

November 19, 2012

Mariannette Miller-Meeks, B.S.N., M.Ed., M.D.
Director
Iowa Department of Public Health
Lucas State Office Building
321 East 12th Street
Des Moines, IA 50319

Dear Dr. Miller-Meeks:

On November 1, 2012, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Iowa Agreement State Program. The MRB found the Iowa program is adequate to protect public health and safety and is compatible with the U.S. Nuclear Regulatory Commission's program.

Section 5.0, 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 Iowa Agreement State Program during this review. Based on the results of the current IMPEP review, the next full review of the Iowa Agreement State Program will take place in approximately 5 years, with a periodic meeting tentatively scheduled for August 2014. The Iowa Agreement State Program received an extension of one 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:
Iowa Final IMPEP Report

cc w/encl.: Melanie Rasmusson, Chief
Bureau of Radiological Health

Karen Beckley, NV
Organization of Agreement States
Liaison to the MRB



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

AUGUST 6-10, 2012

FINAL REPORT

Enclosure

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Iowa Agreement State Program. The review was conducted during the period of August 6-10, 2012, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Minnesota.

Based on the results of this review, the review team recommended, and the Management Review Board (MRB) agreed, that Iowa's performance be found satisfactory for all performance indicators reviewed. The review team did not make any recommendations regarding program performance by the State and determined that the recommendation from the 2007 IMPEP review, regarding decommissioning financial assurance, should be closed.

Accordingly, the review team recommended, and the MRB agreed, that the Iowa Agreement State Program be found adequate to protect public health and safety and compatible with NRC's program. The review team recommended, and the MRB agreed, that the next IMPEP review take place in approximately five years.

1.0 INTRODUCTION

This report presents the results of the review of the Iowa Agreement State Program. The review was conducted during the period of August 6-10, 2012, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Minnesota. 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 September 15, 2007 to August 10, 2012, were discussed with Iowa managers on the last day of the review.

A draft of this report was provided to Iowa for factual comment on September 6, 2012. The State responded by electronic mail dated September 28, 2012. A copy of the State's response is included as an Attachment to this report. A Management Review Board (MRB) met on November 1, 2012, to consider the proposed final report. The MRB found the Iowa Agreement State Program adequate to protect public health and safety, and compatible with the NRC's program.

The Iowa Agreement State Program is administered by the Bureau of Radiological Health (the Bureau), which is located within the Division of Environmental Health (the Division). The Division is part of the Department of Public Health (the Department). An organization chart is included as Appendix B.

At the time of the review, the Iowa Agreement State Program regulated 168 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 the NRC and the State of Iowa.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Bureau on May 1, 2012. The Bureau provided its response to the questionnaire on July 5, 2012. A copy of the questionnaire response can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML12191A061.

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

Section 2.0 of this report covers the Bureau's actions in response to the recommendation made during the previous review. Results of the current review of the common performance indicators

are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-common performance indicator and Section 5.0 summarizes the review team's findings.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review which concluded on September 14, 2007, the review team made one performance recommendation regarding the Iowa Agreement State Program. The status of the recommendation is as follows:

“The review team recommends that the State evaluate their decommissioning financial assurance program to identify and secure original financial assurance documentation from current and future licensees who are required to comply with Iowa’s financial assurance requirements.”

Status: The Iowa Agreement State Program has implemented a procedure, including a checklist, to ensure all licenses are compliant with the State’s financial assurance requirements. The State also reviewed its licenses to determine need for financial assurance and identified four licensees. The review team confirmed all original financial assurance documents for these licensees had been obtained and that these documents are kept in a secure location. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the 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.

3.1 Technical Staffing and Training

Considerations central to the evaluation of this indicator include the Bureau’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 Bureau’s questionnaire response relative to this indicator, interviewed managers and staff, reviewed job descriptions and training records, and considered workload backlogs.

The Bureau is composed of several program areas, one of which is the Radioactive Materials Program (the Program). The Program is responsible for radioactive materials licensing, inspection, and emergency response activities. Two technical staff members left the Program during the review period. One of those positions was filled in March 2012 and one position was vacant at the time of this review. At the time of the review, there were two technical staff members and one administrative staff member with various degrees of involvement in the radioactive materials program, totaling approximately 2.2 full-time equivalents (FTE). The review team noted that staffing levels did not present any performance issues affecting implementation of the Agreement State Program; however, loss of a technical staff member could potentially impact the Bureau’s ability to remain current on all regulatory actions. This was discussed with Department managers during the exit meeting on August 10, 2012.

The Bureau has a documented training plan for technical staff that is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and the NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." Staff members are assigned increasingly complex duties as they progress through the qualification process. The review team concluded that the Bureau's training program is adequate to carry out its regulatory duties and noted that Iowa management supports the Bureau's training program.

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

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

The review team verified that Iowa's inspection frequencies for all types of radioactive material licenses are at least as frequent as similar license types listed in Inspection Manual Chapter (IMC) 2800, "Materials Inspection Program." From the beginning of the review period until January 2012, the Bureau inspected licensees more frequently than similar license types. Starting in January 2012, the Bureau changed their inspection frequencies to match inspection frequencies for similar license types as established in IMC 2800.

The Bureau conducted 143 Priority 1, 2, and 3 inspections during the review period. None of these inspections were conducted overdue by more than 25 percent of the inspection frequency prescribed in IMC 2800. The Bureau performed 17 initial inspections during the review period, none of which were conducted overdue. Overall, the review team calculated that the Bureau performed zero percent of its inspections overdue during the review period.

The review team evaluated the Bureau's timeliness in providing inspection findings to licensees. A sampling of inspection reports indicated that the inspection findings were communicated to the licensees within the Bureau's goal of 30 days after the inspection.

During the review period, the Bureau granted 192 reciprocity permits, 38 of which were candidate licensees for reciprocity inspections 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 Bureau met and exceeded the NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity in three of the four calendar years covered by the five year review period. For the one year that the Bureau fell below the NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity, the Bureau inspected 13 percent of candidate licensees for reciprocity. This was due to the Bureau needing to focus its attention on other programmatic priorities.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Iowa's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 22 radioactive materials inspections conducted during the review period. The casework reviewed included inspections conducted by three Bureau inspectors and covered inspections of various license types, including: medical broad scope, medical institutions, radionuclide production (cyclotron), industrial radiography, self-shielded irradiators, nuclear pharmacy, mobile nuclear medicine, portable gauges, and Increased Security Controls for Large Quantities of Radioactive Materials (Increased Controls). Appendix C lists the inspection casework files reviewed as well as the results of the inspector accompaniments.

Based on the evaluation of casework, the review team noted that inspections covered all aspects of licensed radiation safety programs. The review team found that inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that a licensee's performance with respect to health and safety was acceptable. The documentation supported violations, recommendations made to licensees, unresolved safety concerns, the effectiveness of corrective actions taken to resolve previous violations and discussions held with licensees during exit interviews.

The inspection procedures utilized by the Bureau are consistent with the inspection guidance outlined in IMC 2800. An inspection report is completed by the inspector which is then peer reviewed by another inspector. Between July 2011 and March 2012, a second inspector was not employed by the program, and thus, the peer review process was suspended. If the peer reviewer is qualified for a particular type of inspection, that person signs the "approval" signature block on the inspection report. The Bureau Chief accompanied all inspectors on an annual frequency.

