



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

November 9, 2023

Nathan Saunders, Program Manager
Radiation Control Program
Division of Environmental and
Community Health
Maine Department Health and Human Services
286 Water Street, Key Plaza
Augusta, ME 04333-0011

Dear Nathan Saunders:

On October 12, 2023, the Management Review Board (MRB), which consisted of the U.S. Nuclear Regulatory Commission (NRC) senior managers and an Organization of Agreement States MRB member, met to consider the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Maine Agreement State Program. The MRB Chair, in consultation with the MRB, found the Maine Agreement State Program adequate to protect public health and safety and compatible with the NRC's program.

The enclosed final report documents the IMPEP team's findings and summarizes the results of the MRB meeting. Based on the results of the current IMPEP review, the MRB determined that the next periodic meeting take place in approximately 2 years with the next IMPEP review taking place in approximately 4 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,

A handwritten signature in cursive script that reads "Catherine Haney".

Signed by Haney, Cathy
on 11/09/23

Catherine Haney
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, Compliance, Administration,
and Human Capital Programs
Office of the Executive Director for Operations

Enclosures:

1. 2023 Maine Final IMPEP Report
2. 2023 Maine MRB Meeting
Participants

SUBJECT: MAINE FINAL IMPEP REPORT DATE NOVEMBER 9, 2023

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

JULY 10-14, 2023

FINAL REPORT

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 from July 10-14, 2023. An in-person inspector accompaniment was conducted during the week of May 30, 2023.

The team found Maine's program's performance to be satisfactory for six of the seven performance indicators: Technical Staffing and Training; Status of Materials Inspection Program; Technical Quality of Inspections; Technical Quality of Licensing Actions; Technical Quality of Incident and Allegation Activities; and Sealed Source and Device Evaluation Program. The team also found Maine's performance to be satisfactory, but needs improvement for the Legislation, Regulations, and Other Program Elements performance indicator. The finding for the Legislation, Regulations, and Other Program Elements performance indicator remains unchanged from the previous IMPEP review. During this review period, Maine issued final regulations to adopt the required NRC regulations for compatibility. These regulations were not all adopted timely, were missing regulations on reporting requirements, and resulted in several NRC staff comments.

The team did not make any recommendations and there were no recommendations from the previous review for the team to consider.

Accordingly, the team recommended and the Management Review Board (MRB) Chair agreed, that the Maine Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. The team also recommended and the MRB Chair agreed that a periodic meeting take place in approximately two years with the next full IMPEP review taking place in approximately four years.

1.0 INTRODUCTION

The Maine Agreement State Program (Maine) review was conducted from July 10-14, 2023, by a team of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of New York. Team members are identified in Appendix A. An in-person inspector accompaniment was conducted on May 31, 2023. The inspector accompaniment is identified in Appendix B. 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 July 24, 2019. Preliminary results of the review, which covered the period of July 27, 2019, to July 14, 2023, were discussed with the Maine managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common performance indicators and applicable non-common performance indicators was sent to Maine on November 18, 2022. Maine provided its response to the questionnaire on June 26, 2023. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) [ML23181A090](#).

Maine is administered by the Radiation Control Program which is located within the Division of Environmental and Community Health (the Division). The Division is part of the Maine Center for Disease Control and Prevention within the Maine Department of Health and Human Services. Organizational charts for Maine are available in ADAMS [ML23181A087](#).

The 2023 IMPEP team issued a draft report to Maine on August 23, 2023, for factual comment ([ML23212B157](#)). Maine responded to the draft report by email dated August 28, 2023, from Mr. Michael Abbott, Associate Director, Division of Environmental and Community Health ([ML23243A874](#)). Maine did not have any comments to the draft report. The Management Review Board (MRB) was conducted on October 12, 2023, to discuss the team's findings and recommendations.

At the time of the review, Maine regulated 89 specific licenses authorizing possession and use of radioactive materials. The review focused on the radiation control program as it is carried out under Section 274b. of the Atomic Energy Act of 1954, as amended.

