



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 11, 2017

Angela Leek, Chief
Bureau of Radiological Health
Department of Public Health
Lucas State Office Building, 5th Floor
321 East 12th Street
Des Moines, IA 50319

Dear Ms. Leek:

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 8 – 10, 2017. 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 the NRC's program.

The 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. 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 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 is scheduled for Tuesday, October 24, 2017, at 1:00 p.m. ET. The NRC will provide invitational travel for you or your designee to attend the MRB meeting at the NRC Headquarters in Rockville, Maryland. The 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.

A. Leek

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If you have any questions regarding the enclosed report, please contact me at 301-415-5804.

Thank you for your cooperation.

Sincerely,

/RA/

Paul Michalak, Chief
Agreement State Programs Branch
Division of Material Safety, State, Tribal, and
Rulemaking Programs
Office of Nuclear Material Safety and Safeguards

Enclosure:
2017 Draft IMPEP Report

SUBJECT: IOWA FY2017 DRAFT IMPEP REPORT

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

AUGUST 8 – 10, 2017

DRAFT 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 8 – 10, 2017, by a team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Kansas.

Based on the results of this review, Iowa's performance was found satisfactory for all indicators reviewed.

The team did not make any recommendations and there were no open recommendations from previous IMPEP reviews to close.

Accordingly, the team recommends that the Iowa Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. The team recommends that the next IMPEP review take place in approximately 5 years, with a periodic meeting in approximately 2.5 years.

1.0 INTRODUCTION

This report presents the results of the review of the Iowa Agreement State Program radioactive materials safety program. The review was conducted during the period of August 8 – 10, 2017, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Kansas. 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 (MD 5.6), “Integrated Materials Performance Evaluation Program (IMPEP),” dated February 26, 2004. Preliminary results of the review, which covered the period of August 11, 2012 to August 10, 2017, were discussed with Iowa managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to Iowa on March 16, 2017. Iowa provided its response to the questionnaire on July 13, 2017. A copy of the questionnaire response is available in the NRC’s Agencywide Documents Access and Management System (ADAMS) using Accession Number ML17195A280.

The Iowa Agreement State Program is administered by the Bureau of Radiological Health (the Bureau) which is located within the Division of Acute Disease Prevention, Emergency Response, and Environmental Health (the Division). The Division is part of the Department of Public Health (the Department). Organization charts for Iowa are available in ADAMS (Accession Number ML17195A284).

At the time of the review, the Iowa Agreement State Program regulated 157 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.

The 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.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on August 10, 2012. The final report is available in ADAMS (Accession Number ML12310A146). The results of the review and the status of the recommendation(s) are as follows:

Technical Staffing and Training: Satisfactory
Recommendation: None

Status of Materials Inspection Program: Satisfactory
Recommendation: None

Technical Quality of Inspections: Satisfactory
Recommendation: None

Technical Quality of Licensing Actions: Satisfactory
Recommendation: None

Technical Quality of Incident and Allegation Activities: Satisfactory
Recommendation: None

Compatibility Requirements: Satisfactory
Recommendation: None

Overall finding: Adequate to protect public health and safety and compatible with the NRC's program

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

The ability to conduct effective licensing and inspection programs is largely dependent on having a sufficient number of experienced, knowledgeable, well-trained technical personnel. Under certain conditions, staff turnover could have an adverse effect on the implementation of these programs, and thus could affect public health and safety. Apparent trends in staffing must be explored. Review of staffing also requires a consideration and evaluation of the levels of training and qualification. The evaluation standard measures the overall quality of training available to, and taken by, materials program personnel.

a. Scope

The team used the guidance in State Agreements procedure SA-103, "Reviewing the Common Performance Indicator: Technical Staffing and Training," and evaluated Iowa's performance with respect to the following performance indicator objectives:

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Agreement State training and qualification program is equivalent to NRC Inspection Manual Chapter (IMC) 1248, "Formal Qualifications Program for Federal and State Material and Environmental Management Programs."
- Qualification criteria for new technical staff are established and are being followed or qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing of the licensing and inspection programs.
- Management is committed to training and staff qualification.
- Individuals performing materials licensing and inspection activities are adequately qualified and trained to perform their duties.

