

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

July 14, 2016

Nicole Alexander-Scott, Director Rhode Island Department of Health Three Capitol Hill Providence, RI 02908-5097

Dear Ms. Alexander-Scott:

On June 16, 2016, a Management Review Board (MRB), which consists of U.S. Nuclear Regulatory Commission (NRC) senior managers and an Organization of Agreement States liaison to the MRB, met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Rhode Island Agreement State Program. The MRB found the Rhode Island program adequate to protect public health and safety, but needs improvement, and compatible with the NRC's program.

Section 5.0, page 13, of the enclosed final report contains a summary of the IMPEP team's findings and recommendations. Based on the results of the current IMPEP review, the next full review of the Rhode Island Agreement State Program will take place in approximately four years, with a periodic meeting tentatively scheduled for March 2017. The MRB also determined that Rhode Island should remain in the monitoring process. Monitoring is an informal process that allows the NRC to maintain an increased level of communication with an Agreement State program, and is a useful tool in assessing program improvements.

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 by Patricia K. Holahan for/

Glenn M. Tracy
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, Compliance, Administration,
and Human Capital Programs
Office of the Executive Director for Operations

Enclosure: Rhode Island IMPEP Final Report

cc: See next page

Letter to Nicole Alexander-Scott from Glenn Tracy, Dated July 14, 2016

SUBJECT: RHODE ISLAND 2016 FINAL IMPEP REPORT

cc: Seema Dixit, Chief Center for Health Facilities and Regulations

Angela Leek, IA Organization of Agreement States Liaison to the MRB



INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
REVIEW OF THE RHODE ISLAND AGREEMENT STATE PROGRAM

MARCH 7 - 10, 2016

**FINAL REPORT** 

#### **EXECUTIVE SUMMARY**

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Rhode Island Agreement State Program. The review was conducted during the period of March 7–10, 2016, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Virginia. This IMPEP review was originally scheduled for October 2015; however, the Rhode Island Agreement State Program requested that its review be moved back due to a competing priority investigation being conducted with another agency.

Based on the results of this review. Rhode Island's performance was found satisfactory for four of the performance indicators reviewed: satisfactory, but needs improvement for the indicator. Technical Staffing and Training; and unsatisfactory for the performance indicator, Status of the Materials Inspection Program. The indicator Technical Quality of Inspections was improved from the 2011 review (from satisfactory, but needs improvement to satisfactory). The team determined that the Rhode Island Agreement State Program took actions to correct the issues identified during the 2011 review regarding performance of annual supervisory accompaniments, improving inspection documentation, and conducting initial and subsequent security inspections to verify licensee compliance with the regulations. The Technical Staffing and Training indicator declined from the 2011 IMPEP review (from satisfactory, to satisfactory, but needs improvement). The team determined that staff turnover affected the staffing balance for inspection and licensing, and vacancies were not filled promptly. While the team notes that the Rhode Island Agreement State Program was given approval to hire additional staff in March 2016, hiring actions were not expected to occur until May 2016 which was out of the period of this IMPEP review. The status of the indicator Materials Inspection Program remained unsatisfactory from the 2011 review due to overdue inspections. Poor inspection tracking and staff vacancies were the main contributors to the overdue inspections.

The review team did not make any recommendations and determined that one recommendation from the 2011 IMPEP review, regarding the performance of Priority 1, 2, and 3 inspections in accordance with the inspection priority stated in Inspection Manual Chapter 2800, "Materials Inspection Program" should remain open (Section 2.0). Upon its deliberations, the Management Review Board (MRB) issued two recommendations to Rhode Island. Both recommendations are attributed to the long standing staffing vacancies—one concerns the Program's documentation of its inspection and licensing activities, the second, concerns the timeliness of license renewals (Sections 3.1 and 3.4).

Accordingly, the review team recommended, and the MRB agreed, that the Rhode Island Agreement State Program is adequate to protect public health and safety, but needs improvement, and is 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 4 years. Additionally, the team recommended, and the MRB agreed, that the period of monitoring continue, and further that periodic meetings be held 1 year from this review with a second meeting approximately 18 months after the first periodic meeting in lieu of a followup IMPEP review for the two indicators found satisfactory, but needs improvement, and unsatisfactory.

#### 1.0 INTRODUCTION

This report presents the results of the review of the Rhode Island Agreement State Program's radioactive materials safety program. The review was conducted during the period of March 7–10, 2016, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Virginia. 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 October 29, 2011, to March 10, 2016, were discussed with Rhode Island 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 Rhode Island on December 24, 2015. Rhode Island provided its response to the questionnaire on March 25, 2016. A copy of the questionnaire response can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML16089A393.