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

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on July 22-26, 2019. The final report is available in ADAMS [ML19288A291](#). The results of the review 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

Legislation, Regulations, and Other Program Elements (formerly Compatibility Requirements): Satisfactory, but needs improvement
Recommendation: None

Sealed Source and Device (SS&D) 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 and Agreement State radiation control 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 assessed. 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.
- 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.
- 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.
- 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

Maine is comprised of two technical staff members and one program manager which equals 2.3 full-time equivalent (FTE) for the radiation control program when fully staffed. During the review period, one of the technical staff members left the program and the Radiation Control Program Director (RCPD) assumed another position within the program. After approximately 15 months, the RCPD position was filled. The vacant technical staff position was vacant since January 1, 2023, through the end of the IMPEP review period (approximately 6 months) but has since been filled. The staff member who left the program was a fully qualified license reviewer and inspector and met their 24-hour refresher training requirement. While the position was vacant, the program manager, who is qualified, assisted as needed. The remaining technical staff member is a fully qualified license reviewer and inspector and has met their 24-hour refresher training requirement. Maine has a training and qualification program compatible with the NRC’s IMC 1248. No impacts related to the pandemic were noted in this indicator.

During the IMPEP review period, Maine posted an Environmental Specialist-III Materials Inspector position to fill the vacancy. The position had one applicant who was determined to be qualified for the position and hired. However, a week prior to the start date, the individual decided not to move to Maine and rescinded their acceptance. The position was reposted; at the time of the IMPEP, Maine was reviewing the candidates and beginning the interview process. Since then, Maine has filled the position. Additionally, Maine is working to reclassify their two technical positions (Environmental Specialist-III and Assistant Environmental Engineer) to create new position classifications for Health Physicist I and II. Maine is looking to perform rulemaking to raise fees in support of improving salaries for these new position classifications.

c. Evaluation

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

- Any vacancies, especially senior-level positions, were not filled in a timely manner.

The team considered recommending a finding of “satisfactory but needs improvement” for this indicator. The team concluded that, despite the current one-person technical staff, Maine was fully staffed for most of the review period, the staff were fully trained and qualified, and there were no performance issues associated with licensing, inspection, or response to incidents.

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

d. MRB Chair's Determination

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

3.2 Status of Materials Inspection Program

Inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety and security practices. The frequency of inspections is specified in [IMC 2800](#), "Materials Inspection Program," and is dependent on the amount and type of radioactive 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 prescribed frequencies (<https://www.nrc.gov/materials/miau/mat-toolkits.html>).
- 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.
- Candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 2800 and other applicable guidance or compatible Agreement State Procedure.
- 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 43 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 for initial and routine inspections are the same as those used in NRC's program. A sampling of 20 inspection reports indicated that none of the inspection findings were communicated to the licensees beyond Maine's goal of 30 days after the inspection exit. An Access database is used to track all inspection activities.

Reciprocity inspections were conducted in response to a request received from a licensee of another Agreement State or the NRC to perform work within Maine's jurisdiction. Maine's procedure states that Maine will, at a minimum, inspect 20 percent of candidate reciprocity licensees each calendar year. Candidate licensees are those licensees that have applied for reciprocity and that were not inspected in the previous calendar year or had a significant event within the last two years. The team determined that Maine inspected greater than 20 percent of candidate reciprocity licensees in each calendar year covered by the review period.

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 recommends that Maine's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

d. MRB Chair's Determination

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

3.3 Technical Quality of Inspections

Inspections, both routine and reactive, provide reasonable 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 inspection program.

a. Scope

The team used the guidance in [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 compatible with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated 20 inspection reports and associated enforcement documentation, and interviewed inspectors involved in materials inspections conducted during the review period. The team reviewed casework for inspections conducted by all current and former inspectors and covered medical, industrial, commercial, and academic licenses. The team determined that Maine inspectors used checklists as a reference and starting point for each inspection and added information to the inspection checklist as appropriate. Inspection documentation exists to show that inspectors reviewed previously identified violations and ensured licensee corrective actions had been implemented and had appropriately addressed the violation so that the violation could be closed. For inspections with no violations, Maine inspectors have the option to use Maine form HHE-891 to document and leave inspection findings in the field. If form HHE-891 is not used or if the inspection results in violations, inspection findings are issued using a formal letter addressed to the licensee.

A team member accompanied one inspector during the week of May 30, 2023. The inspector accompaniment was conducted in-person and is identified in Appendix B. The team determined that the inspector was well-prepared, thorough in their evaluation of the licensee, and assessed the impact of licensed activities on health, safety, and security. The inspector observed the use of radioactive material during the inspection and was able to develop a basis of confidence that radioactive materials were being used safely and securely. All findings and conclusions were well-founded and appropriately documented.

