 14 – 18, 2011

PROPOSED FINAL REPORT

Enclosure 1

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Minnesota Agreement State Program. The review was conducted during the period of November 14-18, 2011, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Kentucky.

Based on the results of this review, the review team recommends that Minnesota's performance be found satisfactory for the six performance indicators reviewed. The review team did not make any recommendations regarding program performance by the State. Accordingly, the review team recommends that the Minnesota Agreement State Program be found adequate to protect public health and safety and compatible with NRC's program.

Based on the results of the current IMPEP review, and in accordance with the criteria in NRC Management Directive 5.6, the review team recommends that the next IMPEP review take place in approximately five years (receiving a one year extension for good performance.)

1.0 INTRODUCTION

This report presents the results of the review of the Minnesota Agreement State Program. The review was conducted during the period of November 14-18, 2011, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Kentucky. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of October 20, 2007, to November 18, 2011, were discussed with Minnesota managers on the last day of the review.

[A paragraph on the results of the Management Review Board (MRB) meeting will be included in the final report.]

The Minnesota Department of Health (the Department) is designated as the State's radiation control agency. The Agreement State Program is administered by the Radioactive Materials Unit (the Unit), which is located within the Indoor Environments and Radiation Section (the Section) of the Division of Environmental Health (the Division). The Division is part of the Health Protection Bureau (the Bureau), which is one of four bureaus in the Department. The Unit Supervisor reports to the Section Environmental Health Manager. Organization charts for the Department and the Section are included as Appendix B.

At the time of the review, the Minnesota Agreement State Program (the Program) regulated 178 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between NRC and the State of Minnesota.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Section on September 19, 2011. The Section provided its response to the questionnaire on October 25, 2011. A copy of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML113110142.

The review team's general approach for conduct of this review consisted of: (1) examination of the Section's response to the questionnaire; (2) review of applicable Minnesota statutes and regulations; (3) analysis of quantitative information from the Unit's database; (4) technical review of selected regulatory actions; (5) field accompaniments of three inspectors; and (6) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common performance indicator and the applicable non-common performance indicator and made a preliminary assessment of the Minnesota Agreement State Program's performance.

There were no recommendations made to the State during the previous IMPEP review, which concluded on October 19, 2007. Section 2.0 of this report covers the current review of the common performance indicators. Section 3.0 details the results of the review of the applicable non-common performance indicators, and Section 4.0 summarizes the review team's findings.

2.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review NRC Regional and Agreement State radioactive materials programs. These indicators are: (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

2.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the Unit's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Section's questionnaire response relative to this indicator; interviewed managers and staff, reviewed job descriptions and training records, and considered any workload backlogs.

The Minnesota Agreement State Program is composed of the Unit Supervisor (Supervisor), four technical staff, and one administrative assistant. The Supervisor is responsible for coordinating materials inspections, licensing and compliance activities. Technical staff perform both licensing and inspection duties and respond to incidents and allegations. The Supervisor and technical staff also perform emergency response duties. Based on information provided by the Unit, the review team estimated that the Unit routinely expends approximately 4.8 full-time equivalents (FTE) to administer the Agreement State program, including administrative duties.

In September 2010, the former Supervisor retired and a technical staff member was subsequently promoted to the Supervisor position. In addition, during the review period, two technical staff members left the Unit and three technical staff members were hired into the Unit. There are no open positions currently.

Due to a State budget impasse, Minnesota state government services were shut down from July 1, 2011, until July 20, 2011. During this period, the Department retained two staff members for the Agreement State program and all other staff members were laid off. On June 30, 2011, the Department submitted a contingency plan to NRC which described the Department's plans for continuity of operations during the State government shutdown. On July 1, 2011, the NRC responded to the Department's letter and found that the contingency plan was acceptable for the short term and provided adequate assurance that the Program would continue to respond to emergencies and protect public health and safety in case of a radioactive material event during the temporary government shutdown.

The review team noted that the Program experienced stable funding during the review period. The Government shutdown did not affect overall funding of the Program. The Program is totally funded through licensee fees which have not been increased since the 2007 IMPEP review.