The review team determined that the inspection findings were appropriate and prompt regulatory actions were taken, as necessary. Inspection findings were clearly stated and documented in the reports and sent to the licensees with an appropriate letter detailing the results of the inspection. The Bureau issues to the licensee a letter, indicating a clear inspection or a Notice of Violation, which details the results of the inspection. Licensees are required to respond in writing to cited violations within 30 days. All findings are reviewed by the senior health physicist.

The review team verified that the Bureau maintains an adequate supply of calibrated survey instruments to support its inspection program and emergency response activities. Instruments are calibrated by the Iowa Homeland Security and Emergency Management Division calibration laboratory or by instrument manufacturers. The Bureau uses a database to track each instrument, its current location, and next calibration date.

Accompaniments of two Bureau inspectors were conducted by an IMPEP team member during the week of July 23, 2012. The inspectors were accompanied during health and

safety inspections of an industrial radiography and a portable gauge licensee. The accompaniments are identified in Appendix C. During the accompaniments, the inspectors conducted performance-based inspections. The inspectors demonstrated appropriate inspection techniques and knowledge of the regulations. The inspectors were trained, 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 and safety and security at the licensed facilities.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Iowa's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 23 specific licensing actions. 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, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/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 four new licenses, eight renewals, three termination actions, and eight amendments. Files reviewed included a cross-section of license types, including: broadscope, medical diagnostic and therapy (including high dose rate remote afterloader, unsealed radioiodine therapy, and temporary/permanent implant brachytherapy), industrial radiography, research and development, nuclear pharmacy, fixed gauges, and blood irradiators. The casework sample represented work from two license reviewers. A list of the licensing casework evaluated is provided in Appendix D.

The review team found that the licensing actions were thorough, complete, consistent, and of high quality with health, safety, and security concerns properly addressed. License tie-down conditions were stated clearly and were supported by information contained in the file. Deficiency letters clearly stated regulatory positions, were used at the proper time, and identified substantive deficiencies in the licensees' documents. Terminated licensing actions were well documented, showing appropriate transfer and survey records. License reviewers use the Bureau's licensing guides, policies, checklists, and standard license conditions specific to the type of licensing actions to ensure consistency in licenses.

All qualified license evaluators have signature authority for licensing actions. Licenses are signed by the license reviewer and given a "Concurrence" signature by a peer reviewer. During the approximately 12-month period in which the Bureau had only one qualified license reviewer,

there was only one signature on the licenses. Licenses are issued for a five year period under a timely renewal system.

The review team discovered one new license issued for a high dose rate remote afterloader facility that included an authorized user who was added to the license without proper documentation to verify the training, experience, and preceptor attestation. The review team brought this to the attention of the Bureau, who immediately contacted the licensee and determined that this specific authorized user was only listed on this facility's license and not listed on any other license issued by the Bureau, the NRC, or another Agreement State. In addition, the Bureau requested this physician's training, experience, and preceptor authorization be sent in and approved by the Bureau before the physician could perform any further cases. Upon further discussion with the Bureau staff indicated a misunderstanding regarding preceptor attestation requirements, as stated in the Iowa regulations, in situations where a potential authorized user is board certified. Due to this misunderstanding, staff indicated no preceptor attestation information would be requested for potential authorized users whose submitted board certification is recognized by the NRC. While the review team was on-site, the Bureau committed to and began reviewing all medical licensing files where authorized users were added to a license from 2008 to present. Iowa's revised medical regulations became effective in July 2008 and licensing actions from that point forward would need to document the required training and experience for authorized users. Any authorized user added to a license without preceptor attestation was contacted for the preceptor documentation. The Bureau completed the review of its medical licensing files and obtained from its licensees the preceptor statements. The action was completed on October 15, 2012 (ML122890825).

Based on the casework evaluated, the review team concluded that the licensing actions were of high quality and consistent with the Bureau's licensing procedures, the State's regulations, and good health physics practices. The review team attributed the consistent use of templates and quality assurance reviews to the overall quality noted in the casework reviews.

The Bureau performs pre-licensing checks of all new applicants. The Bureau's pre-licensing review methods incorporate the essential elements of the NRC's revised pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended. All new licensees, not known to the Bureau, receive a pre-licensing site visit which includes an evaluation of the applicant's radiation safety and security programs prior to receipt of the initial license.

The review team examined the Bureau's licensing practices regarding the Increased Controls and Fingerprinting Orders. The review team noted that the State has incorporated the criteria for implementing the Increased Controls Order into rule, and uses legally binding license conditions that meet the criteria for implementing the fingerprinting requirement, as appropriate. The review team analyzed the Bureau's methodology for identifying those licenses and found the rationale was thorough and accurate. The review team confirmed that license reviewers evaluated new license applications and license amendments using the same criteria. The Bureau requires full implementation of the Increased Controls prior to issuance of a new license or license amendment that meets the established criteria.

The review team examined the Bureau's implementation of its procedure for the control of sensitive information. This procedure addresses the identification, marking, control, handling,

preparation, transportation, transmission, and destruction of documents that contain sensitive information related to the Increased Controls. Files that contained sensitive information were further secured in locked file cabinets.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Iowa's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Bureau's actions in responding to incidents and allegations, the review team examined the Bureau's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Iowa in the Nuclear Material Events Database (NMED) against those contained in the Bureau's files, and evaluated the casework for 12 radioactive materials incidents. A list of the incident casework examined, with case-specific comments, may be found in Appendix E. The review team also evaluated the Bureau's response to five allegations involving radioactive materials, including four allegations referred to the State by the NRC during the review period.

The review team examined the Bureau's incident and allegation processes, including written procedures for handling allegations and incident response, file documentation, notification of incidents to the NRC Headquarters Operations Center, and the use of NMED software. When notification of an incident or an allegation is received, the Bureau Chief and senior health physicist determine the appropriate level of initial response.

The review team identified 30 radioactive material incidents in NMED for Iowa during the review period, of which 12 required reporting. Four non-reportable incidents in Iowa were reviewed for reportability and found to be correctly categorized as non-reportable by the Bureau.

The incidents selected for review included the following categories: lost radioactive material, potential overexposure, medical events, equipment failures, leaking source, and facility contamination. The review team determined that the Bureau's response to incidents was adequate. Initial responses were prompt and well-coordinated. The Bureau performed on-site investigations when incidents were discovered during routine inspections. Three of the 12 incidents evaluated by the review team were discovered in this manner.

The review team determined that the Bureau did not perform on-site investigations for three of the incidents evaluated during this review. One of the incidents involved a medical procedure in which a brachytherapy source was dislodged from a patient. A second medical case, concerned a patient treated with iodine-131 who entered a medical center for unrelated treatment without notifying the medical center staff of contamination potential. A third incident involved a leaking source which caused contamination of equipment in a hot laboratory. Each of these incidents presented potential for personnel exposure and an on-site presence by the Bureau may have identified causative factors which were not readily apparent to the licensees. Rather, the Bureau chose to perform initial investigations of the incidents by telephone and then perform a follow-up review of the incident during the next routine inspection. The Bureau Chief informed the review team that for future incidents, strong consideration would be given to an on-site response, as opposed to telephone follow-ups.

The review team determined that the Bureau took suitable enforcement and follow-up actions to reported incidents. 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 Bureau notified the NRC Headquarters Operations Center and entered the information into NMED, in a prompt manner.