The team reviewed Maine's supervisory accompaniments completed during the review period. The team found that a supervisory accompaniment was performed for each inspector in calendar years 2019, 2020, 2021, and 2022. No supervisory accompaniments had been performed in calendar year 2023 as of the date of the on-site review. Management stated that they plan to complete and document the supervisory accompaniment of the qualified inspector before the end of the calendar year.

The team reviewed Maine's supply of radiation detection equipment. The team determined that Maine had an ample supply of equipment to support its inspection program and that the equipment was calibrated in a timely manner. No impacts related to the pandemic were seen related to this indicator.

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

d. MRB Chair's Determination

The MRB Chair agreed with the team's recommendation and found Maine's performance with respect to this performance 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, implementation of those procedures, and documentation of communications and associated actions between Maine's 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 [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., pre-licensing guidance, Title 10 of the *Code of Federal Regulations* (10 CFR) Part 37, financial assurance, etc.).
- 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 (RSRM) are appropriately implemented including the physical protection of Category 1 and Category 2 quantities of radioactive material (10 CFR Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

b. Discussion

During the review period, Maine performed 190 radioactive materials licensing actions. The team evaluated 28 of those licensing actions. The licensing actions selected for review included 2 new applications, 20 amendments, 3 renewals, and 3 terminations. The team evaluated casework from current and former license reviewers, which included the following license types and actions: broad scope, medical diagnostic and therapeutic, industrial radiography, academic, nuclear pharmacy, gauges, self-shielded irradiators, and financial assurance.

Licensing actions were well documented and addressed health, safety, and security issues. All licensing actions included a checklist to ensure that all the essential elements were covered. Renewal applications demonstrated a thorough analysis of the licensee's inspection and enforcement history.

The team noted that all necessary licensee commitments were obtained, and deficiency letters and license conditions were well supported by information contained in the

licensing files. All new licenses included the NRC's "Checklist to Provide a Basis for Confidence that Radioactive Material will be used as Specified on the License" (Pre-Licensing Guidance). The team also determined that Maine adopted and properly implemented the most current version of the RSRM checklist during the review period.

The team determined that appropriate financial assurance instruments were properly submitted when required, and that licenses containing security related information were properly marked. Each license reviewer had the proper signature authority. No impacts related to the pandemic were noted in this indicator.

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 recommends that Maine's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

d. MRB Chair's Determination

The MRB Chair agreed with the team's recommendation and found Maine's performance with respect to this performance 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, safety, and security. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures internal and external coordination, timely incident reporting, and investigative and follow-up actions, are a significant indicator of the overall quality of the incident response and allegation programs.

a. Scope

The team used the guidance in [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 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) and closed when all required information has been obtained.
- Allegations are investigated in a prompt, appropriate manner.
- Concerned individuals are notified within 30 days 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 radioactive materials incidents which included two lost or stolen radioactive materials, one medical event, one damaged industrial radiography equipment, two leaking sources, and one building fire. Maine dispatched inspectors for on-site follow-up for one potentially risk-significant case.

When notified of an incident, management and staff meet to discuss the incident and determine the appropriate level of response, which can range from an immediate response to reviewing the incident during the next routine scheduled inspection. Those determinations are made based on both the circumstances and the health and safety significance of the incident. The team found that Maine's evaluation of incident notifications and its response to those incidents was thorough, well balanced, complete, and comprehensive.

The team also evaluated Maine's reporting of incidents to the NRC's Headquarters Operations Officer (HOO). The team noted that in each case requiring HOO notification, Maine reported the incidents within the required time frame. The team also evaluated whether Maine had failed to report any required incidents to the HOO. The team did not identify any missed reporting requirements.

During the review period, one allegation was received by Maine. The team evaluated the allegation and determined that Maine's evaluation of the allegation was thorough, well balanced, complete, and comprehensive. No allegations were referred to the State by the NRC during the review period. No impacts related to the pandemic were noted in this indicator.

c. Evaluation

The team determined that, during the review period, Maine met the performance indicator objectives listed in Section 3.5.a. Based on the criteria in MD 5.6, the team recommends that Maine's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

d. MRB Chair's Determination

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

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Legislation, Regulations, and Other Program Elements; (2) SS&D Evaluation Program; (3) Low-Level Radioactive Waste (LLRW) Disposal Program; and (4) Uranium Recovery Program. The NRC retains regulatory authority for LLRW Disposal, and Uranium Recovery Programs therefore, only the first two non-common performance indicators applied to this review.