The Unit has a documented training plan that is consistent with the guidance in the NRC's Inspection Manual Chapter 1246, "Formal Qualification Programs in the Nuclear Materials Safety and Safeguards Program Area." All technical staff members have a Bachelor's degree in a science discipline. Technical staff members attend NRC courses, or equivalent, as part of their inspection and license reviewer qualification process. In addition the staff has on-the-job training to supplement formal course work. Under the direction of the Supervisor, technical staff members are assigned increasingly complex licensing actions and accompany more experienced inspectors on complex inspections. Inspectors are assigned independent

inspections after demonstrating competence during accompaniment evaluations by the Supervisor. The review team confirmed the qualifications of all technical staff through review of qualification journals, training records, and documentation of supervisory accompaniments. The review team concluded that management is supportive of staff training opportunities.

The Supervisor and one senior technical staff member are fully qualified to perform both licensing and inspection activities and have completed the required training in each of these areas. The two technical staff members who were hired in late 2010 are currently in the qualification process and can independently perform inspections of lower priority (i.e., priority 5) licensees. The Supervisor anticipates both staff members being fully qualified by the end of calendar year 2012. The review team concluded that the Unit has a well-balanced staff and an adequate number of trained personnel to carry out its regulatory responsibilities.

Based on the IMPEP evaluation criteria, the review team recommends that Minnesota's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

2.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation was based on the Unit's questionnaire response relative to this indicator, data gathered from the Unit's database, examination of completed inspection casework, and interviews with managers and staff members.

The Unit tracks all inspection activities in a computer database. The review team observed that the database could easily be queried by managers and staff to determine the inspection status for any licensed facility. In addition, the notification of licensees working under reciprocity in the state was also easily accessible from the database.

The review team verified that the Unit's inspection frequencies for all types of radioactive materials licenses are at least the same frequency as those listed in NRC's IMC 2800, "Materials Inspection Program." The review team confirmed the Unit is conducting Increased Controls inspections in conjunction with the routine health and safety inspections.

The Unit conducted 135 Priority 1, 2, and 3 inspections during the review period. The Unit indicated in its response to the questionnaire that no inspections were conducted overdue by more than 25 percent of the inspection frequency prescribed by IMC 2800. The review team verified that no Priority 1, 2, or 3 inspections were conducted overdue during the review period or found overdue at the time of the review.

The review team evaluated the Unit's timeliness for conducting initial inspections. The review team noted that the Unit issued 11 new licenses during the review period and conducted all initial inspections within 12 months after license issuance as prescribed by IMC 2800.

The review team evaluated the Unit's timeliness of issuance of inspection reports. The Unit has a policy of issuing the inspection findings to licensees within 30 days from the date of the inspection. All inspection reports are submitted for both a peer and supervisory review. Based on a review of 48 inspection reports, the review team identified 2 of the inspection findings were communicated to the licensees beyond the Unit's 30-day goal.

During the review period, the Unit granted 97 reciprocity permits, 39 of which were candidate licensees based upon the criteria in IMC 1220 "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20." The review team determined that the Unit exceeded the NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity in each of the four years covered by the review period.

Based on the IMPEP evaluation criteria, the review team recommends that Minnesota's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

2.3 Technical Quality of Inspections

The review team evaluated inspection reports, enforcement documentation, and inspection field notes and interviewed the responsible inspector for 28 radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by eight current and former inspectors and covered a wide variety of inspection types. These included radiation therapy, mobile nuclear medicine, veterinarian nuclear medicine, industrial radiography, portable gauges, gamma knife, nuclear pharmacy, Positron Emission Tomography production, well logging, and research. The casework included initial, routine, reciprocity, and Increased Controls inspections. Appendix C lists the inspection casework files reviewed.

Based on the evaluation of casework, the review team determined that inspections covered all aspects of the licensees' radiation safety and security programs. The review team noted that the inspections covered the Increased Controls, fingerprinting, and the National Source Tracking System when appropriate. The review team found that inspection reports were very thorough, complete, consistent, and of high quality with sufficient documentation to ensure that licensees' performances with respect to health, safety, and security were acceptable. Inspection report documentation supported violations, recommendations made to licensees, and unresolved safety issues. All inspection reports are peer-reviewed by a qualified inspector and are approved by the Unit Supervisor.

