

January 29, 2008

Mr. Thomas P. Hogan, Manager  
Indoor Environments and Radiation Section  
Division of Environmental Health  
Minnesota Department of Health  
P. O. Box 64975  
St. Paul, MN 55164-0975

Dear Mr. Hogan:

On January 8, 2008, 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 Agreement State 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 review team's findings. Based on the results of the current IMPEP review, the next full review of the Minnesota Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled for October 2009.

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/*

Martin J. Virgilio  
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/enclosure:  
George Johns, Supervisor  
Minnesota Radioactive Materials Program

Dennis O'Dowd, New Hampshire  
Organization of Agreement States  
Liaison to the MRB

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LETTER TO THOMAS P. HOGAN FROM MARTIN J. VIRGILIO DATED: January 29, 2008

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE MINNESOTA AGREEMENT STATE PROGRAM

October 15-19, 2007

**FINAL REPORT**

ENCLOSURE

## 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 October 15-19, 2007, by a review team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the City of New York. 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 the February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of March 31, 2006, to October 19, 2007, were discussed with Minnesota managers on the last day of the review.

A draft of this report was issued to Minnesota for factual comment on November 16, 2007. The State responded by e-mail on December 7, 2007, from George Johns, Supervisor, Radioactive Materials Program (the Program). A copy of the State's response is included as the Attachment to this report. The Management Review Board (MRB) met on January 8, 2008, to consider the proposed final report. The MRB found the Minnesota Agreement State Program to be 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 Program, located within the Indoor Environments and Radiation Section (the Section), administers the Agreement State program. The Section is part of the Division of Environmental Health (the Division), within the Health Protection Bureau (the Bureau). The Bureau is one of four bureaus in the Department. Organization charts for the Department, the Division, and the Section are included as Appendix B.

At the time of the review, the Program regulated approximately 185 specific licenses. 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 the 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 Program on July 19, 2007. The Program provided its response to the questionnaire on August 13, 2007. A copy of the questionnaire response may be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML072410053.

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

Results of the review for the common performance indicators are presented in Section 2.0. Section 3.0 details the results of the review of the applicable non-common performance indicator, and Section 4.0 summarizes the review team's findings.

## 2.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing 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 Program'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 Program's questionnaire response relative to this indicator; interviewed Program managers and staff; and reviewed job descriptions, training plans, and training records. The review team also considered any possible workload backlogs in evaluating this indicator.

The Supervisor, who heads the Program, is responsible for coordinating materials inspections, licensing, and compliance activities. The Program consists of the Supervisor, four radiation specialists, and one administrative assistant. The Program's responsibilities also include emergency response activities. The Program has three levels of radiation specialists with each level requiring more comprehensive responsibilities.

The Program has a documented training plan that is consistent with the guidance in the NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Materials Safety and Safeguards Program Area." The staff also has on-the-job training to supplement the course work. Under the direction of the Supervisor, staff members are assigned increasingly complex licensing actions and accompany more experienced inspectors on complicated inspections. Inspectors are assigned independent inspections after demonstrating competence during accompaniment evaluations by the Supervisor. The review team confirmed the qualifications of all staff through review of qualification journals, training records, and documentation of supervisory accompaniments. Four staff members, including the Supervisor, attended the NRC's Security Systems and Principles Course. The review team concluded that Program managers are supportive of staff training opportunities.

All technical staff members are fully qualified to perform both licensing and inspection activities and have completed the required training in each of these areas. The Program has not experienced any turnover since becoming an Agreement State; therefore, at the time of the review, the Program was fully staffed. The review team concluded that the Program had an adequate number of staff members to carry out its regulatory responsibilities.

Minnesota licensees are assessed an annual fee and a fee for license amendments. The review team noted that the Program had stable funding during the review period.

The State of Minnesota does not have an oversight board or committee to provide direction to the Agreement State program.