In evaluating the effectiveness of the Bureau's response to allegations, the review team evaluated the completed casework for five allegations, including four that the NRC referred to the Bureau during the review period. The review team concluded that the Bureau took prompt and appropriate actions in response to concerns raised. One of the allegation investigations involved an extensive on site reenactment of an alleged industrial radiography overexposure. The review team noted that the Bureau documented the investigations of concerns and retained all necessary documentation to appropriately close the allegations. The Bureau notified the concerned individuals of the conclusion of their investigations. The review team determined that the Bureau adequately protected the identity of concerned individuals.

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

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review 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. NRC's Agreement with Iowa does not relinquish regulatory authority for a sealed source and device evaluation, low level radioactive waste disposal, or uranium recovery program; therefore, only the first non-common performance indicator applied to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

Iowa became an Agreement State on January 1, 1986. The current effective statutory authority is contained in Chapters 17A and 136C, of the Code of Iowa. The Department is designated as the State's radiation control agency. The Bureau implements the radiation control program.

The review team noted that legislation affecting the radiation control program in Chapters 136C.3 subsection 5, 136.8, and 136C.14 subsection 2 was passed during the review period. These amendments were minor and cleaned up existing language to reflect modern terms and current practice.

4.1.2 Program Elements Required for Compatibility

The Iowa regulations governing radiation protection requirements are located in Section 641, Chapters 38 through 45 of the Iowa Administrative Code and apply to all ionizing radiation. The Bureau requires a license for possession and use of all radioactive material, including naturally-occurring materials, such as radium, and accelerator-produced radionuclides.

The review team examined the State's administrative rulemaking process and found that the process takes one year from the development stage to the final approval. Each rule is filed with the office of the administrative rules coordinator which indexes and publishes the rule in the Iowa administrative bulletin, after which the rule becomes effective in 35 days. The public, NRC, other agencies, and potentially impacted licensees and registrants are offered an opportunity to comment during the process. Comments are considered and incorporated, as appropriate, before the regulations are finalized.

The review team noted that the State's rules and regulations are not subject to "sunset" laws. The State may adopt the regulations of another agency by reference and also has the authority to issue other legally binding requirements in lieu of regulations until compatible regulations become effective.

The review team evaluated Iowa's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the State Regulation Status Sheet that FSME maintains.

During the review period, Iowa submitted 21 final regulation amendments and one legally binding license condition to the NRC for a compatibility review. 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 noted that, with the most recent rulemaking package, the State is up to date on all NRC amendments. A list of regulations that are due for adoption can be found at: http://nrc-stp.ornl.gov/rss_regamendments.html.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Iowa's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Iowa's performance was found satisfactory for all of performance indicators reviewed. The review team did not make any recommendations regarding program performance by the State and determined that the recommendation from the 2007 IMPEP review should be closed. Accordingly, the review team recommended, and the MRB agreed, that the Iowa 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.

LIST OF APPENDICES

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

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

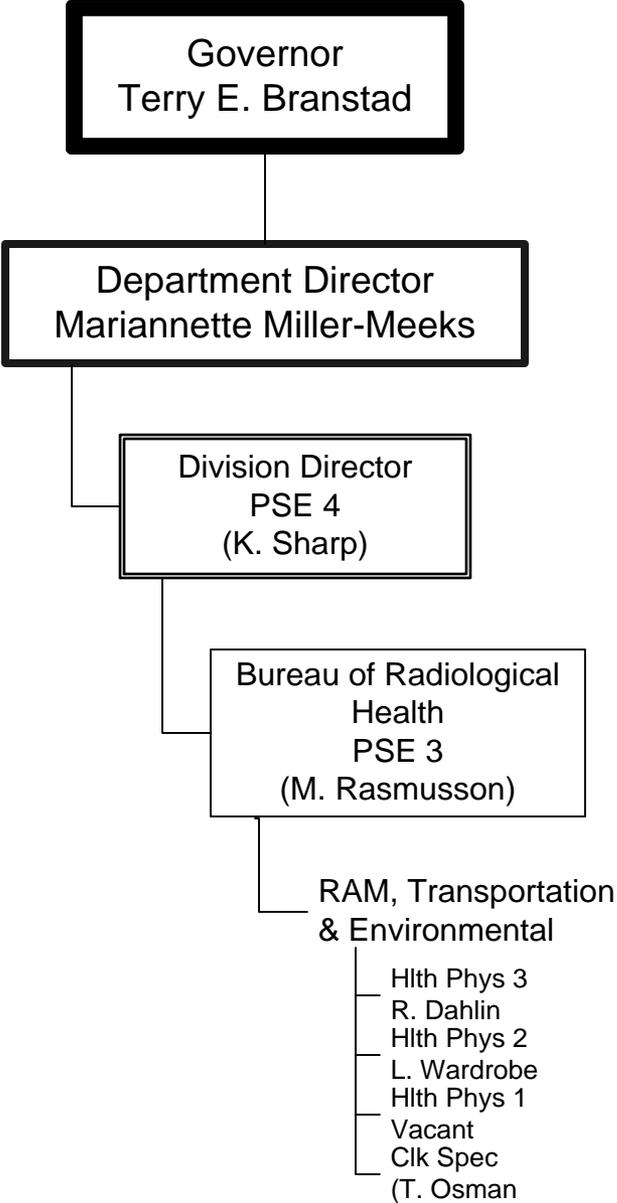
Name	Area of Responsibility
Monica Orendi, Region I	Team Leader Technical Staffing and Training Status of Materials Inspection Program Compatibility Requirements
James Lynch, Region III	Technical Quality of Inspections Technical Quality of Incident and Allegation Activities Inspector Accompaniments
Sherrie Flaherty, Minnesota	Technical Quality of Licensing Actions

APPENDIX B

IOWA ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML12191A046

IOWA DEPARTMENT OF PUBLIC HEALTH



APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1 Licensee: Element Materials Technology Inspection Type: Routine, Unannounced Inspection Date: 7/24/12	License No.: 0316-1-77-IR1 Priority: 1 Inspector: RD
File No.: 2 Licensee: Foth Infrastructure and Environment, LLC Inspection Type: Routine, Unannounced Inspection Date: 7/24/12	License No.: 0260-1-77-PG Priority: 5 Inspector: LW
File No.: 3 Licensee: Alliance Imaging, Inc. Inspection Type: Routine, Announced Inspection Date: 6/7/11	License No.: 0329-1-00-NV1 Priority: 2 Inspector: RD
File No.: 4 Licensee: Avera McKennan Hospital Inspection Type: Initial, Unannounced Inspection Date: 9/30/09	License No.: 0358-1-75-M2 Priority: 5 Inspector: NF
File No.: 5 Licensee: Midwest Industrial X-Ray, Inc. Inspection Type: Routine, Unannounced Inspection Date: 6/8/11	License No.: 0075-1-78-IR1 Priority: 1 Inspector: NF
File No.: 6 Licensee: CB & I, Inc. Inspection Type: Routine, Unannounced Inspection Date: 4/13/09	License No.: 0115-1-77-IR1 Priority: 1 Inspector: NF
File No.: 7 Licensee: LifeServe Blood Center Inspection Type: Routine, Unannounced Inspection Date: 7/26/12	License No.: 0133-1-77-I1 Priority: 5 Inspectors: RD, LW
File No.: 8 Licensee: Hot Shots NM, LLC Inspection Type: Routine, Unannounced Inspection Date: 8/20/08	License No.: 0207-1-82-NP Priority: 1 Inspector: NF