While on site, the review team evaluated the Unit's handling and storing of sensitive documents. The team noted that inspection reports were appropriately marked as containing sensitive information. Inspection files containing Increased Controls documents were protected in locked cabinets in a limited access room.

The Unit has a policy to accompany all staff performing radioactive materials inspections on an annual basis. All inspector accompaniments were performed annually during the review period except for one missed accompaniment in 2010 due to a managerial transition. The accompaniment reports contained sufficient details to document the areas covered during the accompaniments.

The review team noted that the Unit has an adequate supply of survey instruments to support its inspection program, as well as to respond to incidents and emergency conditions. Appropriate, calibrated survey instruments, such as Geiger-Mueller (GM) meters, scintillation detectors, ion chambers, micro-R meters, and neutron detectors, were observed to be available. The Unit also has portable multi-channel analyzers for field identification of radioisotopes. Instruments are calibrated at least annually, or as needed, with sources that were traceable to the National Institute of Standards and Technology. The Unit uses a database to track each instrument, its

current location, and its calibration due date. In addition, the Unit supplies calibrated radiation detection equipment to the Minnesota Department of Transportation's Hazardous Materials Inspectors, and the Minnesota Highway Patrol. The Unit receives laboratory and sample analysis support from the Public Health Laboratory Division within the Department.

A review team member accompanied three of the Unit's inspectors during the period of October 17-19, 2011. The inspectors conducted inspections at a medical licensee, an industrial radiography licensee, and a portable gauge licensee. The inspector accompaniments are listed in Appendix C. The inspectors demonstrated performance-based inspection techniques and knowledge of the regulations. The inspectors were well trained, prepared for the inspections, and thorough in their audits of the licensees' radiation safety and security programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspectors held entrance and exit meetings with the appropriate level of licensee management. The review team determined that the inspections were adequate to assess radiological health, safety, and security at the licensed facilities.

Based on the IMPEP evaluation criteria, the review team recommends that Minnesota's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

2.4 Technical Quality of Licensing Actions

The review team examined completed casework and interviewed license reviewers for 18 licensing actions covering 17 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, security requirements, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate correspondence, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer and supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included two new licenses, five renewals, nine amendments, and two license terminations. Casework reviewed included a cross-section of license types, including: industrial radiography, broad scope - medical and academic, nuclear medicine - diagnostic and therapeutic, research and development, portable gauge, fixed gauge, nuclear pharmacy, and veterinary. A listing of the licensing casework reviewed can be found in Appendix D.

The review team found that the licensing actions were thorough, complete, consistent, and of high quality with health, safety, and security issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file and enforceable. The review team found that actions terminating licenses were well documented, included the appropriate material survey records, and contained documentation of proper disposal or transfer of radioactive material, as appropriate.

The Unit has two fully qualified license reviewers including the supervisor, and two partially qualified license reviewers. License reviewers use the Unit's licensing guidance which is

compatible with NRC's NUREG-1556 series. Licenses are created and tracked using a local database. Licensing actions are tracked on a master list which is accessible to all license reviewers but not linked directly to the database. Once completed all licensing actions are peer reviewed by another qualified license reviewer, and then reviewed and signed by the Unit Supervisor. The Unit identified six licensees requiring financial assurance; all licensees had financial assurance in place prior to the review period.

The review team verified that the Unit uses legally binding license conditions that meet the criteria for implementing the Increased Controls Orders, including fingerprinting, as appropriate. There are currently 24 licenses that are required to meet these requirements. Files containing Increased Control licenses are kept in a locked file room. The review team determined that these licenses and corresponding cover letters were marked as containing sensitive information as required. In addition, the review team verified that the Unit is identifying and marking sensitive security-related information appropriately in accordance with their policy.

The review team assessed the Unit's implementation of the pre-licensing guidance. The Unit has implemented the essential elements of NRC's pre-licensing guidance issued on September 22, 2008, and transmitted to the Agreement States via Office of Federal and State Materials and Environmental Management Programs (FSME) Letter RCPD-08-020, "Requesting Implementation of the Checklist to Provide a Basis for Confidence That Radioactive Material Will Be Used as Specified on a License and the Checklist for Risk-significant Radioactive Material." The Unit has incorporated a basic pre-licensing checklist into the licensing process. The Unit completes pre-licensing visits as required. New licensees that fall under the Increased Controls also have a full security inspection performed prior to issuing the license.