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, was 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 Program's questionnaire response relative to this indicator, data gathered from the Program's database, examination of completed inspection casework, and interviews with Program managers and staff.

The review team verified that the Program's inspection priorities for various license types are at least as frequent as similar license types listed in IMC 2800, "Materials Inspection Program." In response to the questionnaire, the Program indicated that there was one routine inspection overdue. The Program completed the inspection prior to the on-site portion of this review. Initial inspections were scheduled and conducted within one year of license issuance, with one exception. One initial inspection was conducted one month overdue. The initial inspection was performed overdue because the Program was not aware that the license issued by the NRC prior to the transfer of regulatory authority was a new license; therefore, the inspection was incorrectly scheduled in the Program's database. No inspections were overdue at the time of the IMPEP review.

The review team determined that during the review period, the Program conducted approximately 31 Priority 1, 2, and 3 inspections, based on the inspection frequencies established in IMC 2800. In addition, the Program performed 19 initial inspections during the review period. Overall, the review team calculated that 4 percent of all Priority 1, 2, and 3 and initial inspections conducted by the Program during the review period were performed overdue.

The review team evaluated the timeliness of the issuance of inspection findings through the review of inspection casework. The review team found that inspection findings letters were routinely sent to licensees within 30 days of the inspection date. Inspection reports are completed by the inspectors and undergo peer reviews before being sent to the Supervisor for final review and signature.

During the review period, the Program granted 52 reciprocity permits to candidate licensees based on 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 Program exceeded the NRC's goal of inspecting 20 percent of candidate licensees operating under reciprocity during this review period.

The review team determined that the Program adequately planned for the initial set of Increased Controls inspections of affected licensees. The review team evaluated the Program's prioritization methodology and found it acceptable. The Program identified 23 licensees subject

to the Increased Controls. The Program completed all of its Increased Controls inspections by June 2007.

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, was satisfactory.

### 2.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 21 radioactive materials inspections conducted during the review period. The casework reviewed included inspections conducted by six of the Program's staff members and covered inspections of various license types, including: broadscope medical, medical - written directive required, medical - private practice, fixed and portable gauges, industrial radiography, broadscope academic, irradiator, medical - therapy, nuclear pharmacy, manufacturer and distribution, Increased Controls, and reciprocity. Appendix C lists the inspection casework files reviewed, with case-specific comments, as well as the details of the inspector accompaniments.

Based on the evaluation of casework, the review team noted that inspections covered all aspects of licensed radiation programs. The inspection procedures used by the Program are consistent with the inspection guidance outlined in IMC 2800. The review team found that inspection reports were generally thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that licensees' performances with respect to health, safety, and security were acceptable. All inspection findings were clearly stated, documented in the reports, and reviewed by the Supervisor. The documentation supported violations and any discussions held with licensees during exit interviews. The review team identified that some inspection documents containing sensitive information were not consistently marked. The review team discussed this matter with the Supervisor and Program staff and encouraged them to evaluate their procedures and policies for marking and handling sensitive information. The Program will review and revise its procedure for identifying and marking sensitive information on all documents using the NRC's "Guidance on Screening Criteria for Security-Related Sensitive Unclassified Non-Safeguards Information," issued December 2005.

The review team determined that the inspection findings were appropriate and prompt, and regulatory actions were taken, as necessary. When the Program issues a notice of violation, the licensee is required to provide a written corrective action plan within 30 days. All findings are reviewed by the Supervisor.

The review team verified that all of the Program's radioactive materials inspectors were accompanied annually during the review period. The accompaniment reports contained sufficient details to document the areas covered during the accompaniments.

The review team noted that the Program has an adequate supply of survey instruments to support their 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 a neutron detector, were observed to be available. The Program 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 Program uses a database to track each instrument, its current location, and its calibration due date. In addition, the Program supplies calibrated radiation detection equipment to the Minnesota Department of Transportation's Hazardous Materials Inspectors, the Minnesota Department of Public Safety's Commercial Vehicle Section, and a HAZMAT team.

