



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

July 20, 2015

Kenneth Albert RN, Esq., Director
Maine Center for Disease Control
and Prevention
286 Water Street
11 State House Station
Augusta, ME 04333-0011

Dear Mr. Albert:

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 Maine on June 16–19, 2015. The review team's preliminary findings were discussed with your staff on the last day of the review. The review team's proposed recommendations are that the Maine 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 Management Review Board meeting is scheduled for Tuesday, September 1, 2015 at 1:00 p.m. EST. 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.

K. Albert

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If you have any questions regarding the enclosed report, please contact me at 301-415-5422.

Thank you for your cooperation.

Sincerely,

/RA Stephen Poy for/

Christian E. Einberg, Branch Chief
Agreement State Programs Branch
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
ME 2015 Draft IMPEP Report

cc: Jay Hyland, Manager
Division of Environmental Health

Mr. Albert

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ME 2015 Draft IMPEP Report

cc: Jay Hyland, Manager
Division of Environmental Health

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

June 16–19, 2015

DRAFT REPORT

Enclosure

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Maine Agreement State Program. The review was conducted during the period of June 16–19, 2015, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of New Jersey.

Based on the results of this review, Maine's performance was found satisfactory for all performance indicators reviewed. The review team did not make any new recommendations and determined that two recommendations from the 2011 IMPEP review, regarding addressing staffing vacancies and performing annual inspector accompaniments, should be closed. The review team determined that one recommendation from the 2011 IMPEP review, regarding expediting action to complete the promulgation of overdue regulations, should remain open.

Accordingly, the review team recommends that the Maine Agreement State Program is adequate to protect public health and safety and is compatible with the NRC's program. The review team recommends that the next IMPEP review take place in approximately 4 years and that a periodic meeting be held in 2 years.

1.0 INTRODUCTION

This report presents the results of the review of the Maine Agreement State Program radioactive materials safety program. The review was conducted during the period of June 16-19, 2015, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of New Jersey. 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 May 7, 2011, to June 19, 2015, were discussed with Maine 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 the State on November 7, 2014. The State provided its response to the questionnaire on June 1, 2015. A copy of the questionnaire response can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML15153A007.

The Maine Agreement State Program (the Program) is administered by the Radiation Control Program which is part of the Division of Environmental Health. Organization charts for the State can be found using the Accession Number ML15153A010.

At the time of the review, the Program regulated 108 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 Maine.

The review team evaluated the information gathered against the established criteria for each common and the applicable non-common performance indicators and made a preliminary assessment of the Maine Agreement State Program's performance.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on May 6, 2011. The final report is available in ADAMS using Accession Number ML112140281. The results of the review and the status of the recommendations are as follows:

Technical Staffing and Training: Satisfactory but Needs Improvement

Recommendation: The review team recommends that the State develop and implement a strategy to address current and future staffing vacancies in order to maintain the effectiveness and efficiency of the Program. (Section 3.1 of the 2011 IMPEP report)

Status: The goal of the Program is to maintain two technical staff to support the activities in the radioactive materials program. The program manager recognizes that, if the Program were to lose one or both technical staff members in the future, work needing to

be done to protect public health and safety could be severely impacted. The program manager created a staff development plan to cross train additional radiation control program staff to help support licensing and inspection activities should a future vacancy arise. The Program is in the process of cross training one individual from the radon program. Based on the above information, the review team determined that by hiring staff to fill the vacant positions and by cross training an additional staff member to address future staffing vacancies, the Program has adequately addressed this recommendation. The review team recommends that this recommendation be closed.

Status of Materials Inspection Program: Satisfactory

Recommendation: None

Technical Quality of Inspections: Satisfactory

Recommendation: The review team recommends that annual supervisor accompaniments be performed for each radioactive materials staff member to ensure quality and consistency within the program. (Section 3.3 of the 2011 IMPEP report)

Status: The two technical staff who conduct radioactive materials inspections became qualified materials inspectors in 2013. The program manager performed annual supervisory accompaniments for these inspectors in 2013 and 2014 and has completed one supervisory accompaniment in 2015. The review team recommends that this recommendation be closed.

