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

October 31, 2019

Nirav C. Shah, M.D., MPH, Director
Maine Center for Disease
and Prevention
286 Water Street
11 State House Station
Augusta, ME 04333-0011

Dear Dr. Shah:

On October 10, 2019, the Management Review Board (MRB), which consisted of U.S. Nuclear Regulatory Commission (NRC) senior managers and an Organization of Agreement States Liaison to the MRB, met to consider the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Maine Agreement State Program. The MRB found the Maine program adequate to protect public health and safety and compatible with the NRC program.

The enclosed final report documents the IMPEP team's findings and recommendations and summarizes the results of the MRB meeting (Section 5.0). Based on the results of the current IMPEP review, the next full review of the Maine Agreement State Program will take place in approximately 4 years, with a periodic meeting in approximately 2 years.

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/

John W. Lubinski, Director
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Maine Final IMPEP Report

cc: James Grice, Manager
Radiation Program
Hazardous Materials and Waste
Management Division, State of Colorado
Organization of Agreement States
Liaison to the MRB

SUBJECT: MAINE FY2019 FINAL INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM DATED: DATE

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Protecting People and the Environment

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE MAINE PROGRAM

July 22-26, 2019

FINAL REPORT

Enclosure 1

EXECUTIVE SUMMARY

The results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Maine Agreement State Program (Maine) are discussed in this report. The review was conducted during the period of July 22-26, 2019, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Arizona.

Based on the results of this review, Maine's performance was found satisfactory for six indicators: Technical Staffing and Training, Status of Materials Program, Technical Quality of Inspections, Technical Quality of Licensing Actions, Technical Quality of Incidents and Allegations, and Sealed Source and Device Evaluation Program, and satisfactory, but needs improvement for the Compatibility Requirements performance indicator.

The team did not make any recommendations. The team determined, and the MRB agreed, that the recommendation from the 2015 IMPEP review should be closed regarding regulation adoption to address the outstanding comments from the 2011 IMPEP review.

Accordingly, the team recommended, and the MRB agreed, that Maine be found adequate to protect public health and safety and compatible with the NRC's program. The team recommended, and the MRB agreed, that the next IMPEP review take place in approximately 4 years with a periodic meeting in approximately 2 years.

1.0 INTRODUCTION

The Maine Agreement State Program (Maine) review was conducted during the period of July 22-26, 2019, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Arizona. Team members are identified in Appendix A. The review was conducted in accordance with the "Agreement State Program Policy Statement", published in the *Federal Register* on October 18, 2017 (82 FR 48535), and NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)", dated February 26, 2004. Preliminary results of the review, which covered the period of June 20, 2015 to July 26, 2019, were discussed with Maine managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common performance indicators and the applicable non-common performance indicators was sent to Maine on November 14, 2018. Maine provided its response to the questionnaire on June 26, 2019. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML19178A012.

A draft of this report was issued to Maine on August 16, 2019, for factual comment (ADAMS Accession Number ML19225D266). Maine responded to the draft report by electronic mail dated September 18, 2019, from Jay Hyland, Program Manager, Radiation Control Program, (ADAMS Accession Number ML19262D340). The Management Review Board (MRB) convened on October 10, 2019, to discuss the team's findings and recommendation.

Maine is administered by the Radiation Control Program (the Program) which is part of the Division of Environmental and Community Health (the Division). The Division is part of the Department of Health and Human Services (the Department). Organization charts for Maine are available in ADAMS using Accession Number ML19178A014.

At the time of the review, Maine regulated 96 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Maine.

The 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 Maine's performance.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on June 19, 2015. The final report is available in ADAMS using Accession Number ML15251A018. The results of the review and the status of the associated recommendation 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: The 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 the 2011 IMPEP review)

Status: Maine promulgated changes to its regulations to incorporate comments from the NRC letters dated August 31, 2006, and June 18, 2010. The changes to the regulations were adopted in May 2019. The NRC reviewed Maine's final regulations and all the outstanding comments were resolved.

This recommendation is closed.

Sealed Source and Device Evaluation Program: 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 could affect public health and safety. Apparent trends in staffing must be explored. Review of staffing also requires 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 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 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 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

When fully staffed, Maine is comprised of 3 staff members which contributes 2.3 FTE for the radioactive materials program. Currently, there are no vacancies. During the review period one staff member left the program and one staff member was hired. The position was vacant for 9 months. The team did not identify any issues related to performance because of the staff turnover.