Two review team members conducted accompaniments of three of the Program's inspectors during the weeks of August 6 and August 13, 2007. The inspectors were accompanied during health, safety, and security inspections of medical therapy, medical private practice, mobile medical, and portable gauge licenses. The accompaniments are identified in Appendix C. During the accompaniments, all of the inspectors demonstrated appropriate inspection techniques and knowledge of the regulations and conducted performance-based inspections. The inspectors were well prepared for the inspection and thorough in their audits of the licensees' radiation safety programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspections were adequate to assess radiological health, safety, and security at the 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, was satisfactory.

#### 2.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 18 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequate facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of the license conditions, security, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, product certifications, supporting documentation, and consideration of enforcement history, supervisory review as indicated, and proper signatures. The casework was checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included three new licenses, two renewals, six amendments (one denied in part), one termination with decommissioning, and six financial assurance files. The sampling included the following license types: broadscope manufacturing and distribution, portable gauge, fixed gauge, broadscope medical, medical institution - no written directive required, medical institution - diagnostic and therapy, measuring systems, general license distribution, and gamma knife. A listing of the licensing casework evaluated, with case-specific comments, may 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, in most cases, and auditable. The review team noted some instances where license conditions were not backed by information contained in the file. This issue was discussed with Program managers. The

Program will review and revise its policy for including essential supplemental information in the license file.

Licenses and correspondence are generated using standardized conditions and formats. Licensing staff appropriately used the Program's licensing guides, policies, and standard license conditions. The license evaluators use checklists that generally follow the NRC's NUREG-1556, "Consolidated Guidance About Materials Licenses," to assist in the reviews. Licensees' compliance histories were taken into account when reviewing all renewal applications and major amendments.

Licenses are issued for a 5-year period under a timely renewal system. Each licensing action is given a technical peer review by a fellow license evaluator using a multi-phase process. The Supervisor performs a second technical review and signs the license. In addition, the Environmental Health Manager, who oversees the Section, also reviews and signs the license. The Program is planning to move to a system where the license will be signed by the preparing license evaluator, the peer-reviewing license evaluator, and the Supervisor.

The Program's policy for license issuance includes the requirement for all licenses to be sent by certified mail with return receipt requested. The review team believes that this practice, if used for licenses containing sensitive unclassified, non-safeguards information (SUNSI), would place additional control on SUNSI documents that contain information that could be used for malevolent purposes. This method would ensure that the license document is received by the correct licensed facility and to the appropriate addressee. First class mail does not provide that protection of sensitive information. The review team recommended, and the MRB agreed, that the Program's policy of sending licenses by certified mail with return receipt requested be identified as a good practice.

Terminated licensing actions were well documented, showing appropriate radioactive material transfer and survey records. Confirmatory surveys were conducted, when appropriate. The review team evaluated financial assurance documents and decommissioning activities conducted by the Program, and identified some cases of missing documents or missing statements in the financial assurance records. The Program was not familiar with certain aspects of the requirements of each of the financial instruments. This was discussed with the Program manager who will review and revise their procedure for financial assurance requirements using the guidance found in NRC's NUREG-1757, Volume 3, "Consolidated Decommissioning Guidance – Financial Assurance, Recordkeeping, and Timeliness – Final Report."

The Program kept good track of the progress of licensing actions from receipt of request to issuance of license, paying attention to timeliness in processing. The review team found that some documents in the licensing files and some outgoing documents to licensees (i.e., cover letters and licenses) containing sensitive information were not marked or identified. This issue was previously mentioned from the inspection standpoint in Section 2.3 of this report and was also discussed with Program managers.

The review team noted that the Program has a procedure for doing pre-licensing visits. To date, the Program has only performed one pre-licensing visit on a naturally occurring or accelerator-produced radioactive material license.

