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 lowa Agreement State Program during this review. Based on the results of the current IMPEP review, the next full review of the lowa Agreement State Program will take place in approximately 5 years, with a periodic meeting tentatively scheduled for August 2014. The lowa 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

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

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Letter to M. Miller-Meeks from Michael F. Weber dated November 19, 2012

SUBJECT: IOWA 2012 FINAL IMPEP REPORT

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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 lowa managers on the last day of the review.

A draft of this report was provided to lowa 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 lowa 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 noncommon 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 <u>Technical Staffing and Training</u>

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 <u>Status of Materials Inspection Program</u>

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 lowa'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. 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 <u>Technical Quality of Inspections</u>

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 lowa's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.4 <u>Technical Quality of Licensing Actions</u>

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 lowa 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,

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 <u>Technical Quality of Incident and Allegation Activities</u>

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 lowa during the review period, of which 12 required reporting. Four non-reportable incidents in lowa 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 <u>Compatibility Requirements</u>

4.1.1 Legislation

lowa 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 lowa regulations governing radiation protection requirements are located in Section 641, Chapters 38 through 45 of the lowa 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 lowa 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: <u>http://nrc-stp.ornl.gov/rss_regamendents.html</u>.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that lowa'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

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

File No.: 2 Licensee: Foth Infrastructure and Environment, LLC Inspection Type: Routine, Unannounced Inspection Date: 7/24/12

File No.: 3 Licensee: Alliance Imaging, Inc. Inspection Type: Routine, Announced Inspection Date: 6/7/11

File No.: 4 Licensee: Avera McKennan Hospital Inspection Type: Initial, Unannounced Inspection Date: 9/30/09

File No.: 5 Licensee: Midwest Industrial X-Ray, Inc. Inspection Type: Routine, Unannounced Inspection Date: 6/8/11

File No.: 6 Licensee: CB & I, Inc. Inspection Type: Routine, Unannounced Inspection Date: 4/13/09

File No.: 7 Licensee: LifeServe Blood Center Inspection Type: Routine, Unannounced Inspection Date: 7/26/12

File No.: 8 Licensee: Hot Shots NM, LLC Inspection Type: Routine, Unannounced Inspection Date: 8/20/08 License No.: 0316-1-77-IR1 Priority: 1 Inspector: RD

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

License No.: 0329-1-00-NV1 Priority: 2 Inspector: RD

License No.: 0358-1-75-M2 Priority: 5 Inspector: NF

License No.: 0075-1-78-IR1 Priority: 1 Inspector: NF

License No.: 0115-1-77-IR1 Priority: 1 Inspector: NF

License No.: 0133-1-77-I1 Priority: 5 Inspectors: RD, LW

License No.: 0207-1-82-NP Priority: 1 Inspector: NF Iowa Final IMPEP Report Inspection Casework Reviews

File No.: 9 Licensee: WOS Testing, Inc. Inspection Type: Routine, Unannounced Inspection Dates: 6/23-25/09

File No.: 10 Licensee: Radiology Group, PC, SC Inspection Type: Routine, Unannounced Inspection Date: 9/13/11

File No.: 11 Licensee: Nuclear Sonics Associates, Inc. Inspection Type: Routine, Unannounced Inspection Dates: 10/31-11/1/07

File No.: 12 Licensee: Iowa State University Inspection Type: Routine, Announced Inspection Dates: 4/26-28/11

File No.: 13 Licensee: Cardinal Health 414, LLC Inspection Type: Routine, Unannounced Inspection Date: 8/4/09

File No.: 14 Licensee: Grinnell College Inspection Type: Routine, Unannounced Inspection Date: 5/17/11

File No.: 15 Licensee: Mary Greeley Medical Center Inspection Type: Routine, Unannounced Inspection Date: 5/30/12

File No.: 16 Licensee: Genesis Medical Center Inspection Type: Special, Announced Inspection Dates: 11/19-20/08

File No.: 17 Licensee: Clapsaddle-Garber Associates, Inc. Inspection Type: Routine, Unannounced Inspection Date: 5/29/12

Page C.2

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

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

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

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

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

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

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

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

License No.: 0120-1-64-PG Priority: 5 Inspectors: LW, RD Iowa Final IMPEP Report Inspection Casework Reviews

File No.: 18 Licensee: The University of Iowa Inspection Type: Routine, Announced Inspection Dates: 10/11-14/10