File No.: 9

Licensee: WOS Testing, Inc.
Inspection Type: Routine, Unannounced
Inspection Dates: 6/23-25/09

License No.: 0253-1-57-IR1
Priority: 1
Inspectors: NF, RD

File No.: 10

Licensee: Radiology Group, PC, SC
Inspection Type: Routine, Unannounced
Inspection Date: 9/13/11

License No.: 0306-1-82-M1
Priority: 3
Inspector: RD

File No.: 11

Licensee: Nuclear Sonics Associates, Inc.
Inspection Type: Routine, Unannounced
Inspection Dates: 10/31-11/1/07

License No.: 0004-1-77-NV1
Priority: 2
Inspector: RD

File No.: 12

Licensee: Iowa State University
Inspection Type: Routine, Announced
Inspection Dates: 4/26-28/11

License No.: 0014-1-85-AAB
Priority: 2
Inspectors: NF, RD, JC

File No.: 13

Licensee: Cardinal Health 414, LLC
Inspection Type: Routine, Unannounced
Inspection Date: 8/4/09

License No.: 0043-1-77-NP
Priority: 1
Inspectors: NF, MR

File No.: 14

Licensee: Grinnell College
Inspection Type: Routine, Unannounced
Inspection Date: 5/17/11

License No.: 0119-1-79-RD2
Priority: 3
Inspector: NF

File No.: 15

Licensee: Mary Greeley Medical Center
Inspection Type: Routine, Unannounced
Inspection Date: 5/30/12

License No.: 0049-1-85-M1
Priority: 3
Inspectors: RD, LW

File No.: 16

Licensee: Genesis Medical Center
Inspection Type: Special, Announced
Inspection Dates: 11/19-20/08

License No.: 0034-1-82-M1
Priority: 3
Inspector: NF

File No.: 17

Licensee: Clapsaddle-Garber Associates, Inc.
Inspection Type: Routine, Unannounced
Inspection Date: 5/29/12

License No.: 0120-1-64-PG
Priority: 5
Inspectors: LW, RD

File No.: 18

Licensee: The University of Iowa
Inspection Type: Routine, Announced
Inspection Dates: 10/11-14/10

License No.: 0037-1-52-AAB
Priority: 2
Inspectors: RD, NF

File No.: 19

Licensee: Iowa Health-Des Moines
Inspection Type: Routine, Unannounced
Inspection Dates: 2/21-24/11

License No.: 0077-1-77-MET
Priority: 2
Inspectors: RD, JC

File No.: 20

Licensee: Midwest Positron Technology, LC
Inspection Type: Routine, Unannounced
Inspection Dates: 5/23-24/11

License No.: 0308-1-82-PET
Priority: 1
Inspector: RD

File No.: 21

Licensee: Team Industrial Services, Inc.
Inspection Type: Reciprocity, Unannounced
Inspection Date: 4/13/11

License No.: 9009-1-00-IR1
Priority: 1
Inspector: RD

File No.: 22

Licensee: Mercy Medical Center-Des Moines
Inspection Type: Initial, Unannounced
Inspection Date: 4/6/09

License No.: 0357-1-77-HDR
Priority: 2
Inspector: RD

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1

Licensee: Foth Infrastructure and Environment, LLC
Inspection Type: Routine, Unannounced
Inspection Date: 7/24/12

License No.: 0260-1-77-PG
Priority: 5
Inspector: LW

Accompaniment No.: 2

Licensee: Element Materials Technology
Inspection Type: Routine, Unannounced
Inspection Date: 7/24/12

License No.: 0316-1-77-IR1
Priority: 1
Inspector: RD

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: DBI, Inc.

Type of Action: New

Date Issued: 10/4/07

License No.: 0350-1-78-IR1

Amendment No.: N/A

License Reviewer: NF

File No.: 2

Licensee: Siouxland Regional Cancer Center

Type of Action: New

Date Issued: 2/6/09

License No: 0359-1-97-M1

Amendment No.: N/A

License Reviewer: RD

File No.: 3

Licensee: Mary Greeley Medical Center

Type of Action: New

Date Issued: 5/21/09

License No.: 0361-1-85-HDR

Amendment No.: N/A

License Reviewer: NF

Comment: Authorized user added to the license without proper documentation regarding training, experience, and preceptor attestation.

File No.: 4

Licensee: Mercy Medical Center

Type of Action: Renewal

Date Issued: 1/5/11

License No.: 0339-1-57-HDR

Amendment No.: N/A

License Reviewer: RD

File No.: 5

Licensee: Radiology Group, PC, SC

Type of Action: Termination

Date Issued: 4/9/12

License No.: 0306-1-82-M1

Amendment No.: 01

License Reviewer: RD

File No.: 6

Licensee: Radiology Consultants of Iowa, PLC

Type of Action: Termination

Date Issued: 6/19/08

License No.: 0041-1-57-M1

Amendment No.: 01

License Reviewer: RD

File No.: 7

Licensee: Keokuk Steel Casting

Type of Action: Termination

Date Issued: 1/24/08

License No.: 0341-1-56-IR2

Amendment No.: 01

License Reviewer: RD

File No.: 8

Licensee: Catholic Health Initiatives – Iowa Corp
Type of Action: Amendment
Date Issued: 7/17/12

License No.: 0124-1-77-M1
Amendment No.: 06
License Reviewer: RD

File No.: 9

Licensee: Ottumwa Regional Health Center
Type of Action: Renewal
Date Issued: 12/12/07

License No.: 0016-1-90-M1
Amendment No.: N/A
License Reviewer: RD

File No.: 10

Licensee: Avera McKennan
Type of Action: Renewal
Date Issued: 1/7/08

License No.: 0315-1-00-NV1
Amendment No.: N/A
License Reviewer: RD

File No.: 11

Licensee: Hot Shots NM, LLC
Type of Action: Renewal
Date Issued: 11/30/09

License No.: 0289-1-57-NP
Amendment No.: N/A
License Reviewer: RD

File No.: 12

Licensee: Midwest Positron Technology, LC
Type of Action: Renewal
Date Issued: 7/30/12

License No.: 0308-1-82-PET
Amendment No.: N/A
License Reviewer: RD

File No.: 13

Licensee: Lifeserve Blood Center
Type of Action: Renewal
Date Issued: 1/23/09

License No.: 0281-1-97-I1
Amendment No.: N/A
License Reviewer: NF

File No.: 14

Licensee: University of Iowa
Type of Action: Renewal
Date Issued: 4/1/08

License No.: 0037-1-52-AAB
Amendment No.: N/A
License Reviewer: NF

File No.: 15

Licensee: Great River Medical
Type of Action: Amendment
Date Issued: 6/11/12

License No.: 0022-1-29-M1
Amendment No.: 02
License Reviewer: NF

File No.: 16

Licensee: Mercy Medical
Type of Action: Amendment
Date Issued: 3/5/12

License No.: 0017-1-57-MET
Amendment No.: 08
License Reviewer: RD

File No.: 17

Licensee: Iowa Health – Des Moines
Type of Action: Amendment
Date Issued: 9/26/11

License No.: 0310-1-77-HDR
Amendment No.: 05
License Reviewer: RD

File No.: 18

Licensee: St. Anthony Regional Medical Center
Type of Action: Amendment
Date Issued: 5/12/11