Based on the IMPEP evaluation criteria, the review team recommends that Minnesota's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

2.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Unit's actions in responding to incidents and allegations, the review team examined the Unit's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Minnesota in the Nuclear Material Events Database (NMED) against those contained in the Unit's files, and evaluated the casework for 13 radioactive materials incidents. A listing of the incident casework examined, with case-specific comments, may be found in Appendix E. The review team also evaluated the Unit's response to three allegations involving radioactive materials, including one allegation referred to the State by the NRC during the review period.

The incidents selected for review included the following categories: medical events, lost material, damaged equipment, leaking sources, and equipment failure. The review team determined that the Unit's response to incidents was complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. The Unit dispatched inspectors for on-site investigations, as appropriate, in all of the cases reviewed and took suitable enforcement and follow-up actions. If the incident met the reportability thresholds, as established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300 "Reporting Material Events," the State notified the NRC Headquarters Operations Center and entered the information into NMED, in a prompt manner. As additional incident details were learned, the

NMED records were updated, using the NMED software.

The review team noted that at the conclusion of investigations, inspectors generated reports that thoroughly documented their findings; however, two of the incident reports could not be located during the review. The Unit Supervisor stated that all incident investigation reports would be tracked in the future.

In evaluating the effectiveness of Minnesota's actions responding to allegations, the review team evaluated the casework for three allegations, one of which was referred to the State by the NRC. The Unit evaluated each allegation and determined the proper level of response. The review team determined that the Unit took prompt and appropriate action in response to all concerns raised. All of the allegations reviewed were appropriately closed, appropriate parties were notified of the actions taken, and alleged identities were protected. The review team identified no performance issues from the evaluation of the allegation casework.

Based on the IMPEP evaluation criteria, the review team recommends that Minnesota's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

3.0 NON-COMMON PERFORMANCE INDICATORS

3.1 Compatibility Requirements

3.1.1 Legislation

Minnesota became the 34th Agreement State on March 31, 2006. The current effective statutory authority is contained in the *Minnesota Statutes*, Sections 144.12 through 144.1205. Section 144.1202 authorized the Governor to enter into the Agreement with the Commission and contains provisions for the orderly transfer of regulatory authority over affected licenses from NRC to the State. This Section identifies the Minnesota Department of Health as the lead agency for the Agreement State program.

3.1.2 Program Elements Required for Compatibility

Minnesota's regulations for the control of radiation are located in the *Minnesota Rules Chapters 4731 and 4732*. Minnesota requires a license for possession and use of all radioactive materials, including naturally occurring radioactive materials, such as radium, and accelerator-produced radionuclides.

The review team examined the State's administrative rulemaking process and found that the process typically takes approximately one year after drafting before a rule becomes effective. Draft rules are developed by Unit staff and then sent to the Office of the Revisor of Statutes. Proposed rules are then published for comment in a Notice of Intent to Adopt Rules in the *Minnesota Register*. A hearing opportunity is offered upon publication of the notice. An Administrative Law Judge approves final rules prior to submission to the Secretary of State for final approval. At the conclusion of the rulemaking process, a Notice of Adoption is published in the *Minnesota Register*. The Governor's office is informed of proposed rules at each step in the process. The State has the authority to issue legally-binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective. Minnesota's regulations are not subject to any sunset provisions.

The review team evaluated the Unit's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted, and verified the final adoption of regulations with data obtained from the State Regulation Status Sheet maintained by FSME. Since the previous IMPEP review, the Department has completed and adopted twelve amendments. During the onsite review, the Unit submitted the following final amendment due for adoption by September 28, 2012.

- "Medical Use of Byproduct Material –Authorized User Clarification," Part 35 (74 FR 33901).

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than three years after they become effective. There were no amendments overdue at the time of the review.