4.1 Legislation, Regulations, and Other Program Elements

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 State's agreement with the NRC. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of adequate 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 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 Program Element Table indicating the Compatibility Categories for those Program Elements other than regulations can be found on the NRC website at the following address: <https://scp.nrc.gov/regtoolbox.html>.

a. Scope

The team used the guidance in [SA-107](#), "Reviewing the Non-Common Performance Indicator: Legislation, Regulations, and Other Program Elements," 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 of 1954, 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

Maine became an Agreement State on April 1, 1992. Maine's current effective statutory authority is contained in the 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 radiation control program was passed during the review period.

Maine's administrative rulemaking process takes approximately 180 days to finalize a rule after a pre-legal review has been completed by the Attorney General. After the completion of the pre-legal review, the public, NRC, other agencies, and potentially impacted licensees and registrants are offered an opportunity to comment during the process. Comments are considered and incorporated, as appropriate, before the regulations are finalized and approved by the Attorney General and the Governor. During the pre-legal review, which does not have a defined time period, the Attorney General reviews and provides comments. Maine described delays resulting from previous Attorney General reviews both before and during the pandemic. The team noted that Maine's rules and regulations are not subject to "sunset" laws.

During the review period, Maine submitted no proposed regulation amendments, 21 final regulation amendments, and no legally binding requirements or license conditions to the NRC for a compatibility review. In a letter dated January 26, 2023, the NRC received the final regulation amendments incorporating 21 Regulation Amendment Tracking System Identification Numbers (RATS IDs). These final regulations had been adopted in October 2022. At the time of the submission, 14 of these amendments were overdue (e.g., past the time for State adoption). Eleven of the 14 were due during the previous IMPEP review period. During this review period, three amendments were overdue and seven were adopted timely.

The following RATS IDs were overdue for adoption, but are now complete:

Overdue by the 2019 IMPEP review period ending July 26, 2019

1. 2011-1, "Decommissioning Planning, Parts 20, 30, 40, and 70"
2. 2012-2, "Advance Notification to Native American tribes of Transportation of Certain Types of Nuclear Waste"
3. 2012-3, "Technical Corrections - Parts 30, 34, 40, and 71"
4. 2012-4, "Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70"
5. 2013-1, "Physical Protection of Byproduct Material, 10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, 51, 71 and 73"
6. 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, 170, and 171"
7. 2015-1, "Domestic Licensing of Special Nuclear Material - Written Reports and Clarifying Amendments, 10 CFR Part 70"
8. 2015-2, "Safeguards Information - Modified Handling Categorization, Change for Materials Facilities, 10 CFR Parts 30, 37, 73, and 150"
9. 2015-3, "Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements, 10 CFR Part 71"
10. 2015-4, "Miscellaneous Corrections, 10 CFR Parts 37 and 40"
11. 2015-5, "Miscellaneous Corrections, 10 CFR Parts 19, 20, 30, 32, 37, 40, 61, 70, 71, and 150"

Overdue by the October 2022 adoption and within the 2023 IMPEP review period

1. 2018-1, "Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments, 10 CFR Parts 30, 32 and 35"
2. 2018-2, "Miscellaneous Corrections - Organizational Changes, 10 CFR Parts 37, 40,

- 70, and 71”
3. 2018-3, “Miscellaneous Corrections to 10 CFR Parts 1, 2, 34, 37, 50, 71, 73, and 140”

The following were adopted timely:

1. 2019-1, “Miscellaneous Corrections to 10 CFR Parts 2, 21, 37, 50, 52, 73, and 110”
2. 2019-2, “Organizational Changes and Conforming Amendments to 10 CFR Parts 1, 2, 37, 40, 50, 51, 52, 55, 71, 72, 73, 74, 100, 140, and 150”
3. 2020-1, “Individual Monitoring Devices 10 CFR Parts 34, 36, and 39”
4. 2020-2, “Social Security Number Fraud Prevention 10 CFR Parts 9 and 35”
5. 2020-3, “Miscellaneous Corrections 10 CFR Parts 1, 2, 19, 20, 21, 30, 34, 35, 40, 50, 51, 52, 60, 61, 62, 63, 70, 71, 72, 73, 74, 75, 76, 110, and 140”
6. 2021-1, “Miscellaneous Corrections, 10 CFR Parts 2, 11, 20, 25, 32, 35, 37, 50, 52, 55, 70, 72, 73, 95, and 110”
7. 2021-2, “Miscellaneous Corrections, 10 CFR Parts 9, 37, 40, 50, 51, 52, 55, 71, 73, and 110”

At the time of the review, Maine had completed all necessary regulations submittals.