License No.: 0313-1-14-HDR
Amendment No.: 01
License Reviewer: NF

File No.: 19

Licensee: Northern Shared Medical Services, Inc
Type of Action: Amendment
Date Issued: 8/5/11

License No.: 0298-1-00-NV1
Amendment No.: 01
License Reviewer: RD

File No.: 20

Licensee: Midwest Industrial X-Ray, Inc
Type of Action: Amendment
Date Issued: 6/27/11

License No.: 0075-1-78-IR1
Amendment No.: 02
License Reviewer: RD

File No.: 21

Licensee: SSAB Iowa, Inc
Type of Action: Renewal
Date Issued: 7/22/10

License No.: 0259-1-70-FG
Amendment No.: N/A
License Reviewer: NF

File No.: 22

Licensee: Siouxland Regional Cancer Center
Type of Action: Amendment
Date Issued: 3/16/10

License No.: 0359-1-97-M1
Amendment No.: 01
License Reviewer: RD

File No.: 23

Licensee: Mercy Medical Center
Type of Action: Amendment
Date Issued: 9/26/08

License No.: 0339-1-57-HDR
Amendment No.: 02
License Reviewer: RD

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Pharmacy Services of the Quad Cities

Date of Incident: 10/4/07

Investigation Date: 10/5/07

License No.: 0207-1-82-NP

NMED No.: 070617

Type of Incident: Equipment Failure

Type of Investigation: Telephone

File No.: 2

Licensee: University of Iowa

Date of Incident: 10/19/07

Investigation Date: 10/19/07

License No.: 0037-1-52-AAB

NMED No.: 070654

Type of Incident: Medical Event

Type of Investigation: Telephone

Comment: The State did not perform an on-site inspection.

File No.: 3

Licensee: Keokuk Steel Castings

Date of Incident: 2/26/08

Investigation Date: 11/6/08

License No.: 3325-1-56-XRF

NMED No.: 080775

Type of Incident: Lost Source

Type of Investigation: Telephone

File No.: 4

Licensee: Marshalltown Medical & Surgical Center

Date of Incident: 5/3/09

Investigation Date: 5/28/09

License No.: 0053-1-64-M1

NMED No.: 090543

Type of Incident: Leaking Source

Type of Investigation: Telephone

Comment: The State did not perform an on-site inspection.

File No.: 5

Licensee: SSAB Iowa, Inc.

Date of Incident: 1/7/10

Investigation Date: 1/12/10

License No.: 0259-1-70-FG

NMED No.: 100032

Type of Incident: Equipment Failure

Type of Investigation: Telephone

File No.: 6
Licensee: Radiology Group BC
Date of Incident: 8/7/10
Investigation Date: 8/17/10

License No.: 0306-1-82-M1
NMED No.: 100420
Type of Incident: Overexposure
Type of Investigation: Telephone

Comment: The State did not perform an on-site inspection.

File No.: 7
Licensee: Tjaden Biosciences
Date of Incident: 12/3/09
Investigation Date: 10/7/10

License No.: 0344-1-29-MD
NMED No.: 100502
Type of Incident: Contamination
Type of Investigation: On-Site

File No.: 8
Licensee: Mercy Medical Center
Date of Incident: 2/10/11
Investigation Date: 2/11/11

License No.: 0339-1-57-HDR
NMED No.: 110104
Type of Incident: Medical Event
Type of Investigation: Telephone

File No.: 9
Licensee: Midwest Industrial X-Ray
Date of Incident: 6/24/11
Investigation Date: 6/24/11

License No.: 0075-1-78-IR1
NMED No.: 110323
Type of Incident: Equipment Failure
Type of Investigation: On-Site

File No.: 10
Licensee: Curwood, Inc.
Date of Incident: 11/2/11
Investigation Date: 11/2/11

License No.: 3003-1-77-FG
NMED No.: 110590
Type of Incident: Equipment Failure
Type of Investigation: Telephone

File No.: 11
Licensee: MidAmerican Energy
Date of Incident: 12/27/11
Investigation Date: 12/27/11

License No.: 0040-1-70-FG
NMED No.: 120012
Type of Incident: Equipment Failure
Type of Investigation: Telephone

File No.: 12
Licensee: SSAB Iowa, Inc.
Date of Incident: 5/17/12
Investigation Date: 7/12/12

License No.: 0259-1-70-FG
NMED No.: 120420
Type of Incident: Equipment Failure
Type of Investigation: On-Site

Comment: This incident was discovered during a routine inspection but was not mentioned in the inspection report.

ATTACHMENT

September 28, 2012 email from Melanie Rasmusson
Iowa's Response to the Draft Report
ADAMS Accession No.: ML12277A067

From: Orendi, Monica
Sent: Wednesday, October 03, 2012 9:07 AM
To: Meyer, Karen
Subject: FW: draft IMPEP report
Attachments: draft report.pdf

From: Rasmusson, Melanie [IDPH] [<mailto:Melanie.Rasmusson@idph.iowa.gov>]
Sent: Friday, September 28, 2012 4:56 PM
To: Orendi, Monica
Cc: Lynch, James; Flaherty, Sherrie (MDH) (Sherrie.Flaherty@state.mn.us); Dahlin, Randal [IDPH]; Wardrobe, Leo [IDPH]; Sharp, Ken [IDPH]
Subject: RE: draft IMPEP report

Hi again. I have attached the draft report with our comments. Since it is a pdf file, the track changes function was a little awkward. Please let me know if the changes don't show up on your end. I opened the attachment for a test run and the changes showed up. AND, please also know that the majority of the changes are merely suggestions and up for discussion if necessary. If there are any (or all) that you don't agree with or if you have questions, just let me know.

We would like to thank you for the opportunity to provide comments. As we expressed during the review, we appreciate and believe in the purpose and process of IMPEP. I look forward to hearing from you.

Hope you have a great weekend too!

Melanie

Melanie Rasmusson, MBA, Chief
Iowa Department of Public Health | Bureau of Radiological Health
321 E 12th Street | Des Moines, IA 50319 | PH: 515.281.3478
melanie.rasmusson@idph.iowa.gov

Promoting and Protecting the Health of Iowans

From: Orendi, Monica [<mailto:Monica.Orendi@nrc.gov>]
Sent: Friday, September 28, 2012 2:38 PM
To: Rasmusson, Melanie [IDPH]
Cc: Lynch, James; Flaherty, Sherrie (MDH) (Sherrie.Flaherty@state.mn.us)
Subject: RE: draft IMPEP report

Hi Melanie!

Happy Friday!!!! Tracked changes are perfectly acceptable if that works best for you. Also as another option you can put the suggested changes as bullets into the body of the response letter. Really it all comes down to whatever works easiest for you.

The more clarity we can bring to these reports the better so any suggestions you have please pass along.

Have a great weekend!

Monica

From: Rasmusson, Melanie [IDPH] [<mailto:Melanie.Rasmusson@idph.iowa.gov>]

Sent: Friday, September 28, 2012 3:23 PM

To: Orendi, Monica

Cc: Lynch, James; Flaherty, Sherrie (MDH) (Sherrie.Flaherty@state.mn.us)

Subject: draft IMPEP report

Importance: High

Hi Monica!