The State will need to address the following amendments in upcoming rulemakings or by adopting alternate legally binding requirements:

- "Decommissioning Planning," Parts 20, 30, 40, and 70 (76 FR 35512) that became effective on December 17, 2011, and is due for Agreement State adoption by December 17, 2015.
- "Licenses, Certifications, and Approvals for Materials Licensees," Parts 30, 36, 39, 70, and 150 (76 FR 56951) that became effective on November 14, 2011, and is due for Agreement State adoption by November 14, 2014.

Based on IMPEP evaluation criteria, the review team recommends that Minnesota's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

4.0 SUMMARY

As noted in Sections 2.0 and 3.0 above, Minnesota's performance was found satisfactory for all six performance indicators reviewed. The review team made no recommendations regarding the performance of the Minnesota Agreement State Program. Accordingly, the review team recommends that the Minnesota Agreement State Program be found adequate to protect public health and safety and compatible with NRC's program.

Based on the results of the current IMPEP review, the review team recommends that the next full IMPEP review take place in approximately five years (receiving a one year extension based on good performance.)

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Minnesota Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Donna Janda, Region I	Team Leader Technical Staffing and Training Inspector Accompaniments
Lisa Dimmick, FSME	Status of Materials Inspection Program Compatibility Requirements
Jim Lynch, Region III	Technical Quality of Inspections Technical Quality of Incident and Allegation Activities
Matthew McKinley, Kentucky	Technical Quality of Licensing Actions

APPENDIX B

MINNESOTA ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML113110139

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1	
Licensee: IESCO	License No.: 1181
Inspection Type: Special, Unannounced	Priority: 2
Inspection Dates: 1/22-23/09	Inspector: BJ
File No.: 2	
Licensee: Midwest Industrial X-ray, Inc.	License No.: 1186
Inspection Type: Special, Unannounced	Priority: 1
Inspection Dates: 4/21-29/11	Inspectors: BA, LD, BJ
File No.: 3	
Licensee: Braun Intertec Corporation	License No.: 1082
Inspection Type: Special, Unannounced	Priority: 1
Inspection Date: 9/9/08	Inspector: SF
File No.: 4	
Licensee: Chart Industries	License No.: 1075
Inspection Type: Special, Unannounced	Priority: 1
Inspection Date: 10/14/09	Inspectors: BA, BJ
File No.: 5	
Licensee: Medtronic, Inc.	License No.: 1171
Inspection Type: Routine, Unannounced	Priority: 2
Inspection Date: 9/16/09	Inspector: SF
File No.: 6	
Licensee: Abbott Northwestern Hospital	License No.: 1007
Inspection Type: Routine, Announced	Priority: 2
Inspection Dates: 2/18-23/09	Inspectors: BJ, CV
File No.: 7	
Licensee: Animal Emergency Clinic	License No.: 1215
Inspection Type: Initial, Unannounced	Priority: 5
Inspection Dates: 2/10/11 & 3/6/11	Inspector: BA
File No.: 8	
Licensee: Metropolitan Cardiology Consultants	License No.: 1208
Inspection Type: Initial, Unannounced	Priority: 3
Inspection Dates: 11/12-13/09	Inspectors: BJ, BA

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File No.: 9

Licensee: Stork Twin City Testing
Inspection Type: Special, Unannounced
Inspection Date: 5/13/10

License No.: 1069
Priority: 1
Inspector: BA

File No.: 10

Licensee: DiaSorin, Inc.
Inspection Type: Routine, Unannounced
Inspection Dates: 1/27-28/10

License No.: 1159
Priority: 5
Inspector: BJ

File No.: 11

Licensee: St. Mary's Hospital
Inspection Type: Special, Unannounced
Inspection Date: 12/3/09

License No.: 1077
Priority: 2
Inspectors: GJ, BA

File No.: 12

Licensee: General Dynamics
Inspection Type: Special, Unannounced
Inspection Date: 5/12/11

License No.: 1086
Priority: 2
Inspectors: SF, TP

File No.: 13

Licensee: Lakeview Hospital
Inspection Type: Routine, Unannounced
Inspection Date: 4/12/10

License No.: 1051
Priority: 3
Inspector: GJ

File No.: 14

Licensee: Macalester College
Inspection Type: Routine, Unannounced
Inspection Date: 12/11/07