- License reviewers and inspectors are trained and qualified in a reasonable period of time.

b. Discussion

The Iowa Agreement State Program is composed of three staff members (plus the Bureau Chief) which equals 3.2 full-time equivalent (FTE) for the radioactive materials program including any vacancies in the program. Currently, there is one vacancy. During the review period two staff members left the program and two staff members were hired. One Health Physicist (HP) position was vacant from October 2015 to February 2016 and then was vacant again from June 2016 to present. Iowa has a training and qualification manual compatible with the NRC's IMC 1248.

At the time of the review, Iowa was working towards filling the vacant HP position. Due to the small size of the staff, it was noted that the Iowa program was vulnerable to significant impacts if a full complement of staffing was not maintained. However, the team noted that no performance issues were identified during the review even though the program was not fully staffed during much of the review period.

c. Evaluation

The team determined that during the review period the Iowa program met the performance indicator objectives listed in Section 3.1.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the 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

Periodic inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety practices. The frequency of inspections is specified in NRC IMC, Chapter 2800, "Materials Inspection Program" and is dependent on the amount and kind of material, the type of operation licensed, and the results of previous inspections. There must be a capability for maintaining and retrieving statistical data on the status of the inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated Iowa's performance with respect to the following performance indicator objectives:

- Initial inspections and inspections of Priority 1, 2, and 3 licensees are performed at the frequency prescribed in IMC 2800.

- Candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 1220, "Processing of NRC Form 241, Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters, and Inspection of Agreement State Licensees Operating Under 10 Code of Federal Regulations (CFR) 150.20."
- Deviations from inspection schedules are normally coordinated between technical staff and management.
- There is a plan to perform any overdue inspections and reschedule any missed or deferred inspections; or a basis has been established for not performing any overdue inspections or rescheduling any missed or deferred inspections.
- Inspection findings are communicated to licensees in a timely manner (30 calendar days, or 45 days for a team inspection, as specified in IMC 0610, "Nuclear Material Safety and Safeguards Inspection Reports").

b. Discussion

Iowa performed 172 Priority 1, 2, 3, and initial inspections during review period. None of these inspections were completed overdue. All initial inspections of new licenses were performed within 12 months of license issuance.

Iowa's inspection frequency is the same for many of the similar license types in IMC 2800. In addition, Iowa inspects other license types, such as academic broad scope, high dose rate remote afterloader, nuclear pharmacy, and medical diagnostic, on a more frequent basis than required by IMC 2800.

A sampling of 20 inspection reports indicated that all of the inspection findings were communicated to the licensees within Iowa's goal of 30 days after the inspection exit.

In four of the five years of the review period, Iowa performed greater than 20 percent of candidate reciprocity inspections. In 2016, due to reduced staffing resources and significant involvement in two nuclear reactor exercises, the State did not complete any reciprocity inspections. Of the eight reciprocity opportunities, only four were candidates with respect to IMC 1220. Each of the candidates had been inspected on previous occasions and the State was familiar with the companies.

c. Evaluation

The team determined that during the review period Iowa met the performance indicator objectives listed in Section 3.2.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the team recommends that Iowa's performance with respect to the indicator, Status of the Materials Inspection Program, be found satisfactory.

