February 29, 2012

Aggie Leitheiser, Assistant Commissioner Health Protection Bureau Minnesota Department of Health P. O. Box 64975 St. Paul. MN 55164-0975

Dear Ms. Leitheiser:

On February 14, 2012, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Minnesota Agreement State Program. The MRB found the Minnesota program adequate to protect public health and safety, and compatible with the U.S. Nuclear Regulatory Commission's program.

Section 4.0, page 9, of the enclosed final report contains a summary of the IMPEP team's findings. The review team made no recommendations in regard to program performance by the Minnesota Agreement State Program during this review. Based on the results of the current IMPEP review, the next full review of the Minnesota Agreement State Program will take place in approximately five years from the date of the current review, with a periodic meeting tentatively scheduled for May 2014. The Minnesota Agreement State Program received an extension of 1 year for the next IMPEP review based on two consecutive IMPEP reviews with satisfactory findings for all the performance indicators reviewed.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

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

Enclosure:

Minnesota Final IMPEP Report

cc w/ encl: Dale Dorschner, Environmental Health Manager Indoor Environments and Radiation Section

Sherrie Flaherty, Supervisor Radioactive Materials Unit

Aggie Leitheiser, Assistant Commissioner Health Protection Bureau Minnesota Department of Health P. O. Box 64975 St. Paul, MN 55164-0975

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Letter to A. Leitheiser from Michael F. Weber dated: February 29, 2012

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

NOVEMBER 14 - 18, 2011

FINAL REPORT

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 recommended, and the Management Review Board (MRB) agreed, 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 recommended, and the MRB agreed, that the Minnesota Agreement State Program be found adequate to protect public health and safety and compatible with the 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 recommended, and the MRB agreed, 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 draft of this report was provided to Minnesota for factual comment on December 12, 2011. The State responded by letter dated January 17, 2012. A copy of the State's response is included as an Attachment to this report. A Management Review Board (MRB) met on February 14, 2012, to consider the proposed final report. The MRB found the Minnesota Agreement State Program adequate to protect public health and safety, and compatible with NRC's program.

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 noncommon 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 <u>Technical Staffing and Training</u>

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 recommended, and the MRB agreed, 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 for 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 two of the inspection reports were provided 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 recommended, and the MRB agreed, 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 recommended, and the MRB agreed, 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 recommended, and the MRB agreed, 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 allegers' 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 recommended, and the MRB agreed, 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 recommended, and the MRB agreed, 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 recommended, and the MRB agreed, that the Minnesota Agreement State Program be found adequate to protect public health and safety, and compatible with the NRC's program.

Based on the results of the current IMPEP review, the review team recommended, and the MRB agreed, 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

Technical Quality of Licensing Actions

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

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.

Inspection Type: Special, Unannounced

License No.: 1186

Priority: 1

Inspection Dates: 4/21-29/11 Inspectors: BA, LD, BJ

File No.: 3

Licensee: Braun Intertec Corporation

Inspection Type: Special, Unannounced

Inspection Date: 9/9/08

License No.: 1082

Priority: 1

Inspector: SF

File No.: 4

Licensee: Chart Industries

Inspection Type: Special, Unannounced
Inspection Date: 10/14/09

License No.: 1075
Priority: 1
Inspectors: BA, BJ

File No.: 5

Licensee: Medtronic, Inc.