Technical Quality of Licensing Actions: Satisfactory

Recommendation: None

Technical Quality of Incident and Allegation Activities: Satisfactory

Recommendation: None

Compatibility Requirements: Satisfactory

Recommendation: The review team recommends that the State expedite action to address the comments identified in NRC letters dated August 31, 2006, and June 18, 2010, to promulgate and complete changes to the State regulations.

Status: The Program originally drafted regulations in the summer of 2014 to address the outstanding comments. This package got delayed due to changes to x-ray regulations also included in the rulemaking. To avoid further delays, the program manager decided in June 2015 to remove the changes to the radioactive material regulations from the original package and start the adoption process again. The program manager expects the package containing the changes to the radioactive materials regulations to be finalized in approximately 120 days. The review team determined that since the Program has not yet adopted final regulations addressing comments made by the NRC in August 2006 and June 2010, the Program has not adequately addressed the

recommendation. Therefore, the review team recommends that this recommendation remain open.

Sealed Source and Device Evaluation Program: Satisfactory

Recommendation: None

Overall finding: Adequate and Compatible

Since the 2011 IMPEP review, two periodic meetings were held with the Program to discuss the status of the State's radioactive materials program and the State's actions to address the recommendations made by the 2011 IMPEP review team. During the June 2013 periodic meeting, the program manager described several issues that the Program had been dealing with since the one experienced technical staff member retired, notably a significant number of overdue higher priority inspections, supervisor accompaniments on inspections not being performed, and staff being considered qualified without having had a supervisory field observation of their inspection skills. Based on these issues, the MRB directed that the Program be placed on monitoring and submit a program improvement plan, quarterly calls be conducted between the NRC and the Program to discuss progress being made to address the issues identified during the periodic meeting, and that a periodic meeting be held in 1 year.

During the June 2014 periodic meeting, the Program reported improved performance in the materials program. Both new technical staff members had become fully qualified materials inspectors and license reviewers. In addition, the Program had caught up on all overdue inspections and had no inspections overdue at the time of the meeting. Based on the progress made by the Program since the previous periodic meeting, the MRB directed that the period of monitoring be discontinued.

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 review team used the guidance in State Agreements procedure SA-103, "Reviewing the Common Performance Indicator: Technical Staffing and Training," and evaluated Maine'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 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 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 two staff members and a program manager which equals 2.4 FTE for the radioactive materials program. Currently, there are no vacancies. At the start of the review period the Program had one vacant staff position and lost an additional staff person to retirement in September 2012. This equated to one hundred percent staff turnover since the previous IMPEP review. During the current review period one staff member was hired in June 2012 and one staff member was transferred into the program from the low level waste program in November 2012.

The Program has a training and qualification manual that is not compatible to NRC's IMC 1248; however, the Program has not had any staff go through the qualification process since the NRC issued the revised IMC 1248 in April 2013, making it due for Agreement State adoption by October 2013. Both technical staff members were considered fully qualified license reviewers and inspectors in the fall of 2013. The program manager committed to revising the Program's license reviewer and inspector qualification procedure to make it compatible to IMC 1248.

c. Evaluation

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

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that Maine's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

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 NRC 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 Maine'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 NRC 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 38 priority 1, 2, and 3 and initial inspections during the review period. The Program conducted 50 percent of Priority 1, 2, 3, and initial inspections overdue. Thirteen of 33 priority 1, 2, or 3, and 4 of 5 initial inspections were conducted overdue.

A sampling of 35 inspection reports indicated that seven of the inspection findings were communicated to the licensees beyond the Program's goal of 30 days after the inspection exit. Five of the seven reports contained violations which needed additional handling time.