A draft of this report was issued to Rhode Island on April 11, 2016, for factual comment. Rhode Island responded to the findings and conclusions of the review by letter dated May 10, 2016. A copy of Rhode Island's response can be found in ADAMS using the Accession Number ML16133A029. A Management Review Board (MRB), which consists of NRC senior managers and an Organization of Agreement States liaison to the MRB, met on June 16, 2016, to consider the proposed final report. The MRB found the Rhode Island Agreement State Program adequate to protect public health and safety, but needs improvement, and compatible with the NRC's program.

The Rhode Island Agreement State Program is administered by the Radiation Control Program (the Program) which is located within the Center for Health Facilities and Regulations (the Center). The Center is part of the Rhode Island Department of Health (the Department). Organization charts for the State can be found in ADAMS using the Accession Number ML16089A390.

At the time of the review, the Rhode Island Agreement State Program regulated 45 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 Rhode Island.

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 Rhode Island Agreement State Program's performance.

#### 2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on October 28, 2011. The final report is available in ADAMS (Accession Number ML120240375). The results of the 2011 review and the status of the recommendations are as follows:

Technical Staffing and Training: Satisfactory

## Recommendation (1):

The review team recommends that the State document its training and qualification program for license reviewers and inspectors, including the reimplementation, use, and update of licensing and inspection qualification cards for each staff member. (Section 3.1 of the 2011 IMPEP report)

#### Status:

The Program developed a new procedure "Rhode Island Department of Health Qualification Program for Radioactive Material's Inspectors and License Reviewers (March 2016)" which is compatible to the NRC's Inspection Manual Chapter (IMC) 1248 and has provided it to staff going through the qualification process. Additionally, the Program has updated inspector and license reviewer qualification cards (memos) to document what items each inspector/license reviewer is qualified to perform. The review team recommended, and the MRB agreed, that this recommendation be closed.

Status of Materials Inspection Program: Unsatisfactory

#### Recommendation (2):

The review team recommends that the State take appropriate measures to conduct Priority 1, 2, and 3 inspections and initial inspections in accordance with the inspection priority in IMC 2800. (Section 3.2 of the 2011 IMPEP report)

#### Status:

The Program conducted a total of 41 Priority 1, 2, and 3 and initial inspections during the current review period. Of those 41 inspections, 11 inspections were completed overdue. The review team calculated that the Program performed 27 percent of its inspections overdue during the review period. The review team determined that poor inspection tracking was a main contributor to the Program performing inspections overdue, along with the staffing vacancies. As discussed in Section 3.2 of this report, the review team recommended that the indicator Status of Materials Inspection Program be again found unsatisfactory. Accordingly, the review team recommended, and the MRB agreed, that this recommendation remain open.

Technical Quality of Inspections: Satisfactory, but needs improvement

## Recommendation (3):

The review team recommends that the State take measures to ensure that inspection records and narrative reports are documented in accordance with the Program's Inspection Manual. (Section 3.3 of the 2011 IMPEP report)

#### Status:

The review team's evaluation of the quality of inspection casework demonstrated that inspection records and narrative reports were documented in accordance with the Program's inspection manual. Inspection records and reports now include the focus areas examined, sufficient information to support cited violations, identification of non-cited violations, closed violations that were identified during the previous inspection, and succinct description of the scope of the program. The review team recommended, and the MRB agreed, that this recommendation be closed.

Note: The MRB acknowledged the improved quality of inspection documentation since the 2011 IMPEP review with the closure of this recommendation, but also noted some missing licensing and inspection documentation attributed to staffing vacancies. As discussed in Section 3.1 of this report, the MRB recommended that the Program management take measures to ensure proper documentation of inspection tracking dates and ensure the Program's licensing and inspection files are complete.

#### Recommendation (4):

The review team recommends that a Program supervisor or other appropriately qualified senior staff member accompany each inspector, at least annually, to ensure quality and consistency in the inspection program. (Section 3.3 of the 2011 IMPEP report)

#### Status:

The review team determined that the Program supervisor or designated senior staff member performed an accompaniment of each inspector, at least annually, for each year of the review period. The review team recommended, and the MRB agreed, that this recommendation be closed.

#### Recommendation (5):

The review team recommends that the State conduct initial and subsequent security related inspections in a manner that provides for verification of licensee compliance with the requirements. (Section 3.3 of the 2011 IMPEP report)

#### Status:

The review team determined through observations of inspector performance and examination of inspection casework that the State conducted initial and subsequent security related inspections which verified licensee compliance with the requirements. The review team recommended, and the MRB agreed, that this recommendation be closed.