The review team examined the list of licensees that the Program determined to meet the criteria for the Increased Controls, per COMSECY-05-0028, "Staff Response to SRM for COMSECY-05-0015: Initiatives for Increasing Agreement State Participation in the Control of Sources." The review team determined that the Program had correctly identified the licensees that require the Increased Controls based on these criteria. The Program also required their licensees currently under an NRC Order for additional security measures to implement the Increased Controls. Each licensee was issued a license amendment, requiring the Increased Controls, in accordance with the time lines established by the NRC in the Staff Requirements Memorandum for COMSECY-05-0028.

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, was satisfactory.

## 2.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Program's actions in responding to incidents and allegations, the review team examined the Program'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 Program's files, and evaluated the casework for 11 radioactive materials incidents. A listing of the casework examined can be found in Appendix E. The review team also evaluated the Program's response to two allegations, involving radioactive materials, referred to the State by the NRC during the review period.

The incidents selected for review included lost radioactive material and damaged equipment. The review team determined that the Program'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. When notified of an incident, the Supervisor and staff decided on the appropriate level of initial response. The Program dispatched inspectors for on-site investigations in appropriate situations and took suitable enforcement and follow up actions when necessary.

The review team identified 11 byproduct material incidents in NMED for Minnesota during the review period, of which seven required reporting. The review team evaluated the Program's timeliness in reporting incidents to the NRC Headquarters Operations Center, and determined that, following notification from the licensee, the Program reported all incidents within the required time frame. Program staff members incorporated incident information into their incident database and provided that information electronically to the NRC's contractor responsible for maintaining NMED. The database was updated as needed. The review team found that incident information in NMED for Minnesota incidents was up to date and complete.

In evaluating the effectiveness of the State's response to allegations, the review team evaluated the casework for two allegations referred to the State by the NRC during the review period. The review team concluded that the Program took prompt and appropriate action in response to all concerns raised. Both of the allegations were appropriately closed, and affected individuals were notified of the actions taken. The State adequately protected the identity of concerned individuals.

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, was satisfactory.

### 3.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State Programs: (1) Compatibility Requirements, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. Minnesota's Agreement with the NRC does not relinquish authority for a Sealed Source and Device Evaluation Program, a Low-Level Radioactive Waste Disposal Program, or a Uranium Recovery Program; therefore, only the first non-common performance indicator was applicable to this review.

#### 3.1 Compatibility Requirements

##### 3.1.1 Legislation

Minnesota became the 34<sup>th</sup> 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 NRC and contains provisions for the orderly transfer of regulatory authority over affected licenses from NRC to the State. This Section also identifies the Minnesota Department of Health as the lead agency for the Agreement State program. In addition to their response to the questionnaire, the Program provided the review team with the opportunity to review copies of legislation that affects the radiation control program.

##### 3.1.2 Program Elements Required for Compatibility

The State's regulations for control of radiation are located in the *Minnesota Rules Chapter 4731* and apply to all ionizing radiation, whether emitted from a radionuclide or device. 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 1 year after drafting before a rule becomes effective. Draft rules are developed by Program 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 Program's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the State under the NRC's adequacy and compatibility policy, and verified the adoption of regulations with data

obtained from the Office of Federal and State Materials and Environmental Management Programs' State Regulation Status Sheet.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally-binding requirements no later than three years after they become effective. The review team identified the following regulation as overdue for adoption at the time of the review. Minnesota's addressed this amendment in a rulemaking package that became effective on November 20, 2007.

- "Financial Assurance for Materials Licensees," 10 CFR Part 30, 40, 70 amendments (68 FR 57327) that became effective December 3, 2003, and was due for Agreement State adoption by December 3, 2006.

The State uses legally-binding requirements, in the form of license conditions, to address the following four regulations. All are part of the current rulemaking package discussed above. The review team sampled the State's licenses to ensure that license conditions were used appropriately.

- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697) that became effective on October 1, 2004, and was due for Agreement State adoption by October 1, 2007.
- "Security Requirements for Portable Gauges Containing Byproduct Material," 10 CFR Part 30 amendment (70 FR 2001), that became effective on July 11, 2005, and is due for Agreement State adoption by July 11, 2008.
- "Medical Use of Byproduct Material - Recognition of Specialty Boards," 10 CFR Part 35 amendment (70 FR 16336 and 71 FR 1926), that became effective on April 29, 2005, and is due for Agreement State adoption by April 29, 2008.
- "Minor Amendments," 10 CFR Part 20, 30, 32, 35, 40 and 70 amendments (71 FR 15005) that became effective March 27, 2006, and is due for Agreement State adoption by March 27, 2009.

Based on the 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, Minnesota's performance was found to be satisfactory for all performance indicators reviewed. The review team made no recommendations regarding program performance and identified one good practice. Accordingly, the review team recommended, and the MRB agreed, that the Minnesota Agreement State Program was 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 recommended, and the MRB agreed, that the next full IMPEP review take place in approximately 4 years.

Below is the good practice, as mentioned earlier in the report:

The Program's policy for license issuance includes the requirement for all licenses to be sent by certified mail with return receipt requested. The review team believes that this practice, if used for licenses containing sensitive unclassified, non-safeguards information (SUNSI), would place additional control on SUNSI documents that contain information that could be used for malevolent purposes. This method would ensure that the license document is received by the correct licensed facility and to the appropriate addressee. First class mail does not provide that protection of sensitive information. The review team recommended, and the MRB agreed, that the Program's policy of sending licenses by certified mail with return receipt requested be identified as a good practice.

## LIST OF APPENDIXES AND ATTACHMENT

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
Attachment	December 7, 2007, E-mail from George Johns Minnesota's Response to Draft IMPEP Report

## APPENDIX A

### IMPEP REVIEW TEAM MEMBERS

<b>Name</b>	<b>Area of Responsibility</b>
Linda McLean, Region IV	Team Leader Technical Staffing and Training
Michelle Beardsley, Region I	Status of Materials Inspection Program Technical Quality of Inspections
Tobias Lickerman, New York	Technical Quality of Licensing Actions
James Lynch, Region III	Technical Quality of Incident and Allegation Activities Compatibility Requirements Inspector Accompaniments
Randy Erickson, Region IV	Inspector Accompaniments



APPENDIX B

MINNESOTA ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML072410053

PAGES 11-13

## APPENDIX C

### INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1  
Licensee: Hennepin County Med. Ctr.  
Inspection Type: Routine, Unannounced  
Inspection Dates: 3/5-6/07  
License No.: 1164-100-27  
Priority: 2  
Inspectors: BJ, SF, SM, CV

File No.: 2  
Licensee: Mayo Clinic  
Inspection Type: Special, Announced  
Inspection Dates: 11/16/06  
License No.: 1047-201-55  
Priority: 2  
Inspectors: BJ, SF, GJ, CV

File No.: 3  
Licensee: Pro Source Technology  
Inspection Type: Initial, Announced  
Inspection Date: 5/23/07  
License No.: 1196-100-02  
Priority: 5  
Inspector: CV

File No.: 4  
Licensee: 3M Corporation  
Inspection Type: Routine, Unannounced  
Inspection Dates: 1/22-24/07  
License No.: 1116-101-62  
Priority: 5  
Inspectors: TD, SF, BJ, CV

File No.: 5  
Licensee: Acuren Inspections  
Inspection Type: Routine, Unannounced  
Inspection Dates: 10/16-18/07  
License No.: 1191-101-89  
Priority: 1  
Inspectors: CV, GJ

File No.: 6  
Licensee: Immanuel St. Joseph's  
Inspection Type: Routine, Unannounced  
Inspection Date: 12/19/06  
License No.: 1025-200-07  
Priority: 2  
Inspectors: SF, GJ, CV