License No.: 1175
Priority: 5
Inspector: CV

File No.: 15

Licensee: Southdale Medical Diagnostics, LLC
Inspection Type: Initial, Unannounced
Inspection Date: 6/4/09

License No.: 1204
Priority: 5
Inspectors: SM, BJ

File No.: 16

Licensee: RRHS University Medical Center - Mesabi
Inspection Type: Routine, Unannounced
Inspection Date: 9/14/11

License No.: 1139
Priority: 3
Inspector: TP

File No.: 17

Licensee: Midwest Asphalt Corporation
Inspection Type: Routine, Unannounced
Inspection Date: 10/12/11

License No.: 1013
Priority: 5
Inspectors: LD, BJ

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File No.: 18

Licensee: Southern Minnesota Construction
Inspection Type: Routine, Unannounced
Inspection Date: 8/31/11

License No.: 1073
Priority: 5
Inspector: TP

File No.: 19

Licensee: St. Luke's Hospital
Inspection Type: Routine, Unannounced
Inspection Date: 1/18/11

License No.: 1137
Priority: 3
Inspectors: SF, TP, LD

File No.: 20

Licensee: PETNET Solutions, Inc.
Inspection Type: Routine, Announced
Inspection Dates: 10/25/07 & 11/13/07

License No.: 1017
Priority: 2
Inspectors: SM, SF

File No.: 21

Licensee: Mayo Clinic
Inspection Type: Initial, Unannounced
Inspection Dates: 2/11-14/08

License No.: 1047
Priority: 2
Inspectors: SF, GJ, BJ, CV

File No.: 22

Licensee: Mobile Imaging Services
Inspection Type: Routine, Unannounced
Inspection Date: 6/10/09

License No.: 1009
Priority: 3
Inspector: CV

File No.: 23

Licensee: Fairview Southdale Hospital
Inspection Type: Routine, Unannounced
Inspection Date: 7/9/08

License No.: 1039
Priority: 3
Inspectors: BJ, CV

File No.: 24

Licensee: Baker Hughes Oilfield Operations, Inc.
Inspection Type: Reciprocity, Announced
Inspection Date: 11/12/10

License No.: 9057
Priority: 3
Inspector: BJ

File No.: 25

Licensee: MIKON Corporation
Inspection Type: Reciprocity, Unannounced
Inspection Date: 4/13/10

License No.: 9059
Priority: 5
Inspector: BJ

File No.: 26

Licensee: Lifescan Minnesota
Inspection Type: Routine, Unannounced
Inspection Date: 10/17/11

License No.: 1024
Priority: 5
Inspector: TP

File No.: 27

Licensee: Braun Intertec Corporation
Inspection Type: Routine, Unannounced
Inspection Date: 11/18/11

License No.: 1082
Priority: 1
Inspector: BJ

File No.: 28

Licensee: City of Minneapolis
Inspection Type: Routine, Unannounced
Inspection Date: 11/19/11

License No.: 9059
Priority: 5
Inspector: LD

INSPECTOR ACCOMPANIMENTS

The following inspector accompaniments were performed prior to the on-site IMPEP review:

Accompaniment No.: 1

Licensee: Lifescan Minnesota
Inspection Type: Routine, Unannounced
Inspection Date: 10/17/11

License No.: 1024
Priority: 5
Inspector: TP

Accompaniment No.: 2

Licensee: Braun Intertec Corporation
Inspection Type: Routine, Unannounced
Inspection Date: 10/18/11

License No.: 1082
Priority: 1
Inspector: BJ

Accompaniment No.: 3

Licensee: City of Minneapolis
Inspection Type: Routine, Unannounced
Inspection Date: 10/19/11

License No.: 1015
Priority: 5
Inspector: LD

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Animal Emergency Clinic
Type of Action: New
Date Issued: 09/07/10

License No.: 1215
Amendment No.: 100
License Reviewer: BA

File No.: 2
Licensee: 3M
Type of Action: Renewal
Dates Issued: 11/07/07

License No.: 1066
Amendment No.: 200
License Reviewer: SF

File No.: 3
Licensee: Metropolitan Cardiology Consultants
Type of Action: Amendment
Dates Issued: 10/28/10