Technical Quality of Licensing Actions: Satisfactory

Recommendation: None

Technical Quality of Incident and Allegation Activities: Satisfactory

Recommendation: None

Compatibility: Satisfactory, but needs improvement

#### Recommendation (6):

The review team recommends that the State adopt all currently overdue regulations required for compatibility and adopt future regulation amendments within their required 3-year time frame. (Section 4.1 of the 2011 IMPEP report)

#### Status:

The Program has adopted all regulations that are currently due for purposes of compatibility. At the time of the review, there were no regulation amendments overdue for adoption. Additionally, the Program adopted all regulation changes that were required to be adopted during the review period within the required 3-year time frame. The review team recommended, and the MRB agreed, that this recommendation be closed.

Overall finding from 2011: Adequate to protect public health and safety, but needs improvement, and compatible with the NRC's program. Implement a period of monitoring.

#### 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>

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 review team used the guidance in State Agreements procedure SA-103, "Reviewing the Common Performance Indicator: Technical Staffing and Training," and evaluated Rhode Island'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 the NRC IMC 1248, "Formal Qualifications Program for Federal and State Materials and Environmental Management Programs."
- Qualification criteria for new technical staff are established and are being followed or that 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 Program is composed of five technical staff members and a program manager who are all partially allocated to support the Program. The total effort allocated by all six employees is approximately three full-time equivalents for the radioactive materials

program. These numbers include the two technical staff vacancies present in the program at the time of the review. During the review period, one of the staff members left the program and one staff member was hired. The two open positions have been vacant since September of 2012 and July of 2013, respectively. The Program has a training and qualification manual compatible with the NRC's IMC 1248. Staff going through the qualification process have been assigned the Program's training and qualification journal to complete. Qualification cards for qualified staff have been updated and the Program is tracking refresher training for qualified staff.

#### c. <u>Evaluation</u>

The team determined that during the review period Rhode Island did not fully meet the performance indicator objectives listed in Section 3.1.a. The staff vacancies have resulted in a backlog of licensing renewal actions, poor tracking of inspection due dates leading to 27 percent of inspections being performed overdue during the review period, and missing documentation in the Program's licensing and inspection files. A letter of support dated January 14, 2016, was sent to the Governor of Rhode Island. This letter stressed the importance of addressing staffing vacancies to ensure the long term success and viability of the Program. The Rhode Island Department of Health management responded to the NRC in a letter dated February 1, 2016. The response letter described the State's path forward to address the staffing vacancies. On March 3, 2016, Rhode Island posted two positions that will directly support the Program: one technical staff position and the other a licensing aide. The Program filled these vacancies on May 29, 2016, and June 12, 2016, respectively.

The review team identified several instances of missing licensing and inspection documents as well as errors in the inspection tracking system which were determined to be attributed to the long standing staffing vacancies. The MRB recommended that the Program management take measures to ensure proper documentation of inspection tracking dates and ensure the Program's licensing and inspection files are complete.

#### d. Results

The review team considered the criteria in MD 5.6 and concluded that because (1) some staff turnover could adversely affect the program, (2) some vacant positions were not readily filled during the review period, and (3) there was some evidence of a lack of management attention or actions to deal with staffing problems, a rating of satisfactory, but needs improvement should be recommended for this indicator.

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Rhode Island's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory, but needs improvement.

# 3.2 Status of the 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 IMC 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 review team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated Rhode Island'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 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

The Program's inspection frequency is the same for similar license types in IMC 2800. The Program performed 41 Priority 1, 2, 3, and initial inspections during the review period. Rhode Island conducted 27 percent of Priority 1, 2, 3, and initial inspections overdue. Eleven of 37 Priority 1, 2, and 3 inspections were conducted overdue during the review period. The four initial inspections of new licenses were performed within 12 months of license issuance.

In 3 of the 4 years of the review period, the Program performed greater than 20 percent of candidate reciprocity inspections. The Program could not find any records of reciprocity inspections conducted in calendar year 2014. Additionally, poor tracking of reciprocity inspections contributed to the Program being unable to produce any measureable data for the 2014 calendar year.