Maine has a training and qualification program compatible with the NRC's IMC 1248. Both staff members are fully qualified to review licensing actions and perform inspections. In addition, each staff member tracks their progress in meeting the 24-hour refresher training.

c. Evaluation

The team determined that, during the review period, Maine met the performance indicator objectives listed in Section 3.1.a. Based on the criteria in MD 5.6, the team recommended that Maine's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Maine's performance with respect to this indicator, 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 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 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 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

Maine performed 64 Priority 1, 2, 3, and initial inspections during the review period. No Priority 1, 2, 3 or initial inspections were conducted overdue during the review period. Maine's inspection frequencies are the same for similar license types in IMC 2800.

A sampling of 18 inspection reports indicated that 2 of the inspection findings were communicated to the licensees beyond Maine's goal of 30 days after the inspection exit. The reports were issued 3 and 30 days beyond the 30-day goal. That latter report was late due to its proximity to the holiday season coupled with health-related issues with the

inspector. Each year of the review period, Maine performed greater than 20 percent of candidate reciprocity inspections.

c. Evaluation

The team determined that, during the review period, Maine met the performance indicator objectives listed in Section 3.2.a. Based on the criteria in MD 5.6, the team recommended that Maine's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Maine's performance with respect to this indicator, 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 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, 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.
- 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 the quality of inspection reports, enforcement documentation, and interviewed inspectors involved in materials inspections conducted during the review period. The casework reviewed included inspections conducted by three of Maine's inspectors and covered medical, industrial, commercial, academic, research, and nuclear gauges.

The team found that inspection documents were complete and inspection findings were well-founded. Inspection findings were clearly communicated to the licensee and violations were directly correlated to a regulation or license condition. The team determined that the inspection reports addressed previously identified open items and violations. In addition, the team determined that supervisory accompaniments were conducted annually for all inspectors.

A team member accompanied two program inspectors the week of April 8, 2019. The inspector accompaniments are identified in Appendix B. No performance issues were noted during the inspection accompaniments. The inspectors were well prepared, and thorough, and assessed the impact of licensed activities on health, safety, and security.

An adequate supply of calibrated instruments is available to support the program and are calibrated at the required frequency. Calibration records for the instruments are maintained on file.

c. Evaluation

The team determined that, during the review period, Maine met the performance indicator objectives listed in Section 3.3.a. Based on the criteria in MD 5.6, the team recommended that Maine's performance with respect to the indicator, Technical Quality of Inspections be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Maine's performance with respect to this indicator, 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 Maine 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 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 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 (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

b. Discussion

During the review period, Maine performed 286 radioactive materials licensing actions. The team evaluated 20 of those licensing actions. The licensing actions selected for review included four new applications, nine amendments, four renewals, and three terminations. The team evaluated casework which included the following license types and actions: medical and academic broad scope, medical diagnostic and therapy, industrial radiography, research and development, nuclear pharmacy, gauges, self-shielded irradiators, and financial assurance. The casework sample represented work from three license reviewers.

Licensing actions were well documented and properly addressed health, safety and security issues. Renewal applications demonstrated a thorough analysis of the licensee's inspection and enforcement history. Each completed action contained an administrative review, either by a peer or the radioactive materials manager, in its entirety. The initial reviewer signs the license.

The team determined that Maine's three industrial radiography licenses did not include maximum possession limits for the material. In Radiation Control Program Director (RCPD) letter, 10-007, "Requesting Implementation of a Policy on Maximum Possession Limits for Radioactive Materials Licenses," dated June 21, 2010, Agreement States had 18 months to implement the necessary changes to applicable licensees (e.g., industrial

radiography, portable and fixed gauges, etc.) The Maine staff had previously modified the industrial radiography licenses with the intent to add maximum possession limits for these licensees, but the change did not meet the intent. After discussions with the team, the Maine staff began the process to request maximum possession limits from the licensees and administratively correct the licenses. The team examined other licenses that would require maximum possession limits and determined those licenses had been updated correctly.