License No.: 1208
Amendment No.: 102
License Reviewer: SF

File No.: 4
Licensee: Mayo Clinic
Type of Action: Amendment
Date Issued: 05/25/10

License No.: 1047
Amendment No.: 206
License Reviewer: BJ

File No.: 5
Licensee: US Steel Corporation
Type of Action: Amendment
Date Issued: 01/26/09

License No.: 1081
Amendment No.: 105
License Reviewer: GJ

File No.: 6
Licensee: Twin Ports Testing
Type of Action: New
Date Issued: 01/05/10

License No.: 1211
Amendment No.: 100
License Reviewer: SF

File No.: 7
Licensee: IESCO
Type of Action: Amendment
Date Issued: 08/03/11

License No.: 1181
Amendment No.: 201
License Reviewer: BJ

Comment:

MDH did not perform a site visit/inspection to ensure compliance with security requirements for vehicles prior to amending the license to allow an existing fixed site radiographer to conduct licensed operations at temporary job sites. The basis for this decision was that the licensee was known to be compliant and they made specific commitments to maintain compliance. Also, the licensee was due for inspection within the year.

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File No.: 8
Licensee: Fairview Maple Grove Medical Center
Type of Action: Amendment
Date Issued: 04/22/08

License No.: 1202
Amendment No.: 101
License Reviewer: BJ

File No.: 9
Licensee: PETNET Solutions
Type of Action: Amendment
Date Issued: 09/28/10

License No.: 1017
Amendment No.: 108
License Reviewer: BJ

File No.: 10
Licensee: Xcel Energy
Type of Action: Renewal
Date Issued: 06/14/11

License No.: 1072
Amendment No.: 200
License Reviewer: LD

File No.: 11
Licensee: Xerium Technologies
Types of Action: Renewal
Dates Issued: 08/10/11

License No.: 1183
Amendment No.: 200
License Reviewer: TP

File No.: 12
Licensee: Bemidji State University
Types of Action: Termination
Dates Issued: 10/24/11

License No.: 1144
Amendment No.: 103
License Reviewer: TP

File No.: 13
Licensee: Beckman Coulter
Type of Action: Termination
Date Issued: 02/21/08

License No.: 1148
Amendment No.: 101
License Reviewer: CV

File No.: 14
Licensee: Ulland Brothers
Type of Action: Amendment
Date Issued: 04/26/11

License No.: 1199
Amendment No.: 103
License Reviewer: TP

File No.: 15
Licensee: NewPage Corporation Duluth Mills
Type of Action: Renewal
Date Issued: 04/11/11

License No.: 1193
Amendment No.: 200
License Reviewer: TP

File No.: 16
Licensee: North Country Health Services
Type of Action: Amendment
Date Issued: 03/01/11