#### c. Evaluation

The team determined that during the review period Rhode Island did not meet all of the performance indicator objectives listed in Section 3.2.a. Specifically, Rhode Island inspected 27 percent of Priority 1, 2, and 3 inspections overdue during the review period. According to MD 5.6, the threshold for an unsatisfactory performance of this indicator is more than 25 percent of higher priority licensees are inspected at intervals that exceed the tolerance allotted for the inspection interval. Additionally, the Program could not produce any documentation to support completing reciprocity inspections in calendar year 2014. Therefore, Rhode Island did not meet the criteria of inspecting greater than 20 percent of candidate licensees for reciprocity.

#### d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Rhode Island's performance with respect to the indicator, Status of the Materials Inspection Program, be found unsatisfactory.

# 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 a program's inspection capability.

#### a. Scope

The review team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated Rhode Island'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 conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.
- For programs with separate licensing and inspection staffs, to verify that procedures are established and followed to provide feedback information to license reviewers.
- For Agreement States, to determine if inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

# b. <u>Discussion</u>

The review team evaluated the inspection reports, enforcement documentation, and interviewed inspectors for 13 materials inspections conducted during the review period. The casework reviewed included inspections conducted by both of Rhode Island's inspectors and covered medical, industrial, commercial, academic, research, blood irradiators, and medical and academic broadscope licensees.

A review team member accompanied the two program inspectors on February 18 and 19, 2016. The inspector accompaniments are identified in Appendix B.

Supervisory accompaniments were conducted annually for all inspectors by the Program Supervisor or senior staff member.

#### c. Evaluation

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

## d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Rhode Island'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, and security. An assessment of licensing procedures, actual implementation of these procedures, and documentation of communications and associated actions between the Rhode Island licensing staff and regulated community will be a significant indicator of the overall quality of the program.

#### a. Scope

The review team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated Rhode Island'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 meet 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 are inspectable.
- 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 (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled and secured.

## b. <u>Discussion</u>

The review team evaluated 15 radioactive materials licensing actions. The licensing actions selected for review included three new applications, eight amendments, three renewals, and one termination. The review team evaluated casework which included the

following license types and actions: medical broad scope, medical diagnostic, medical therapy, industrial radiography, research and development, academic broad scope, gauges, stereotactic radiosurgery, and decommissioning actions. The team verified that no Rhode Island licensees were subject to financial assurance requirements. The casework sample represented work from two license reviewers. The team determined that all licensing actions were of high quality using a thorough, concise, and easily understood process prior to issuing any licensing action, no matter how minor or complex.

The team noted that the Program has 13 overdue renewals, ranging from 1 month to 14 years overdue. Interviews with the staff confirmed that these renewals were evaluated for any health and safety concerns upon receipt. Further, contact with the licensees is maintained on an annual basis, and confirmation of the applicability of the material submitted would be acquired from the licensees prior to completing the renewal requests to ensure the information is current.

Given that 28 percent of the licenses are under timely renewal ranging from several months to 14 years, and the Program attributes the backlog to staffing vacancies, the MRB recommended that Program management develop and implement an action plan to reduce the licensing renewal backlog.

Interviews with license reviewers revealed a performance-based application of the Pre-Licensing guidance; however, documentation was not completed in some cases, and for cases in which the reviewer completed a checklist, it could not be located to record this use. The team discussed the need to record and retain this document. The team also noted that some documents and files containing sensitive information were not marked as such and were not secured. The team brought this to the attention of the Program. The Program took immediate action to correct this by labeling all applicable documents and folders, and securing them in a locked cabinet.

#### c. Evaluation

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

# d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Rhode Island'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 follow-up procedures and actions will be a significant indicator of the overall quality of the program.

#### a. Scope

The review team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated Rhode Island'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 follow-up actions are taken to ensure prompt compliance by licensees.
- Follow-up 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 the 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, three radioactive materials incidents were reported to Rhode Island. The review team evaluated all three incidents which included two lost/stolen radioactive materials, and one medical event (Y-90 microspheres underdose). Rhode Island dispatched inspectors for onsite followup for one of the cases reviewed. The review team evaluated the Program's analyses and followup actions for each event, and determined that they were adequate for the type of event.

There was one allegation reported to the Program from the NRC during the review period; however, the Program determined after speaking with the concerned individual, that the concern was not related to licensed activities. The review team agreed with the Program's assessment.

#### c. Evaluation

The team determined that during the review period Rhode Island met the performance indicator objectives listed in Section 3.5.a.

#### d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Rhode Island'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 (SS&D) Program, (3) Low-Level Radioactive Waste Disposal (LLRW) Program, and (4) Uranium Recovery Program. The NRC's Agreement with Rhode Island does not relinquish regulatory authority for a SS&D or uranium recovery program; therefore, only the first and third non-common performance indicators applied to this review.