File No.: 7  
Licensee: Shared Medical Technologies  
Inspection Type: Routine, Unannounced  
Inspection Dates: 4/18-19/07  
License No.: 1041-201-89  
Priority: 3  
Inspector: SF

File No.: 8  
Licensee: Immanuel St. Joseph's  
Inspection Type: Special, Announced  
Inspection Date: 6/26/07  
License No.: 1025-200-07  
Priority: 2  
Inspectors: SM, GJ

File No.: 9

Licensee: St. Francis Regional Med. Ctr.  
Inspection Type: Routine, Unannounced  
Inspection Date: 3/29/07

License No.: 1064-200-70  
Priority: 3  
Inspectors: BJ, SF

File No.: 10

Licensee: Braun Intertec  
Inspection Type: Routine, Announced  
Inspection Dates: 8/8-9/07

License No.: 1082-100-27  
Priority: 1  
Inspector: BJ

File No.: 11

Licensee: Braun Intertec  
Inspection Type: Special, Announced  
Inspection Dates: 8/8-9/07

License No.: 1082-100-27  
Priority: 1  
Inspector: BJ

Comment:

Cover letter was not marked as containing sensitive information although the attached notice of violation was appropriately marked as sensitive.

File No.: 12

Licensee: Midwest Industrial X-Ray  
Inspection Type: Routine, Unannounced  
Inspection Dates: 6/21 & 7/12/07

License No.: 1186-101-89  
Priority: 1  
Inspectors: CV, SM

File No.: 13

Licensee: Midwest Industrial X-Ray  
Inspection Type: Special, Announced  
Inspection Date: 9/6/06

License No.: 1186-101-89  
Priority: 1  
Inspectors: CV, SM

File No.: 14

Licensee: Mallinckrodt, Inc.  
Inspection Type: Routine, Unannounced  
Inspection Date: 8/7/07

License No.: 1023-201-89  
Priority: 2  
Inspectors: SF, GJ

File No.: 15

Licensee: Alpha Omega Services  
Inspection Type: Reciprocity, Special, Announced  
Inspection Date: 9/17/07

License No.: 9039-100-00  
Priority: N/A  
Inspector: CV

Comment:

Inspection report contained sensitive information but was not marked appropriately.

File No.: 16

Licensee: Parker Hughes  
Inspection Type: Decommissioning-Special, Announced  
Inspection Date: 8/15/06

License No.: 1176-101-62  
Priority: N/A  
Inspector: SF

File No.: 17

Licensee: Varian Medical Systems  
Inspection Type: Reciprocity, Special, Announced  
Inspection Date: 8/16/07

License No.: 9013-101-00  
Priority: N/A  
Inspector: CV

File No.: 18

Licensee: Minneapolis Radiation Oncology  
Inspection Type: Routine, Unannounced  
Inspection Dates: 8/17-28/07

License No.: 1162-101-27  
Priority: 2  
Inspector: SF

File No.: 19

Licensee: Memorial Blood Centers  
Inspection Type: Routine, Unannounced  
Inspection Date: 8/1/07

License No.: 1084-101-27  
Priority: 5  
Inspector: BJ

File No.: 20

Licensee: Memorial Blood Centers  
Inspection Type: Special, Announced  
Inspection Date: 8/1/07

License No.: 1084-101-27  
Priority: 5  
Inspector: BJ

Comment:

Inspection report contained sensitive information but was not marked appropriately.