The team evaluated the implementation of the Pre-Licensing Guidance (PLG). Maine conducted pre-licensing site visits for all unknown entities in accordance with the checklist, and properly implemented the PLG. Maine issues a license after the applicant has met the basis for confidence that radioactive material will be used as intended.

The team also evaluated the implementation of the Risk Significant Radioactive Materials (RSRM) checklist. The team determined that Maine is adequately implementing the RSRM checklist. The team noted, that all new applicants that will possess radioactive material equal to or exceeding Category 2 quantities of radioactive material are required to have all increased security requirements in place prior to license issuance. All documentation for each licensing action is found in paper files, with security licensees locked up in a cabinet.

c. Evaluation

The team determined that, during the review period, Maine met the performance indicator objectives listed in Section 3.4.a. Based on the criteria in MD 5.6, the team recommended that Maine's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Maine's performance with respect to this indicator, 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 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 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 (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, seven incidents were reported to Maine. The team evaluated all seven reportable incidents which included: three equipment failures, two lost/stolen/abandoned radioactive materials, one medical event, and one transportation event.

The team found that Maine properly evaluated each incident, interviewed involved individuals, and thoroughly documented its findings. When an incident is reported to Maine, both staff and management evaluate the information received to determine its health and safety significance and then decide on the appropriate response. That response can range anywhere from responding immediately to reviewing the event during the next inspection. The team determined that Maine responds to incidents in accordance with its established procedure.

The team evaluated Maine's timeliness of reporting incidents to the NRC. The team noted that Maine appropriately reviewed and reported six of the seven incidents (either to the NRC Headquarters Operations Officer (HOO) or directly to NMED) within the required timeframes. The team determined that for one incident involving a source disconnect for a radiography camera, the incident should have been reported to the HOO within 24 hours, followed by the submittal of a written report to complete the event reporting process in NMED. That incident was not reported to the HOO within the required timeframe. Maine reported the incident to NMED five days after the incident in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 34.101(a), "Notifications". Maine failed to recognize that the reporting requirements to the HOO in 10 CFR 30.50(b), "Reporting Requirements," also applied to the incident. After discussions with the team, Maine reported the event to the HOO during the week of the review for completeness.

During the review period, one allegation was received by Maine. The team evaluated this allegation and found that Maine took prompt and appropriate action in response to the concerns raised. The allegation was appropriately closed, the concerned individual

was notified of the actions taken, and the alleger's identity was protected whenever possible in accordance with State law.

c. Evaluation

The team determined that, except as noted below, during the review period Maine met the performance indicator objectives listed in Section 3.5.a.

- Notification for one of the seven incidents reported during the review period was not made to the NRC Headquarters Operations Center for an incident requiring a 24-hour or immediate notification.

Maine reported a radiography source disconnect to NMED five days after the incident in accordance with 10 CFR 34.101(a) instead of reporting the incident to the NRC's HOO within 24 hours of event notification as described in 10 CFR 30.50(b).

Based on the criteria in MD 5.6, the team recommended that Maine's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Maine's performance with respect to this indicator, 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 Program. The NRC's Agreement with Maine retains regulatory authority for low-level radioactive waste disposal, and a uranium recovery program; 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. 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 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 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 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.
- Sunset requirements, if any, do not negatively impact the effectiveness of the State's regulations.

b. Discussion

The State of Maine became an Agreement State on April 1, 1992. The current effective statutory authority is contained in Title 22 "Health and Welfare," Chapter 160 "Radiation Protection Act," of the Maine Statutes. The Department is designated as the State's radiation control agency. No legislation affecting the Agreement State Program was passed during the review period.

The State's administrative rulemaking process takes between eight and fourteen months from drafting to finalization of 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. The review team noted that the State's rules and regulations are not subject to "sunset" laws.

During the review period, Maine submitted one final regulation package, which incorporated NRC comments from letters dated August 31, 2006, and June 18, 2010, to the NRC for a compatibility review. As discussed in Section 2.0, a recommendation was generated in the 2011 and 2015 IMPEP reports which stated that Maine needed to

address these outstanding comments. The revised regulations incorporating the changes described in the two NRC letters were adopted in May 2019. The NRC reviewed Maine's final regulations and determined that Maine addressed all the open compatibility comments.