The Program met the criteria of inspecting 20 percent of candidate licensees for reciprocity in 2 of the 4 years of the review period. The Program performed no reciprocity inspections in 2011 and 2012, 27 percent of reciprocity inspections in 2013, and 26 percent of reciprocity inspections in 2014.

c. Evaluation

The review team determined that during the review period Maine did not meet all of the performance indicator objectives listed in Section 3.2.a. Specifically, the Program did not perform high priority and initial inspections at the frequency prescribed in IMC 2800. The Program also did not inspect candidate licensees working under reciprocity in accordance with IMC 1220. The Program's difficulties with timely performance of high priority and initial inspections and with performance of reciprocity inspections were a result of the staff turnover which occurred in the first half of the review period. The Program manager made a decision to allow inspections to go overdue and to forego reciprocity inspections until the new technical staff was fully qualified. This was identified during the June 2013 periodic meeting and subsequently, Maine was placed on monitoring at the special MRB which was held on July 9, 2013. A follow-up periodic meeting was held with the Program on June 3, 2014. By the time of the follow-up periodic meeting the Program had caught up on all its overdue inspections and was again performing reciprocity inspections. Based on the Program's progress, Maine was removed from monitoring during the special MRB held on September 23, 2014. The review team noted that since June 2014, the State performed no overdue inspections.

d. Results

Per the IMPEP evaluation criteria listed in MD 5.6, the review team recognized that Maine's performance for this indicator met the criteria for an unsatisfactory rating. However, the review team determined that the inspection backlog was a purposeful decision on the part of the program manager due to staff turnover and occurred early in the review period. Once the new technical staff was fully qualified, the Program fully addressed the overdue inspections, started performing reciprocity inspections, and took effective corrective action to ensure that no further inspections were performed overdue throughout the remainder of the review period. The review team also acknowledged that Maine had been placed on monitoring during the review period because of this issue and was subsequently removed from monitoring when the MRB determined the Program had adequately addressed it. Based on the Program's performance throughout the review period, the review team recommends that Maine'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 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 Maine'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. Discussion

The review team evaluated the inspection reports and enforcement documentation, and interviewed inspectors for 14 materials inspections conducted during the review period. The casework reviewed included inspections conducted by four of the Program's inspectors, including the program manager, and covered medical, industrial, commercial, academic, research, and nuclear pharmacy licenses.

A review team member accompanied two program inspectors on May 12–13, 2015. The inspector accompaniments are identified in Appendix B. During the inspection accompaniment at the industrial radiography site, the inspector did not have a copy of the National Source Tracking System (NSTS) source inventory for the security portion of the inspection. The inspector did not have access to NSTS at the time of the inspection and did not obtain a copy of the inventory from the program manager, who had access to NSTS, prior to the inspection. Since this inspection, both inspectors now have access to NSTS and bring a copy of the NSTS source inventory while conducting security inspections.

The supervisory accompaniment for the one fully qualified materials inspector was not conducted during 2012 due to the retirement of the inspector. The two staff members brought into the Program in 2012 were not qualified inspectors until 2013 and therefore did not need to be accompanied in 2012. The program manager performed supervisory accompaniments for both of these inspectors in 2013 and 2014. One supervisory accompaniment has been completed in 2015.

c. Evaluation

The team determined that during the review period Maine 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 recommends that Maine'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 State 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 Maine'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. Discussion

During the review period, the Program performed 246 radioactive materials licensing actions. The review team evaluated 16 radioactive materials licensing actions, including 4 new applications, 7 amendments, 2 renewals, and 3 terminations. The casework sample represented work from three current and former license reviewers. The review team evaluated casework which included the following license types and actions: broad scope, medical diagnostic and therapy, commercial manufacturing and distribution, industrial radiography, research and development, academic, nuclear pharmacy, gauges, self-shielded irradiators, service providers, financial assurance, and terminations.