3.3 Technical Quality of Inspections

Inspections, both routine and reactive, provide assurance that licensee activities are carried out in a safe and secure manner. Accompaniments of inspectors performing

inspections, and the critical evaluation of inspection records, are used to assess the technical quality of an Agreement State's inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated Iowa's performance with respect to the following performance indicator objectives:

- Inspections of licensed activities focus on health, safety, and security.
- Inspection findings are well-founded and properly documented in reports.
- Management promptly reviews inspection results.
- Procedures are in place and used to help identify root causes and poor licensee performance.
- Inspections address previously identified open items and violations.
- Inspection findings lead to appropriate and prompt regulatory action.
- Supervisors, or senior staff as appropriate, conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.
- For programs with separate licensing and inspection staffs, procedures are established and followed to provide feedback information to license reviewers.
- For Agreement States, inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated 20 inspection reports as well as enforcement documentation. The team interviewed inspectors involved in materials inspections conducted during the review period. The casework reviewed included inspections conducted by the two current Iowa inspectors and one former inspector, and covered medical, industrial, commercial, academic, research, and service licenses. The team found that findings were well-founded and appropriately documented, and that inspection reports were complete and appropriately reviewed prior to sending close-out letters to the licensee or pursuing enforcement actions.

A team member accompanied two program inspectors in July 2017. The inspector accompaniments are identified in Appendix B. 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. The Bureau Chief accompanied each inspector as least once annually during the review period.

c. Evaluation

The team determined that during the review period Iowa met the performance indicator objectives listed in Section 3.3.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the 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 quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, as well as security. An assessment of licensing procedures, actual implementation of those procedures, and documentation of communications and associated actions between the Iowa licensing staff and regulated community is a significant indicator of the overall quality of the licensing program.

a. Scope

The team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated Iowa's performance with respect to the following performance indicator objectives:

- Licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Essential elements of license applications have been submitted and elements are consistent with current regulatory guidance (e.g., financial assurance, increased controls, pre-licensing guidance).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and can be inspected.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Applicable guidance documents are available to reviewers and are followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).
- Licensing practices for risk-significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (10 CFR Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

b. Discussion

During the review period, Iowa performed 469 radioactive materials licensing actions. The team evaluated 22 radioactive materials licensing actions. The licensing actions selected for review included three new applications, eight amendments, five renewals, two terminations, one bankruptcy, two decommissionings, and one financial assurance

action. The team evaluated casework which included the following license types and actions: broad scope, medical diagnostic and therapy, mobile medical, accelerator, commercial manufacturing and distribution, industrial radiography, research and development, academic, nuclear pharmacy, gauges, and self-shielded irradiators. The casework sample represented work from three license reviewers.

The team found that licensing actions were thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed. The licensing cases reviewed demonstrated that proper guidance was followed, and deficiency letters and license conditions were well supported by information contained in licensing files.

c. Evaluation

The team determined that during the review period Iowa met the performance indicator objectives listed in Section 3.4.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the 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

The quality, thoroughness, and timeliness of response to incidents and allegations of safety concerns can have a direct bearing on public health and safety. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal and external coordination, and investigative and followup actions, are a significant indicator of the overall quality of the incident response and allegation programs.

a. Scope

The team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated Iowa's performance with respect to the following performance indicator objectives:

- Incident response, investigation, and allegation procedures are in place and followed.
- Response actions are appropriate, well-coordinated, and timely.
- On-site responses are performed when incidents have potential health, safety, or security significance.
- Appropriate followup actions are taken to ensure prompt compliance by licensees.
- Followup inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the Nuclear Material Events Database.
- Allegations are investigated in a prompt, appropriate manner.

- Concerned individuals are notified of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

During the review period, nine incidents were reported to Iowa. The team evaluated 11 radioactive materials incidents which included three lost/stolen radioactive materials, three medical events, four damaged equipment, and one leaking source. Although two of the incidents evaluated by the team occurred prior to the review period, both of these incidents included action by the State during the review period and were thus evaluated as well. The State dispatched inspectors for onsite followup for three of the cases reviewed. The team found that inspectors properly evaluated each event, interviewed involved individuals, thoroughly documented their findings, and enforcement actions were taken where appropriate.

During the review period, three allegations were received by Iowa. The team evaluated all three allegations, including two allegations that the NRC referred to the State during the review period. The team found that the Program took prompt and appropriate action in response to the concerns raised. All of the allegations reviewed were appropriately closed, individuals were notified of the actions taken, when appropriate, and allegeders' identities were protected.