# 4.1 <u>Compatibility Requirements</u>

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. The 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 3 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 6 months following NRC designation.

#### a. Scope

The review team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," and evaluated Rhode Island'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: <a href="https://scp.nrc.gov/rss">https://scp.nrc.gov/rss</a> regamendents.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 3 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 6 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

Rhode Island became an Agreement State on January 1, 1980. The Rhode Island Agreement State Program's current effective statutory authority is contained in Section 23-1.3 – Radiation Control, of the Rhode Island Statutes. 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 12-18 months from drafting to finalizing a rule. The public, the 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 and approved. The review team noted that the State's rules and regulations are subject to "sunset" laws and need to be administratively refiled every 5 years. The next administrative refiling for the Program will take place in 2017.

During the review period, Rhode Island submitted 17 final regulation amendments and one legally binding license condition to the NRC for a compatibility review. Eight of the amendments were overdue for State adoption at the time of submission. These eight amendments were identified as overdue at the time of the 2011 IMPEP review (see Section 2.0 for the recommendation made during the 2011 IMPEP review). In order to address the previous recommendation the Program adopted final regulations for those eight overdue amendments in addition to amendments that were due to be adopted during the review period. At the time of this review, no amendments were overdue. However, there are outstanding compatibility comments on final regulations that the Program is in the process of addressing. The Program expects those changes to be promulgated in final by the summer of 2017.

#### c. Evaluation

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

#### d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Rhode Island's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

# 4.2 Low-Level Radioactive Waste Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by states Through Agreement," to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although Rhode Island has such authority to regulate a LLRW disposal facility, the NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the

need to regulate a LLRW disposal facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatible LLRW program. There are no plans for a commercial LLRW disposal facility in Rhode Island. Accordingly, the team did not review this indicator.

#### 5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Rhode Island's performance was found satisfactory for four performance indicators reviewed, satisfactory, but needs improvement for the indicator, Technical Staffing and Training, and unsatisfactory for the performance indicator, Status of the Materials Inspection Program. The review team did not make any recommendations and determined that the recommendations from the 2011 IMPEP review can be closed with the exception of the recommendation regarding Status of the Materials Inspection Program which should remain open. The MRB issued two recommendations to the Program both attributed to the long standing staffing vacancies—one concerning the Program's documentation of its inspection and licensing activities, the second concerning the timeliness of license renewals.

Accordingly, the review team recommended, and the MRB agreed, that the Rhode Island Agreement State Program be found adequate to protect public health and safety, but needs improvement, 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 4 years. In lieu of a followup IMPEP review for the two indicators found satisfactory, but needs improvement, and unsatisfactory, the review team recommended, and the MRB agreed, that a periodic meeting be held 1 year from this review with a second meeting approximately 18 months after the first periodic meeting. Additionally, the review team recommended and the MRB agreed, that Rhode Island remain on monitoring.

Below are the recommendations, as mentioned in the report, for evaluation and implementation by the State:

#### RECOMMENDATIONS:

- The review team recommends that the State take appropriate measures to conduct Priority 1, 2, and 3 inspections and initial inspections in accordance with the inspection priority in IMC 2800. This recommendation remains open from the 2011 IMPEP review. (Section 2.0 and 3.2)
- 2. The MRB recommends that the Program management take measures to ensure proper documentation of inspection tracking dates and ensure the Program's licensing and inspection files are complete. (Section 3.1)
- 3. The MRB recommends that Program management develop and implement an action plan to reduce the licensing renewal backlog. (Section 3.4)

# LIST OF APPENDICES

Appendix A IMPEP Review Team Members

Appendix B Inspection Accompaniments

# APPENDIX A

# IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Michelle Beardsley, NMSS	Team Leader Technical Quality of Inspections Technical Quality of Incident and Allegation Activities Inspector Accompaniments
Monica Ford, Region I	Technical Staffing and Training Status of the Materials Inspection Program Compatibility Requirements
Beth Schilke, Virginia	Technical Quality of Licensing Actions

# APPENDIX B

# INSPECTION ACCOMPANIMENTS

The following inspection accompaniments were performed prior to the onsite IMPEP review:

Accompaniment No.: 1	License No.:
License Type: Nuclear Pharmacy	Priority: 2
Inspection Date: 02/18/16	Inspector: DK
Accompaniment No.: 2	License No.:
License Type: Industrial Radiography	Priority: 1
Inspection Date: 02/19/16	Inspector: CW