Inspection Type: Routine, Unannounced
Inspection Date: 9/16/09

License No.: 1171
Priority: 2
Inspector: SF

File No.: 6

Licensee: Abbott Northwestern Hospital
Inspection Type: Routine, Announced
Inspection Dates: 2/18-23/09
License No.: 1007
Priority: 2
Inspectors: BJ, CV

File No.: 7

Licensee: Animal Emergency Clinic

Inspection Type: Initial, Unannounced

Priority: 5
Inspection Dates: 2/10/11 & 3/6/11

License No.: 1215
Priority: 5
Inspector: BA

File No.: 8

Licensee: Metropolitan Cardiology Consultants

Inspection Type: Initial, Unannounced

Inspection Dates: 11/12-13/09

License No.: 1208

Priority: 3

Inspectors: BJ, BA

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 License No.: 1077
Inspection Type: Special, Unannounced Priority: 2

Inspection Date: 12/3/09 Inspectors: GJ, BA

File No.: 12

Licensee: General Dynamics License No.: 1086

Inspection Type: Special, Unannounced Priority: 2
Inspection Date: 5/12/11 Inspectors: SF, TP

File No.: 13

Licensee: Lakeview Hospital License No.: 1051

Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 4/12/10 Inspector: GJ

File No.: 14

Licensee: Macalester College
License No.: 1175
Inspection Type: Routine, Unannounced
Priority: 5

Inspection Date: 12/11/07 Inspector: CV

File No.: 15

Licensee: Southdale Medical Diagnostics, LLC
Inspection Type: Initial, Unannounced

License No.: 1204
Priority: 5

Inspection Type: Initial, Oriannounced Friority, 5
Inspection Date: 6/4/09 Inspectors: SM, BJ

File No.: 16

Licensee: RRHS University Medical Center - Mesabi License No.: 1139
Inspection Type: Routine, Unannounced Priority: 3

Inspection Date: 9/14/11 Inspector: TP

File No.: 17

Licensee: Midwest Asphalt Corporation License No.: 1013
Inspection Type: Routine, Unannounced Priority: 5

Inspection Date: 10/12/11 Inspectors: LD, BJ

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
Inspection Dates: 10/25/07 & 11/13/07

Inspectors: SM, SF

File No.: 21

Licensee: Mayo Clinic License No.: 1047

Inspection Type: Initial, Unannounced Priority: 2
Inspection Dates: 2/11-14/08 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

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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 License No.: 1066
Type of Action: Renewal Amendment No.: 200
Dates Issued: 11/07/07 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 License No.: 1047
Type of Action: Amendment Amendment No.: 206
Date Issued: 05/25/10 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 License No.: 1181
Type of Action: Amendment Amendment No.: 201
Date Issued: 08/03/11 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.

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 License No.: 1072
Type of Action: Renewal Amendment No.: 200
Date Issued: 06/14/11 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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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 License No.: 1082

Date of Incident: 8/21/08

Investigation Date: 8/22/08

NMED Log No.: 080494

Type of Incident: Equipment Failure

Type of Investigation: Site

File No.: 2

Licensee: Braun Intertec Corporation License No.: 1082

Date of Incident: 6/18/09 NMED Log No.: 090591
Investigation Date: 7/13/09 Type of Incident: Damaged Equipment
Type of Investigation: Telephone

File No.: 3

Licensee: Metropolitan Cardiology Consultants License No.: 1208

Date of Incident: 10/6/11 NMED Log No.: 110602
Investigation Date: 10/7/11 Type of Incident: Lost Source
Type of Investigation: Telephone

File No.: 4

Licensee: Abbott Northwestern Hospital License No.: 1007

Date of Incident: 11/13/08 NMED Log No.: 090020 Investigation Date: 11/14/08 Type of Incident: Lost Source Type of Investigation: Telephone

File No.: 5

Licensee: Abbott Northwestern Hospital License No.: 1007

Date of Incident: 3/17/11 NMED Log No.: 10144
Investigation Date: 4/5/11 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

File No.: 8

Licensee: American Engineering and Testing

Date of Incident: 5/20/09

NMED Log No.: 090506

Investigation Date: 5/21/09 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

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

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 License No.: 1047
Date of Incident: 11/9/10 NMED Log No.: 100563
Investigation Date: 11/15/10 Type of Incident: Medical Event
Type of Investigation: Site

$\mathsf{ATTACHMENT}(\mathsf{S})$

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