At the time of the 2019 IMPEP review, the team determined that Maine had eight regulation amendments that were overdue for adoption. The overdue amendments are as follows:

- Regulation Amendment Tracking Sheet Identification (RATS ID) 2012-2: "Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste," 10 CFR Part 71 (77 FR 34194), that was due for Agreement State adoption by August 10, 2015.

- RATS ID 2012-3: "Technical Corrections," 10 CFR Parts 30, 34, 40, 71 (77 FR 39899), that was due for Agreement State adoption by August 6, 2015.

- RATS ID 2012-4: "Requirements for Distribution of Byproduct Material," 10 CFR Parts 30, 31, 32, 40, and 70 (77 FR 43666), that was due for Agreement State adoption by October 23, 2015.

- RATS ID 2013-2: "Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions," 10 CFR Parts 30, 40, 70 (78 FR 32310), that was due for Agreement State adoption by August 27, 2016.

- RATS ID: 2015-1: "Domestic Licensing of Special Nuclear Material – Written Reports and Clarifying Amendments," 10 CFR Part 70 (79 FR 57721, 80 FR 143), that was due for Agreement State adoption by January 26, 2018.

- RATS ID 2015-2: "Safeguards Information – Modified Handling Categorization, Change for Materials Facilities," 10 CFR Parts 30, 37, 73, and 150 (79 FR 58664, 80 FR 3865), that was due for Agreement State adoption by January 28, 2018.

- RATS ID 2015-4: "Miscellaneous Corrections," 10 CFR Parts 37, 40 (80 FR 45841), that was due for Agreement State adoption by September 2, 2018.

- RATS ID 2015-5: "Miscellaneous Corrections," 10 CFR Parts 19, 20, 30, 32, 37, 40, 61, 70, 71, and 150 (80 FR74974), that was due for Agreement State adoption by December 31, 2018.

These overdue regulation changes range from seven months to four years for adoption. The team also determined that Maine adopted changes to all other program elements within six months of the changes made by the NRC and that no changes to program elements other than regulations were overdue at the time of the review.

The team examined the eight amendments overdue for adoption to determine whether the rule changes in each amendment were significant. Of the eight amendments overdue for adoption, the team determined two amendments to be significant: RATS ID 2012-4 and RATS ID 2013-2. Additionally, the team noted that RATS ID 2015-2 also appeared significant. However, after examining the Summary of Change document the team determined that all changes to regulations required for compatibility impacted 10 CFR Part 37 regulations and noted that Maine adopts 10 CFR Part 37 by reference with no date referenced. Therefore, even though Maine did not recognize that the license condition it submitted in 2016 to meet RATS ID 2013-1 also covered RATS ID 2015-2, the requirements are in place and cover changes made in the later NRC rulemaking. The team determined that this regulation that appears overdue for adoption is due to an administrative error and therefore does not consider it to be significant.

The team discussed with Maine the reason for the overdue regulations. Program management stated that the State administration in place between 2011 and 2019 made it difficult to promulgate changes to regulations. A decision was made by the Program management to hold any rule changes until a changeover in the administration occurred. The one exception was the adoption by license condition of requirements equivalent to 10 CFR Part 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.” Since there were no equivalent existing regulations in place, Maine was able to use a license condition to adopt these requirements. For the eight overdue regulation amendments, Maine was not able to use license conditions to adopt the requirements because regulations already existed.

The team noted that as soon as a new administration took office in January 2019, the Program staff immediately started working on promulgation of the overdue NRC amendments. Maine first promulgated rule changes to address outstanding NRC comments as discussed in Section 2.0. These changes became final in May 2019. Once those regulations went into effect, Program staff immediately began working on amending its regulations to incorporate the changes for the eight overdue amendments, the two amendments not yet overdue for adoption, and to incorporate equivalent requirements to 10 CFR Part 37 into its regulations so that the license conditions would no longer be needed. These draft changes were submitted to the NRC for a compatibility review on July 23, 2019. Maine expects these regulation changes to become final before the end of June 2020.

c. Evaluation

The team determined that, except as noted below, during the review period Maine met the performance indicator objectives listed in Section 4.1.a.

- Regulations pertaining to eight amendments will be adopted by Maine greater than three years after the effective date of the NRC regulation.