I have a few minor comments to make on the draft – at this point they are mostly suggestions for clarity. I tend to edit things to death. What is the most efficient and effective way to relay my “suggestions”? Can I use track changes on the electronic document?

Thanks so much,

Melanie

Melanie Rasmusson, MBA, Chief
Iowa Department of Public Health | Bureau of Radiological Health
321 E 12th Street | Des Moines, IA 50319 | PH: 515.281.3478
melanie.rasmusson@idph.iowa.gov

Promoting and Protecting the Health of Iowans

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Summary of Comments on IA Response to Draft Report.pdf

This page contains no comments

September 6, 2012

Marianette Miller-Meeks, B.S.N., M.Ed., M.D.
Director
Iowa Department of Public Health
Lucas State Office Building
321 East 12th Street
Des Moines, IA 50319

Dear Dr. Miller-Meeks:

The U.S. Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the evaluation of Agreement State programs. Enclosed for your review is the draft IMPEP report, which documents the results of the Agreement State review, held in Iowa on August 6-10, 2012. I was the team leader for the review. The review team's preliminary findings were discussed with you and your staff on the last day of the review. The review team's proposed recommendations are that the Iowa Agreement State Program be found adequate to protect public health and safety and compatible with NRC's program.

NRC conducts periodic reviews of Agreement State programs to ensure that public health and safety are adequately protected from the potential hazards associated with the use of radioactive materials and that Agreement State programs are compatible with the NRC's program. The process, titled IMPEP, employs a team of NRC and Agreement State staff to assess Agreement States' and NRC Regional Offices' radioactive materials programs. All reviews use common criteria in the assessment and place primary emphasis on performance. One additional area applicable to your program has been identified as a non-common performance indicator and is also addressed in the assessment. The final determination of adequacy and compatibility of each Agreement State program, based on the review team's report, is made by a Management Review Board (MRB) composed of NRC managers and an Agreement State program manager who serves as a liaison to the MRB.

In accordance with procedures for implementation of IMPEP, we are providing you with a copy of the draft team report for your review and comment prior to submitting the report to the MRB. Comments are requested within 4 weeks from your receipt of this letter. This schedule will permit the issuance of the final report in a timely manner that will be responsive to your needs.

The team will review the response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. The MRB meeting to discuss the results of the Iowa IMPEP review has been scheduled for Thursday, November 1, 2012. The NRC will provide invitational travel for you or your designee to attend the MRB meeting at NRC Headquarters in Rockville, Maryland. NRC has video conferencing capability if it is more convenient for the State to participate through this medium. Please contact me if you desire to establish a video conference for the meeting.

This page contains no comments

-2-

If you have any questions regarding the enclosed report, please contact me at 610-337-5214 or by email at Monica.Orendi@nrc.gov.

Thank you for your cooperation.

Sincerely,

/RA/

Monica Lynn Orendi
State Agreements Officer
Division of Nuclear Materials Safety
U.S. NRC Region I

Enclosure:
As stated

cc w/ encl: Melanie Rasmusson, Chief
Bureau of Radiological Health

This page contains no comments



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

AUGUST 6-10, 2012

DRAFT REPORT

Enclosure

This page contains no comments

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Iowa Agreement State Program. The review was conducted during the period of August 6-10, 2012, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Minnesota.

Based on the results of this review, the review team recommends that Iowa's performance be found satisfactory for all performance indicators reviewed. The review team did not make any recommendations regarding program performance by the State and determined that the recommendation from the 2007 IMPEP review, regarding decommissioning financial assurance, should be closed.

Accordingly, the review team recommends that the Iowa Agreement State Program be found adequate to protect public health and safety and compatible with NRC's program. The review team recommends that the next IMPEP review take place in approximately five years.

Iowa Draft IMPEP Report

Page 1

1.0 INTRODUCTION

This report presents the results of the review of the Iowa Agreement State Program. The review was conducted during the period of August 6-10, 2012, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Minnesota. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementations 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 September 15, 2007 to August 10, 2012, were discussed with Iowa 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 Iowa Agreement State Program is administered by the Bureau of Radiological Health (the Bureau), which is located within the Division of Environmental Health (the Division). The Division is part of the Department of Public Health (the Department). An organization chart is included as Appendix B.

At the time of the review, the Iowa Agreement State Program regulated 168 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 Iowa.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Bureau on May 1, 2012. The Bureau provided its response to the questionnaire on July 5, 2012. A copy of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML12191A061.

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

Section 2.0 of this report covers the State's actions in response to recommendations made during previous reviews. Results of the current review of the common performance indicators are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-common performance indicator and Section 5.0 summarizes the review team's findings.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on September 14, 2007, the review team made one recommendation regarding the Iowa Agreement State Program's performance. The status of the recommendation is as follows:

"The review team recommends that the State evaluate their decommissioning financial assurance program to identify and secure original financial assurance documentation from current and future licensees who are required to comply with Iowa's financial assurance requirements."

Status: Iowa has implemented a procedure, including a checklist, to ensure all licenses are compliant with the State's financial assurance requirements. The Program also reviewed its licenses to determine need for financial assurance and identified four licensees. The review team confirmed all original financial assurance documents for these licensees had been obtained and that these documents are kept in a secure location. This recommendation is closed.

3.0 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.

3.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the Bureau'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 Bureau's questionnaire response relative to this indicator, interviewed managers and staff, reviewed job descriptions and training records, and considered workload backlogs.

The Bureau is managed by the Division. The Radioactive Materials Program (the Program) is responsible for materials inspection, licensing, and emergency response activities. At the time of the review, there were two technical staff members and one administrative staff member with various degrees of involvement in the radioactive materials program, totaling approximately 2.2 full-time equivalents (FTE). Two technical staff members left the Program during the review period. One of those positions was filled in March 2012 and one position was vacant at the time of this review. The review team noted that staffing levels did not present any performance issues affecting implementation of the Agreement State program; however, loss of a technical staff member could potentially impact the Bureau's ability to remain current on all regulatory actions. This was discussed with Department managers during the exit meeting on August 10, 2012.

The Bureau has a documented training plan for technical staff that is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear

Author: mras muss Subject: Replacement Text Date: 9/28/2012 4:01:55 PM
Considerations

Author: mras muss Subject: Highlight Date: 9/28/2012 4:05:06 PM
I propose moving this sentence three sentences down. It is confusing because it appears that at one time we may have had four staff members.

Material Safety and Safeguards Program Area.” Staff members are assigned increasingly complex duties as they progress through the qualification process. The review team concluded that the Bureau’s training program is adequate to carry out its regulatory duties and noted that Iowa management supports the Bureau’s training program.

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

3.2 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 Bureau’s questionnaire response relative to this indicator, data gathered from the Bureau’s database, examination of completed inspection casework, and interviews with management and staff.

The review team verified that Iowa’s inspection frequencies for all types of radioactive material licenses are at least as frequent as similar license types listed in Inspection Manual Chapter (IMC) 2800, “Materials Inspection Program.” From the beginning of the review period until January 2012 the Bureau inspected licensees more frequently than similar license types. Starting in January 2012 the Bureau changed their inspection frequencies to match inspection frequencies for similar license types as established in IMC 2800.

The Bureau conducted 143 Priority 1, 2, and 3 inspections during the review period, based on the inspection frequencies established in IMC 2800. ~~None of these inspections were conducted overdue by more than 25 percent of the inspection frequency prescribed in IMC 2800.~~ In addition, the Bureau performed 17 initial inspections during the review period, none of which were conducted overdue. Overall, the review team calculated that the Bureau performed zero percent of its inspections overdue during the review period.