c. Evaluation

The team determined that during the review period Maine 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 recommends that Maine'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 Maine'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 NRC.
- Incidents are reported to the Nuclear Material Events Database (NMED).
- 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, five incidents were reported to the Program which in turn the Program reported to NMED. The review team evaluated all five radioactive materials incidents which included two lost/stolen radioactive materials events, one medical event, and two damaged equipment events. Although the Program did not dispatch inspectors for onsite follow-up to these events, the Program conducted timely follow up communications with each of the licensees to review each event and determine if the licensee's corrective actions were appropriate for the type of event. In addition, the Program held management meetings with two of the licensees, including the medical licensee, to ensure health and safety issues were promptly addressed and actions taken to prevent recurrence were initiated by the licensees. None of the events involved potentially significant health, safety or security concerns.

No allegations were received by Maine during the review period. The NRC did not refer any allegations to the State during the review period.

c. Evaluation

The team determined that during the review period Maine 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 recommends that Maine'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. The NRC's Agreement with Maine does not relinquish regulatory authority for low level radioactive waste disposal or uranium recovery; therefore, only the first two 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 3 years after the effective date of 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 Maine's performance with respect to the following performance indicator objectives. A complete list of regulation amendments can be found on the NRC Web site at the following address: https://scp.nrc.gov/rss_regamendments.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

Maine became an Agreement State on April 1, 1992. The Program's current effective statutory authority is contained in Title 22 "Health and Welfare," Chapter 160 "Radiation Protection Act", of the Maine Statutes. The Department of Health and Human Services

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 from drafting to finalizing a rule. 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. The review team noted that the State's rules and regulations are not subject to "sunset" laws.

During the review period, the Program submitted three final regulation amendments to the NRC for a compatibility review. Two of the amendments were overdue for State adoption at the time of submission. At the time of this review, no amendments were overdue for adoption.

c. Evaluation

The team determined that during the review period Maine met the performance indicator objectives listed in Section 3.4.1.a. As mentioned in Section 2.0, the review team recommends that the recommendation from the 2011 IMPEP review remain open. Maine has not yet addressed the outstanding comments from the NRC letters dated August 31, 2006 and June 18, 2010.

Recommendation: The review team recommends that the State expedite action to address the comments identified in the NRC letters dated August 31, 2006 and June 18, 2010, to promulgate and complete changes to the State regulations. (open from 2011 IMPEP review)

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that Maine's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

4.2 Sealed Source and Device (SS&D) Evaluation Program

Adequate technical evaluations of SS&D designs are essential to ensure that SS&Ds will maintain their integrity and that the design is adequate to protect public health and safety. NUREG-1556, Volume 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," provides information on conducting SS&D reviews and establishes useful guidance for review teams. Three sub-elements, technical staffing and training, technical quality of the product evaluation program, and evaluation of defects and incidents regarding SS&D's, are evaluated to determine if the SS&D program is satisfactory. Agreement States with authority for SS&D evaluation programs who are not performing SS&D reviews are required to commit in writing to having an SS&D evaluation program in place before performing evaluations.

a. Scope

The review team used the guidance in State Agreements procedure SA-108, "Reviewing the Non-Common Performance Indicator: Sealed Source and Device Evaluation Program," and evaluated Maine's performance with respect to the following performance indicator objectives:

Technical Staffing and Training

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- 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 are filled in a timely manner.
- Management is committed to training and staff qualification.
- Individuals performing SS&D evaluation activities are adequately qualified and trained to perform their duties.
- SS&D reviewers are trained and qualified in a reasonable period of time.

Technical Quality of the Product Evaluation Program

- SS&D evaluations are adequate, accurate, complete, clear, specific, and consistent with NUREG 1556, Volume 3.