File No.: 21

Licensee: Philotechnics  
Inspection Type: Reciprocity-Special, Unannounced  
Inspection Date: 6/19/07

License No.: 9032-100-00  
Priority: N/A  
Inspector: BJ

### INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1

Licensee: Medical Diagnostics  
Inspection Type: Routine, Announced  
Inspection Date: 8/6/07

License No.: 1031-201-62  
Priority: 5  
Inspector: BJ

Accompaniment No.: 2

Licensee: Mobile Imaging Services  
Inspection Type: Routine, Announced  
Inspection Date: 8/7/07

License No.: 1198-100-27  
Priority: 5  
Inspector: CV

Accompaniment No.: 3

Licensee: Braun Intertec Corp.  
Inspection Type: Routine/Special, Announced  
Inspection Date: 8/8/07

License No.: 1082-100-27  
Priority: 1  
Inspector: BJ

Minnesota Final Report  
Inspection Casework Reviews

Page C.4

Accompaniment No.: 4  
Licensee: Minneapolis Radiation Oncology  
Inspection Type: Routine, Announced  
Inspection Date: 8/17/07

License No.: 1162-101-27  
Priority: 2  
Inspector: SF

## APPENDIX D

### LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1 Licensee: Health East St. John's Hospital Type of Action: Amendment (denied in part) Date Issued: 7/31/07	License No.: 1033-202-62 Amendment No.: 02 License Reviewer: CV
File No.: 2 Licensee: Mayo Clinic Type of Action: Amendment Date Issued: 10/26/06	License No.: 1047-201-55 Amendment No.: 01 License Reviewer: SF
File No.: 3 Licensee: Acuren Inspection, Inc. Type of Action: Amendment Date Issued: 4/16/07	License No.: 1191-102-89 Amendment No.: 02 License Reviewer: CV
File No.: 4 Licensee: Global Medical Instrumentation Type of Action: New Date Issued: 10/8/07	License No.: 1102-100-62 Amendment No.: 00 License Reviewer: SF
File No.: 5 Licensee: Pro Source Technologies Type of Action: New Date Issued: 7/6/06	License No.: 1196-100-02 Amendment No.: 00 License Reviewer: BJ
File No.: 6 Licensee: St. Mary's Hospital Type of Action: Amendment Date Issued: 9/17/07	License No.: 1077-103-55 Amendment No.: 03 License Reviewer: CV
File No.: 7 Licensee: Immanuel St. Joseph's Type of Action: Renewal Date Issued: 3/27/06	License No.: 1025-200-07 Amendment No.: 00 License Reviewer: SF
File No.: 8 Licensee: Mobile Imaging Service Type of Action: New Date Issued: 4/2/07	License No.: 1198-100-27 Amendment No.: 00 License Reviewer: CV

File No.: 9

Licensee: Parker Hughes Institute  
Type of Action: Termination with Decommissioning  
Date Issued: 8/18/06

License No.: 1176-101-62  
Amendment No.: 01  
License Reviewer: SF

File No.: 10

Licensee: Medtronic, Inc.  
Type of Action: Amendment  
Date Issued: Pending

License No.: 1166-102-27  
Amendment No.: 02  
License Reviewer: SF

File No.: 11

Licensee: 3M Corporate Health Physics Services  
Type of Action: Amendment  
Date Issued: 2/12/07

License No.: 1116-101-62  
Amendment No.: 01  
License Reviewer: CV

File No.: 12

Licensee: 3M Company  
Type of Action: Renewal  
Date Issued: Pending

License No.: 1066-200-62  
Amendment No.: 00  
License Reviewer: SF

File No.: 13

Licensee: Hennepin County Medical Center  
Type of Action: Financial Assurance  
Date Issued: 6/23/06

License No.: 1164-100-27  
Amendment No.: N/A  
License Reviewer: GJ

File No.: 14

Licensee: Detector Electronics Corp.  
Type of Action: Financial Assurance  
Date Issued: 4/4/06

License No.: 1150-100-27  
Amendment No.: N/A  
License Reviewer: GJ

Comment:

Original letter of credit was not in the file.