The team noted that although responses to incidents and allegations were appropriate, the State had only a narrative describing how the program responds to incidents and allegations as opposed to a documented procedure or procedures involving these actions. The team noted that procedures are especially important given the small number of staff in the program. During the review, the team member from Kansas provided the State with copies of the Kansas procedures for responding to incidents and allegations. Iowa took those procedures and used them to supplement its existing guidance. Program representatives also indicated they would be creating incident and allegation checklists and planned to provide those prior to the MRB meeting.

c. Evaluation

The team determined that during the review period, except for the lack of procedure issue that was resolved while the team was onsite, the State met the performance indicator objectives listed in Section 3.5.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the 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 (SS&D) Evaluation Program, (3) Low-Level Radioactive Waste Disposal (LLRW) Program, and (4) Uranium Recovery (UR) Program. The NRC's Agreement with Iowa does not

relinquish regulatory authority for SS&D evaluation, LLRW, or UR program; therefore, only the first non-common performance indicators applied to this review.

4.1 Compatibility Requirements

State statutes should authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health, safety, and security. The State must be authorized through its legal authority to license, inspect, and enforce legally binding requirements, such as regulations and licenses. NRC regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted in a time frame so that the effective date of the State requirement is not later than three years after the effective date of the NRC's final rule. Other program elements, as defined in Appendix A of State Agreements procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements," that have been designated as necessary for maintenance of an adequate and compatible program, should be adopted and implemented by an Agreement State within six months following NRC designation.

a. Scope

The team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," and evaluated Iowa's performance with respect to the following performance indicator objectives. A complete list of regulation amendments can be found on the NRC website at the following address: <https://scp.nrc.gov/regtoolbox.html>.

- The Agreement State program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of radioactive materials under the Atomic Energy Act, as amended.
- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were adopted no later than three years after the effective date of the NRC regulation.
- Other program elements, as defined in SA-200 that have been designated as necessary for maintenance of an adequate and compatible program, have been adopted and implemented within six months of NRC designation.
- The State statutes authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement.
- The State is authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses.
- Impact of sunset requirements, if any, on the State's regulations.

b. Discussion

Iowa became an Agreement State on January 1, 1986. The Iowa Agreement State Program's current effective statutory authority is contained in Chapters 17A, 136B, 136C, and 136D, of the Code of Iowa. The Department is designated as the State's

radiation control agency. No legislation affecting the radiation control program was passed during the review period.

The State's administrative rulemaking process takes approximately six months to one year from drafting to finalizing a rule. 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 team noted that the State's rules and regulations are not subject to "sunset" laws.

During the review period, Iowa submitted eight final regulation amendments, eight proposed regulation amendments, and no legally binding license conditions to the NRC for a compatibility review. No amendments were overdue for State adoption at the time of submission, and at the time of the review, no amendments were overdue.

c. Evaluation

The team determined that during the review period Iowa met the performance indicator objectives listed in Section 4.1.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the 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 to be satisfactory for all performance indicators reviewed. The team did not make any recommendations regarding program performance by the State and there were no recommendations from the 2012 IMPEP review to be addressed.

Accordingly, the 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 team recommends that the next full IMPEP review take place in approximately 5 years, with a periodic meeting in approximately 2.5 years.

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Inspection Accompaniments

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Bryan Parker, NRC Region III	Team Leader Technical Staffing and Training
James Lynch, NRC Region III	Technical Quality of Inspections Status of Materials Inspection Program Inspector Accompaniments
Judee Walden, Kansas	Technical Quality of Licensing Actions
Lance Rakovan, NRC, NMSS	Technical Quality of Incidents and Allegations Activities Compatibility Requirements

APPENDIX B

INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: 0133-1-77-11
License Type: Self-Shielded Irradiator	Priority: 5
Inspection Date: 7/11/17	Inspector: RD

Accompaniment No.: 2	License No.: 0339-1-57-HDR
License Type: High Dose Rate Remote Afterloader	Priority: 2
Inspection Date: 7/12/17	Inspector: SJ