Evaluation of Defects and Incidents

- SS&D incidents are reviewed to detect possible manufacturing defects and the root causes of these incidents.
- Incidents are evaluated to determine if other products may be affected by similar problems. Appropriate action and notifications to NRC, Agreement States, and others, as appropriate, should occur in a timely manner.

b. Discussion

Technical Staffing and Training

During the review period, the Program did not have any staff qualified to perform SS&D reviews; therefore, the program manager utilized a qualified SS&D reviewer in the Commonwealth of Massachusetts to perform the SS&D reviews. According to the Program manager, the New England States participate in the New England Radiological Health Compact (NERHC) so the Program is able to utilize expertise in another State in the NERHC to help perform the SS&D technical review. The review team confirmed that the Massachusetts SS&D reviewer is qualified to perform SS&D reviews for the Commonwealth of Massachusetts.

The Program has a training and qualification manual that is not compatible with NRC's IMC 1248, Appendix D; however, the Program has not had any staff go through the

qualification process since the NRC issued the revised IMC in April 2013, making it due for Agreement State adoption by October 2013. The Program manager committed to revising the Program's procedure to make it compatible to IMC 1248, Appendix D, before qualifying staff for SS&D reviews.

Technical Quality of the Product Evaluation

At the time of the 2011 IMPEP review, Maine had no manufacturers of SS&Ds in the State and no SS&D certificates had been issued by the Program during the review period. Accordingly, the 2011 IMPEP team did not review this indicator. Since the 2011 IMPEP review, the State received one new SS&D application from a manufacturer.

Maine currently has one SS&D licensee with one active SS&D certificate which was issued in November 2013. Two SS&D actions were issued during the review period. The review team evaluated both of these SS&D actions, one new application and one amendment. Based on the information reviewed, the review team determined that the technical evaluation of the application was comprehensive and of good quality and was performed by a qualified SS&D reviewer in the Commonwealth of Massachusetts on behalf of the Maine program. The IMPEP team suggested to the program manager that the the Program should add a Reviewer's Note to the certificate indicating that the review and evaluation was performed by the Commonwealth of Massachusetts on behalf of Maine.

Evaluation of Defects and Incidents Regarding SS&Ds

No incidents involving SS&D registered products were reported to the State during the review period.

c. Evaluation

The team determined that during the review period Maine met the performance indicator objectives listed in Section 4.2.a. with the exception of having a qualified SS&D reviewer in the Program to perform the technical review. The program manager enlisted the use of a qualified SS&D reviewer from the Commonwealth of Massachusetts to perform the technical review. The program manager plans to continue to utilize qualified SS&D reviewers from other Agreement States until the Program can qualify technical staff to perform the reviews in house.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that Maine's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Maine's performance was found satisfactory for all seven performance indicators reviewed. The review team did not make any new

recommendations regarding program performance by the State and determined that two recommendations from the 2011 IMPEP review should be closed and one recommendation should be kept open.

Accordingly, the review team recommends that the Maine Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. Based on the results of the current IMPEP review, the review team recommends that the next full IMPEP review take place in approximately four years.

Below is the review team's recommendation, as mentioned in the report, for evaluation and implementation by Maine:

The review team recommends that the State expedite action to address the comments identified in the NRC letters dated August 31, 2006 and June 18, 2010, to promulgate and complete changes to the State regulations. (open from 2011 IMPEP review)

LIST OF APPENDICES

Appendix A IMPEP Review Team Members

Appendix B Inspection Accompaniments

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Donna Janda, Region 1	Team Leader Technical Quality of Inspections Technical Quality of Incident and Allegation Activities
Monica Ford, Region I	Technical Staffing and Training Status of Materials Inspection Program Compatibility Requirements
James Lynch, Region III	Inspector Accompaniments
Lymari Sepulveda, NMSS	Sealed Source & Device Evaluation Program
Nancy Stanley, New Jersey	Technical Quality of Licensing Actions

APPENDIX B

INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: 23209
License Type: Industrial Radiography	Priority: 1
Inspection Date: 05/12/15	Inspector: TH

Accompaniment No.: 2	License No.: 19301
License Type: HDR and PET	Priority: 2
Inspection Date: 05/13/15	Inspector: JG