The review team evaluated the Bureau’s timeliness in providing inspection findings to licensees. A sampling of inspection reports indicated that the inspection findings were communicated to the licensees within the Bureau’s goal of 30 days after the inspection.

During the review period, the Bureau granted 192 reciprocity permits, 38 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 Bureau met and exceeded the NRC’s criteria of inspecting 20 percent of candidate licensees operating under reciprocity in three of the four calendar years covered by the five year review period. For the one year that the Program fell below the NRC’s criteria of inspecting 20 percent of candidate licensees operating under reciprocity, the Program inspected 13 percent of candidate licensees for reciprocity. This was due to the Program needing to focus its attention on other Programmatic priorities.

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

Author: mras muss Subject: Cross-Out Date: 9/28/2012 4:11:26 PM
This sentence seems unnecessary to me and therefore causes a little confusion. If it is required to be stated (the 25% mention), then I suggest changing the order of the sentences.
Author: mras muss Subject: Replacement Text Date: 9/28/2012 4:08:47 PM

3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 22 radioactive materials inspections conducted during the review period. The casework reviewed included inspections conducted by four Bureau inspectors and covered inspections of various license types, including: medical broad scope, medical institutions, radionuclide production (cyclotron), industrial radiography, self-shielded irradiators, nuclear pharmacy, mobile nuclear medicine, portable gauges, and Increased Security Controls for Large Quantities of Radioactive Materials (Increased Controls). Appendix C lists the inspection casework files reviewed as well as the results of the inspector accompaniments.

Based on the evaluation of casework, the review team noted that inspections covered all aspects of the licensee's radiation safety programs. The review team found that inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that a licensee's performance with respect to health and safety was acceptable. The documentation supported violations, recommendations made to licensees, unresolved safety issues, the effectiveness of corrective actions taken to resolve previous violations and discussions held with licensees during exit interviews.

The inspection procedures utilized by the Bureau are consistent with the inspection guidance outlined in IMC 2800. An inspection report is completed by the inspector which is then peer reviewed by another inspector. Between July 2011 and March 2012, a second inspector was not employed by the program, and thus, the peer review process was suspended. If the peer reviewer is qualified for a particular type of inspection, that person signs the "approval" signature block on the inspection report. The Bureau Chief accompanied all inspectors on an annual frequency.

The review team determined that the inspection findings were appropriate and prompt regulatory actions were taken, as necessary. Inspection findings were clearly stated and documented in the reports and sent to the licensees with the appropriate letter detailing the results of the inspection. The Bureau issues to the licensee, either a letter indicating a clear inspection or a Notice of Violation in letter format, which details the results of the inspection. Licensees are required to respond in writing to cited violations within 30 days. All findings are reviewed by the senior health physicist.

The review team verified that the Bureau maintains an adequate supply of calibrated survey instruments to support its inspection program and emergency response activities. Instruments are calibrated by the Emergency Management Division calibration laboratory or by instrument manufacturers. The Bureau uses a database to track each instrument, its current location, and next calibration date.

Accompaniments of two Bureau inspectors were conducted by an IMPEP team member during the week of July 23, 2012. The inspectors were accompanied during health and safety inspections of industrial radiography and portable gauge licensees. The accompaniments are identified in Appendix C. During the accompaniments, the inspectors demonstrated appropriate inspection techniques, knowledge of the regulations, and conducted performance based inspections. The inspectors were trained, well-prepared for

- Author: mras muss Subject: Replacement Text Date: 9/28/2012 4:15:28 PM
three
- Author: mras muss Subject: Sticky Note Date: 9/28/2012 4:42:32 PM
While a fourth staff member was employed for less than the 6 month probationary period, he never conducted an inspection.
- Author: mras muss Subject: Replacement Text Date: 9/28/2012 4:16:04 PM
concerns
- Author: mras muss Subject: Replacement Text Date: 9/28/2012 4:17:15 PM
an
- Author: mras muss Subject: Inserted Text Date: 9/28/2012 4:17:26 PM
,
- Author: mras muss Subject: Inserted Text Date: 9/28/2012 4:17:58 PM
Iowa Homeland Security and
- Author: mras muss Subject: Cross-Out Date: 9/28/2012 4:18:29 PM
,
- Author: mras muss Subject: Inserted Text Date: 9/28/2012 4:18:17 PM
an
- Author: mras muss Subject: Inserted Text Date: 9/28/2012 4:18:23 PM
ha
- Author: mras muss Subject: Replacement Text Date: 9/28/2012 4:28:36 PM
During the accompaniments, the inspectors conducted performance based inspections. The inspectors demonstrated appropriate inspection techniques and knowledge of the regulations.

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 and safety and security at the licensed facilities.

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

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 23 specific licensing actions. 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, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/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 four new licenses, eight renewals, three termination actions, and eight amendments. Files reviewed included a cross-section of license types, including: broadscope, medical diagnostic and therapy (including high dose rate remote afterloader, unsealed radioisotope therapy, and temporary/permanent implant brachytherapy), industrial radiography, research and development, nuclear pharmacy, fixed gauges, and blood irradiators. The casework sample represented work from two license reviewers. A listing of the licensing casework evaluated is provided in Appendix D.

Overall, 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 and were supported by information contained in the file. Deficiency letters clearly stated regulatory positions, were used at the proper time, and identified substantive deficiencies in the licensees' documents. Terminated licensing actions were well documented, showing appropriate transfer and survey records. License reviewers use the Bureau's licensing guides, policies, checklists, and standard license conditions specific to the type of licensing actions to ensure consistency in licenses.

All qualified license evaluators have signature authority for licensing actions. Licenses are signed by the license reviewer and given a "Concurrence" signature by a peer reviewer. During the approximately 12-month period in which the Program had only one qualified license reviewer, there was only one signature on the licenses. Licenses are issued for a five year period under a timely renewal system.

The review team discovered one new license issued for a high dose rate remote afterloader facility that included an authorized user who was added to the license without proper documentation to verify the training, experience, and preceptor attestation. The review team

brought this to the attention of the Program, who immediately contacted the licensee and determined that this specific authorized user is only listed on this facility's license and not listed on any other license issued by the Program, the NRC, or another Agreement State. In addition, the Program has requested this physician's training, experience, and preceptor authorization be sent in and approved by the Program before the physician can perform any further cases. Upon further discussion with the Program, staff indicated a misunderstanding regarding preceptor attestation requirements, as stated in the Iowa regulations, in situations where a potential authorized user is board certified. Due to this misunderstanding, staff indicated no preceptor attestation information would be requested for potential authorized users whose submitted board certification is recognized by NRC. While the review team was on-site the Program committed to and began reviewing all medical licensing files where authorized users were added to a license from 2008 to present. Iowa's revised medical regulations became effective in July 2008 and licensing actions from that point forward would need to document the required training and experience for authorized users. Any authorized user added to a license without preceptor attestation will be contacted for the preceptor documentation.

Based on the casework evaluated, the review team concluded that the licensing actions were of high quality and consistent with the Bureau's licensing procedures, the State's regulations, and good health physics practices. The review team attributed the consistent use of templates and quality assurance reviews to the overall quality noted in the casework reviews.