License No.: 1059
Amendment No.: 205
License Reviewer: LD

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License Casework Reviews

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File No.: 17

Licensee: Sanford Medical Center

Type of Action: Amendment

Date Issued: 03/14/11

License No.: 1059

Amendment No.: 206

License Reviewer: BA

File No.: 18

Licensee: Norbord Minnesota

Type of Action: Renewal

Date Issued: 02/28/11

License No.: 1111

Amendment No.: 200

License Reviewer: LD

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Braun Intertec Corporation

Date of Incident: 8/21/08

Investigation Date: 8/22/08

License No.: 1082

NMED Log No.: 080494

Type of Incident: Equipment Failure

Type of Investigation: Site

File No.: 2

Licensee: Braun Intertec Corporation

Date of Incident: 6/18/09

Investigation Date: 7/13/09

License No.: 1082

NMED Log No.: 090591

Type of Incident: Damaged Equipment

Type of Investigation: Telephone

File No.: 3

Licensee: Metropolitan Cardiology Consultants

Date of Incident: 10/6/11

Investigation Date: 10/7/11

License No.: 1208

NMED Log No.: 110602

Type of Incident: Lost Source

Type of Investigation: Telephone

File No.: 4

Licensee: Abbott Northwestern Hospital

Date of Incident: 11/13/08

Investigation Date: 11/14/08

License No.: 1007

NMED Log No.: 090020

Type of Incident: Lost Source

Type of Investigation: Telephone

File No.: 5

Licensee: Abbott Northwestern Hospital

Date of Incident: 3/17/11

Investigation Date: 4/5/11

License No.: 1007

NMED Log No.: 10144

Type of Incident: Medical Event

Type of Investigation: Site

File No.: 6

Licensee: See Company

Date of Incident: 11/5/08

Investigation Date: 12/29/08

License No.: 1161

NMED Log No.: 090365

Type of Incident: Leaking Source

Type of Investigation: Telephone

File No.: 7

Licensee: See Company

Date of Incident: 9/30/11

Investigation Date: 10/4/11

License No.: 1161

NMED Log No.: 110544

Type of Incident: Leaking Source

Type of Investigation: Telephone

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File No.: 8

Licensee: American Engineering and Testing

Date of Incident: 5/20/09

Investigation Date: 5/21/09

License No.: 1089

NMED Log No.: 090506

Type of Incident: Damaged Equipment

Type of Investigation: Telephone

Comment:

The incident investigation report was not in the license file.

File No.: 9

Licensee: Stork Twin City Testing

Date of Incident: 10/5/09

Investigation Date: 10/5/09

License No.: 1069

NMED Log No.: 090766

Type of Incident: Damaged Equipment

Type of Investigation: Site

Comment:

The incident investigation report was not in the license file.

File No.: 10

Licensee: University of Minnesota

Date of Incident: 10/30/09

Investigation Date: 11/2/09

License No.: 1049

NMED Log No.: 090822

Type of Incident: Equipment Failure

Type of Investigation: Telephone

File No.: 11

Licensee: University of Minnesota

Date of Incident: 6/15/10

Investigation Date: 6/18/10

License No.: 1049

NMED Log No.: 100313

Type of Incident: Medical Event

Type of Investigation: Site

File No.: 12

Licensee: Mayo Clinic

Date of Incident: 3/23/10

Investigation Date: 4/6/10

License No.: 1047

NMED Log No.: 100148

Type of Incident: Medical Event

Type of Investigation: Site

File No.: 13

Licensee: Mayo Clinic

Date of Incident: 11/9/10

Investigation Date: 11/15/10

License No.: 1047

NMED Log No.: 100563

Type of Incident: Medical Event

Type of Investigation: Site

ATTACHMENT(S)

January 17, 2012 Letter from Dale Dorschner
Minnesota's Response to the Draft Report
ADAMS Accession No.: ML120240123

**Agenda for Management Review Board Meeting
February 14, 2012 1:00 p.m. - 3:00 p.m. (EST), OWFN-3-B4**

1. Announcement of public meeting. Request for members of the public to indicate they are participating and their affiliation.
2. MRB Chair convenes meeting. Introduction of MRB members, review team members, State representatives, and other participants.
3. Consideration of the Minnesota IMPEP Report.
 - A. Presentation of Findings Regarding Minnesota's Program and Discussion.
 - Technical Staffing and Training
 - Status of Materials Inspection Program
 - Technical Quality of Inspections
 - Technical Quality of Licensing Actions
 - Technical Quality of Incident and Allegation Activities
 - Compatibility Requirements
 - B. IMPEP Team Recommendations.
 - Recommendation for Adequacy and Compatibility Ratings
 - Recommendation for Next IMPEP Review
 - C. MRB Consultation/Comments on Issuance of Report.
4. Request for comments from Minnesota representatives, OAS Liaison, and State IMPEP team members.
5. Adjournment.

Invitees:	Michael Weber, DEDMRT	Cynthia Carpenter, FSME
	Bradley Jones, OGC	Pamela Henderson, FSME
	Mark Satorius, FSME	Duncan White, FSME
	Elmo Collins, RIV	Lisa Dimmick, FSME
	Jennifer Opila, CO	Michelle Beardsley, FSME
	Donna Janda, RI	Karen Meyer, FSME
	James Lynch, RIII	Daniel Merzke, OEDO
	Mathew McKinley, KY	Dale Dorschner, MN
		Sherri Flaherty, MN