File No.: 19 Licensee: Iowa Health-Des Moines Inspection Type: Routine, Unannounced Inspection Dates: 2/21-24/11

File No.: 20 Licensee: Midwest Positron Technology, LC Inspection Type: Routine, Unannounced Inspection Dates: 5/23-24/11

File No.: 21 Licensee: Team Industrial Services, Inc. Inspection Type: Reciprocity, Unannounced Inspection Date: 4/13/11

File No.: 22 Licensee: Mercy Medical Center-Des Moines Inspection Type: Initial, Unannounced Inspection Date: 4/6/09 Page C.3

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

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

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

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

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

File No.: 2 Licensee: Siouxland Regional Cancer Center Type of Action: New Date Issued: 2/6/09

File No.: 3 Licensee: Mary Greeley Medical Center Type of Action: New Date Issued: 5/21/09 License No.: 0350-1-78-IR1 Amendment No.: N/A License Reviewer: NF

License No: 0359-1-97-M1 Amendment No.: N/A License Reviewer: RD

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

File No.: 5 Licensee: Radiology Group, PC, SC Type of Action: Termination Date Issued: 4/9/12

File No.: 6 Licensee: Radiology Consultants of Iowa, PLC Type of Action: Termination Date Issued: 6/19/08

File No.: 7 Licensee: Keokuk Steel Casting Type of Action: Termination Date Issued: 1/24/08 License No.: 0339-1-57-HDR Amendment No.: N/A License Reviewer: RD

License No.: 0306-1-82-M1 Amendment No.: 01 License Reviewer: RD

License No.: 0041-1-57-M1 Amendment No.: 01 License Reviewer: RD

License No.: 0341-1-56-IR2 Amendment No.: 01 License Reviewer: RD Iowa Final IMPEP Report Licensing Casework Reviews

File No.: 8 Licensee: Catholic Health Initiatives – Iowa Corp Type of Action: Amendment Date Issued: 7/17/12

File No.: 9 Licensee: Ottumwa Regional Health Center Type of Action: Renewal Date Issued: 12/12/07

File No.: 10 Licensee: Avera McKennan Type of Action: Renewal Date Issued: 1/7/08

File No.: 11 Licensee: Hot Shots NM, LLC Type of Action: Renewal Date Issued: 11/30/09

File No.: 12 Licensee: Midwest Positron Technology, LC Type of Action: Renewal Date Issued: 7/30/12

File No.: 13 Licensee: Lifeserve Blood Center Type of Action: Renewal Date Issued: 1/23/09

File No.: 14 Licensee: University of Iowa Type of Action: Renewal Date Issued: 4/1/08

File No.: 15 Licensee: Great River Medical Type of Action: Amendment Date Issued: 6/11/12

File No.: 16 Licensee: Mercy Medical Type of Action: Amendment Date Issued: 3/5/12 Page D.2

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

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

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

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

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

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

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

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

License No.: 0017-1-57-MET Amendment No.: 08 License Reviewer: RD Iowa Final IMPEP Report Licensing Casework Reviews

File No.: 17 Licensee: Iowa Health – Des Moines Type of Action: Amendment Date Issued: 9/26/11

File No.: 18 Licensee: St. Anthony Regional Medical Center Type of Action: Amendment Date Issued: 5/12/11

File No.: 19 Licensee: Northern Shared Medical Services, Inc Type of Action: Amendment Date Issued: 8/5/11

File No.: 20 Licensee: Midwest Industrial X-Ray, Inc Type of Action: Amendment Date Issued: 6/27/11

File No.: 21 Licensee: SSAB Iowa, Inc Type of Action: Renewal Date Issued: 7/22/10

File No.: 22 Licensee: Siouxland Regional Cancer Center Type of Action: Amendment Date Issued: 3/16/10

File No.: 23 Licensee: Mercy Medical Center Type of Action: Amendment Date Issued: 9/26/08

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

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

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

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

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

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

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 Iowa Final IMPEP Report Incident Casework Reviews

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

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

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

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

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

File No.: 12 Licensee: SSAB Iowa, Inc. Date of Incident: 5/17/12 Investigation Date: 7/12/12 License No.: 0344-1-29-MD NMED No.: 100502 Type of Incident: Contamination Type of Investigation: On-Site

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

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

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

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

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.

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ATTACHMENT

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