Maine is currently in the process of adopting eight overdue regulation amendments. These eight overdue amendments range from seven months to four years. The policies of the previous State administration impacted the ability of the Program to adopt

compatible regulations. Once a new State administration came into office, the Program staff immediately began working on promulgation of compatible regulations.

The team considered findings of both satisfactory but needs improvement and unsatisfactory for this indicator. In reviewing MD 5.6, the team noted that Maine met two of the three bullets for a finding of satisfactory but needs improvement and one of seven bullets listed for a finding of unsatisfactory. The team determined that Maine had most of the statutory and legal authority required to maintain a compatible program in place even though eight NRC amendments were overdue for adoption at the time of the IMPEP review. Additionally, during its deliberation the team took into consideration the significance of the overdue regulations, the explanation provided by Maine for the delay in rule promulgation, and the fact that once a new State administration entered office, work on the outstanding comments and overdue regulations was immediately started. The team determined that given the administrative nature of the proposed changes, the overdue regulations had no adverse effect to the protection of public health, safety, and security. Therefore, the team concluded that a finding of unsatisfactory is not warranted for this indicator.

Based on the criteria in MD 5.6, the team recommended that Maine's performance with respect to the indicator, Compatibility Requirements, be found satisfactory but needs improvement.

d. MRB Decision

The MRB agreed with the team's recommendation and found Maine's performance with respect to this indicator, satisfactory, but needs improvement.

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 its 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 teams. Under this guidance, 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 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 qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, 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 the guidance in NUREG-1556, Volume 3.

Evaluation of Defects and Incidents

- SS&D incidents are reviewed to identify 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 the NRC, Agreement States, and others, as appropriate, occur in a timely manner.

b. Discussion

Technical Staffing and Training

Maine does not have staff qualified to perform SS&D reviews. Maine utilizes New Hampshire to perform its SS&D reviews. New Hampshire staff reviewed two new actions submitted during the review period. The team confirmed that the New Hampshire staff that reviewed the actions were qualified to perform SS&D reviews.

Technical Quality of the Product Evaluation

Maine has three SS&D licensees and four registration certificates. New Hampshire is currently reviewing one open SS&D action for Maine. The team evaluated two SS&D actions processed during the review period. The actions reviewed included two new sealed sources applications. SS&D evaluations were thorough and of acceptable technical quality and addressed product integrity under normal and likely accident conditions. Health and safety issues were properly addressed, and registrations clearly summarized the product evaluation.

The New Hampshire SS&D reviewers used the NUREG-1556, Volume 3 checklist for the SS&D actions to ensure that all health and safety aspects have been adequately

addressed. The checklists are signed and dated by the lead reviewer and a concurrence reviewer. The concurrence review provides an additional "quality check" to the safety evaluation process.

Evaluation of Defects and Incidents Regarding SS&Ds

There were no incidents involving Maine SS&D registered products related to manufacturing or design of the sources/devices manufactured or distributed 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. Based on the criteria in MD 5.6, the team recommended that Maine's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Maine's performance with respect to this indicator, satisfactory.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Maine's performance was found to be satisfactory for 6 out of 7 performance indicators reviewed and satisfactory, but needs improvement, for the indicator, Compatibility Requirements. The team did not make any recommendations. The team determined, and the MRB agreed, that the recommendation from the 2011 IMPEP review be closed.

Accordingly, the team recommended, and the MRB agreed, that Maine 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 recommended, and the MRB agreed, that the next full IMPEP review take place in approximately 4 years, with a periodic meeting in approximately 2 years

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Areas of Responsibility**
Lizette Roldan-Otero, NMSS	Team Leader Technical Staffing and Training Technical Quality of Inspections Inspection Accompaniments
María Arribas-Colón, NMSS	Status of Materials Inspection Program Sealed Source and Device Evaluation Program
Monica Ford, Region I	Technical Quality of Incident and Allegation Activities Compatibility Requirements
Brian Goretzki, Arizona	Technical Quality of Licensing

APPENDIX B

INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: 05611
License Type: Medical Therapy (HDR)	Priority: 2
Inspection Date: 04/09/19	Inspector: CP

Accompaniment No.: 2	License No.: 23209
License Type: Industrial Radiography	Priority: 1
Inspection Date: 04/10/19	Inspector: TH