The Program performs pre-licensing checks of all new applicants. The Bureau's pre-licensing review methods incorporate the essential elements of NRC's revised pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended. All new licensees receive a pre-licensing site visit which includes an evaluation of the applicant's radiation safety and security programs prior to receipt of the initial license.

The review team examined the Bureau's licensing practices regarding the Increased Controls and Fingerprinting Orders. The review team noted that the State has incorporated the criteria for implementing the Increased Controls Order into rule, and uses legally binding license conditions that meet the criteria for implementing the fingerprinting requirement, as appropriate. The review team analyzed the Bureau's methodology for identifying those licenses and found the rationale was thorough and accurate. The review team confirmed that license reviewers evaluated new license applications and license amendments using the same criteria. The Bureau requires full implementation of the Increased Controls prior to issuance of a new license or license amendment that meets the established criteria.

The review team examined the Bureau's implementation of its procedure for the control of sensitive information. This procedure addresses the identification, marking, control, handling, preparation, transportation, transmission, and destruction of documents that contain sensitive information related to the Increased Controls. Files that contained sensitive information were further secured in locked file cabinets.

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

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Bureau's actions in responding to incidents and allegations, the review team examined the Bureau's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Iowa in the Nuclear Material Events Database (NMED) against those contained in the Bureau's files, and evaluated the casework for 12 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 Bureau's response to five allegations involving radioactive materials, including four allegations referred to the State by the NRC during the review period.

The review team examined the Bureau's incident and allegation processes, including written procedures for handling allegations and incident response, file documentation, notification of incidents to the NRC Headquarters Operations Center, and the use of NMED software. When notification of an incident or an allegation is received, the Bureau Chief and senior health physicist determine the appropriate level of initial response.

The review team identified 30 radioactive material incidents in NMED for Iowa during the review period, of which 12 required reporting. Four non-reportable incidents in Iowa were reviewed for reportability and found to be correctly categorized as non-reportable by the Bureau.

The incidents selected for review included the following categories: lost radioactive material; potential overexposure; medical events; equipment failures; leaking source; and facility contamination. The review team determined that the Bureau's response to incidents was adequate. Initial responses were prompt and well-coordinated. The Bureau performed on-site investigations when incidents were discovered during routine inspections. Three of the 12 incidents evaluated by the review team were discovered in this manner.

The review team determined that the Bureau did not perform on-site investigations for three of the incidents evaluated during this review. One of the incidents involved a medical procedure in which a brachytherapy source was dislodged from a patient. A second medical case had a patient treated with iodine-131 enter a medical center for treatment without notifying staff of contamination potential. A third incident involved a leaking source which caused contamination of equipment in the hot laboratory. Each of these incidents presented potential for personnel exposure and an on-site presence by the Bureau may have identified causative factors which were not readily apparent to the licensees. Rather, the Bureau chose to perform initial investigations of the incidents by telephone and then perform a follow-up review of the incident during the next routine inspection. The Bureau Chief informed the review team that for future incidents, strong consideration would be given to an on-site response, as opposed to telephone follow-ups.

The review team determined that the State  suitable enforcement and follow-up actions to reported incidents. 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.

-  Author: mras muss Subject: Inserted Text Date: 9/28/2012 4:32:09 PM
unrelated

-  Author: mras muss Subject: Inserted Text Date: 9/28/2012 4:32:20 PM
medical center

-  Author: mras muss Subject: Sticky Note Date: 9/28/2012 4:36:34 PM
For consistency, should this say "the Bureau" rather than "the State?" I understand that depending on the circumstance, the State may be appropriate - just trying to remain consistent and as accurate as possible.

-  Author: mras muss Subject: Sticky Note Date: 9/28/2012 4:38:21 PM
Same here even though they are pretty interchangeable.

Author: mras muss Subject: Sticky Note Date: 9/28/2012 4:37:52 PM
Same consideration here with regards to addressing the State or the Bureau. Not trying to split hairs....

Author: mras muss Subject: Inserted Text Date: 9/28/2012 4:38:53 PM
on site

In evaluating the effectiveness of the Bureau's response to allegations, the review team evaluated the completed casework for five allegations, including four that the NRC referred to the State during the review period. The review team concluded that the Bureau took prompt and appropriate actions in response to concerns raised. One of the allegation investigations involved an extensive reenactment of an alleged industrial radiography overexposure. The review team noted that the Bureau documented the investigations of concerns and retained all necessary documentation to appropriately close the allegations. The Bureau notified the concerned individuals of the conclusion of their investigations. The review team determined that the Bureau adequately protected the identity of concerned individuals.

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

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review 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. NRC's Agreement with Iowa does not relinquish regulatory authority for a sealed source and device evaluation, low level radioactive waste disposal, or uranium recovery program; therefore, only the first non-common performance indicator applied to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

Iowa became an Agreement State on January 1, 1986. The current effective statutory authority is contained in Chapters 17A and 136C, of the Code of Iowa. The Department is designated as the State's radiation control agency. The Bureau implements the radiation control program.

The review team noted that legislation affecting the radiation control program in Chapters 136C.3 subsection 5, 136.8, and 136C.14 subsection 2 was passed during the review period. These amendments were minor and cleaned up existing language to reflect modern terms and current practice.

4.1.2 Program Elements Required for Compatibility

The Iowa regulations governing radiation protection requirements are located in Section 641, Chapters 38 through 45 of the Iowa Administrative Code and apply to all ionizing radiation. The Bureau requires a license for possession and use of all radioactive material, including naturally-occurring materials, such as radium, and accelerator-produced radionuclides.

The review team examined the State's administrative rulemaking process and found that the process takes one year from the development stage to the final approval. Each rule is filed with the office of the administrative rules coordinator which indexes and publishes the rule in the Iowa administrative bulletin, after which the rule becomes effective in 35 days. The public, NRC, other agencies, and potentially impacted licensees and registrants are offered an

This page contains no comments

opportunity to comment during the process. Comments are considered and incorporated, as appropriate, before the regulations are finalized.

The review team noted that the State's rules and regulations are not subject to "sunset" laws. The State may adopt the regulations of another agency by reference and also has the authority to issue other legally binding requirements in lieu of regulations until compatible regulations become effective.

The review team evaluated Iowa's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the State Regulation Status Sheet that FSME maintains.

During the review period, Iowa submitted 21 final regulation amendments and one legally binding license condition to the NRC for a compatibility review. 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 noted that, with the most recent rulemaking package, the State is up to date on all NRC amendments.

The review team identified the following regulation amendments that the State will need to address in the future:

- "Licenses, Certifications, and Approvals for Materials Licensees," 10 CFR Parts 30, 36, 39, 40, 70, and 150 amendment (76 FR 56951), that is due for Agreement State adoption on November 14, 2014.
- "Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste," 10 CFR Part 71 amendment (77 FR 34194), that is due for Agreement State adoption on August 10, 2015.
- "Decommissioning Planning," 10 CFR Parts 20, 30, 40, and 70 amendment (76 FR 35512), that is due for Agreement State adoption on December 15, 2015.

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

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Iowa's performance was found satisfactory for all of performance indicators reviewed. The review team did not make any recommendations regarding program performance by the State and determined that the recommendation from the 2007 IMPEP review should be closed. Accordingly, the review team recommends that the Iowa 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 recommends that the next full IMPEP review take place in approximately five years.