File No.: 15

Licensee: U.S. Steel  
Type of Action: Financial Assurance  
Date Issued: 7/31/06

License No.: 1081-102-69  
Amendment No.: N/A  
License Reviewer: GJ

File No.: 16

Licensee: 3M Corporation  
Type of Action: Financial Assurance  
Date Issued: 3/31/06

License No.: 1066-100-62  
Amendment No.: N/A  
License Reviewer: GJ

File No.: 17

Licensee: University of Minnesota  
Type of Action: Financial Assurance  
Date Issued: 5/25/06

License No.: 1049-200-27  
Amendment No.: N/A  
License Reviewer: GJ

Comment:

Statement of intent does not contain dollar amount of financial assurance.

File No.: 18

Licensee: Mayo Clinic  
Type of Action: Financial Assurance  
Date Issued: 4/13/06

License No.: 1047-200-55  
Amendment No.: N/A  
License Reviewer: GJ



## APPENDIX E

### INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1

Licensee: Mayo Clinic  
Date of Incident: 12/6/06  
Investigation Date: 1/10/07

License No.: 1047-201-55  
NMED Log No.: 070179  
Type of Incident: Lost Source  
Type of Investigation: Telephone

File No.: 2

Licensee: 3M Company  
Date of Incident: 9/5/06  
Investigation Date: 9/7/06

License No.: 1066-100-62  
NMED Log No.: 060638  
Type of Incident: Lost Source  
Type of Investigation: Site

File No.: 3

Licensee: Sappi Fine Paper North America  
Date of Incident: 10/18/06  
Investigation Date: 11/9/06

License No.: 1112-102-09  
NMED Log No.: 070178  
Type of Incident: Damaged Gauge  
Type of Investigation: Telephone

File No.: 4

Licensee: American Engineering Testing, Inc.  
Date of Incident: 9/9/07  
Investigation Date: 9/10/07

License No.: 1090-102-62  
NMED Log No.: 070572  
Type of Incident: Damaged Gauge  
Type of Investigation: Site

File No.: 5

Licensee: 3M Corporate  
Date of Incident: 7/1/06  
Investigation Date: 12/7/06

License No.: 1116-101-62  
NMED Log No.: 060752  
Type of Incident: Lost Source  
Type of Investigation: Telephone

File No.: 6

Licensee: University of Minnesota Fairview Riverside  
Date of Incident: 6/30/06  
Investigation Date: 7/28/06

License No.: 1035-200-37  
NMED Log No.: 060428  
Type of Incident: Lost Sources  
Type of Investigation: Telephone

File No.: 7

Licensee: Immanuel St. Joseph's  
Date of Incident: 4/24/07  
Investigation Date: 6/26/07

License No.: 1025-200-07  
NMED Log No.: 070320  
Type of Incident: Lost Source  
Type of Investigation: Site

File No.: 8

Licensee: Asset Management, Inc.  
Date of Incident: 9/13/07  
Investigation Date: 9/13/07

License No.: 1008-200-82  
NMED Log No.: 070578  
Type of Incident: Stolen Gauge  
Type of Investigation: Telephone

File No.: 9

Licensee: Dayton's Bluff Neighborhood Services  
Date of Incident: 6/23/06  
Investigation Date: 6/26/06

License No.: General License  
NMED Log No.: 060421  
Type of Incident: Missing Device  
Type of Investigation: Telephone

File No.: 10

Licensee: Innovex, Inc.  
Date of Incident: 5/10/07  
Investigation Date: 5/14/07

License No.: General License  
NMED Log Nos.: 070532 and 070533  
Type of Incident: Lost Sources  
Type of Investigation: Site

File No.: 11

Licensee: Seagate Technology  
Date of Incident: 10/10/06  
Investigation Date: 11/21/06

License No.: General License  
NMED Log No.: 060711  
Type of Incident: Lost Sources  
Type of Investigation: Site

ATTACHMENT

December 7, 2007, E-mail from George Johns  
Minnesota's Response to Draft IMPEP Report

ADAMS: ML073470337