The NRC staff reviewed the January 2023 submittal of the final revisions of these regulations ([ML23205A161](#)). The NRC’s regulatory review process requires the NRC to send a letter to Maine with these comments and Maine is required to address these comments. The staff’s review of the 21 RATS IDs identified 43 comments. These comments include:

- 34 comments on regulations designated as a compatibility category B, which are considered significant under [SA-107](#) and must be adopted in an essentially identical manner.
- 1 comment on a regulation whose authority is solely that of the NRC.
- 5 comments on regulations designated as compatibility category C, which can be more restrictive than NRC regulations and are important to avoid conflict, duplication, or gaps between Maine and the NRC.
- 3 covering multiple sections and compatibility categories, including compatibility category B and NRC.

During NRC’s review of the January 2023 submittal, the NRC staff recognized that Maine is missing equivalent regulations for 10 CFR 30.50, 40.60, and 70.50 event reporting requirements. These regulations are designated as compatibility category C and so missing them creates a gap between Maine and NRC regulations. The IMPEP review team found that these regulations have been missing since at least 1999. Although these reporting requirements were likely never included in the regulations, events have been reported accurately and timely to the NRC and Maine. These missing regulations could have potentially resulted in enforcement challenges using Maine’s regulations. Maine stated that they had never needed to enforce using these regulations. During the review, Maine discussed short-term solutions to include these regulations, either through issuing an order or through license conditions until rulemaking is complete. Since then, Maine submitted an order for NRC review ([ML23250A220](#)), NRC reviewed and approved the order ([ML23250A272](#)) and Maine notified their licensees.

The team reviewed guidance documents that Maine uses to meet the requirements of other Program Elements (e.g., Pre-Licensing Guidance, Inspection Procedures, etc.) that the NRC has designated as necessary for the maintenance of an adequate and compatible program. All changes to these documents were made within 6 months of the NRC's changes and were determined to be compatible.

Maine intends to adopt RATS IDs 2022-1 and 2022-2 in FY 2024 when they expect to amend their fee rules.

c. Evaluation

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

- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were not adopted within 3 years after the effective date of the NRC regulation.

The team reviewed the MD 5.6 evaluation criteria for “satisfactory but needs improvement” for this indicator. In reviewing MD 5.6, the team noted Maine was overdue adopting three RATS IDs within this IMPEP review period and their adoption resulted in several comments. Therefore, more than a few, but less than most RATS IDs had a delayed adoption. Additionally, Maine had been missing equivalent regulations for 10 CFR 30.50, 40.60, and 70.50 reporting requirements. Therefore, there are more than a few, but less than most regulations missing. Despite this, Maine did not experience significant impacts as licensees have historically been adequately reporting and there had been no need for enforcement action. Maine committed to addressing the NRC staff comments. Although the January 2023 submittal resulted in many comments, the IMPEP team observed that these comments do not result in any significant public health and safety gap. The IMPEP team expects that the comments will be resolved through the regulatory review process.

The IMPEP team notes that Maine adopted seven RATS IDs in a timely manner. After the previous IMPEP review, one of the two staff members at that time dedicated a portion of their time to adopting the RATS IDs and prepared the January 2023 submittal. This same staff member will be addressing the NRC comments on the submittal. Additionally, Maine is developing a near-term solution to ensure the ability to enforce on the reporting requirements.

Based on the IMPEP evaluation criteria in MD 5.6, the team recommends that Maine's performance with respect to the indicator, Legislation, Regulations, and Other Program Elements, be found satisfactory but needs improvement.

d. MRB Chair's Determination

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

4.2 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 the SS&D reviews and establishes useful guidance for teams. In accordance with MD 5.6, 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 [SA-108](#), "Reviewing the Non-Common Performance Indicator: SS&D 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 utilizes qualified staff from the State of New Hampshire to perform these reviews. New Hampshire staff reviewed one new action submitted during the review period. The

team confirmed that the New Hampshire staff that reviewed the action were qualified to perform SS&D reviews.

Technical Quality of the Product Evaluation

Maine has three SS&D licensees and five registration certificates. The team evaluated the one SS&D action processed during the review period. This action was a new application. This SS&D evaluation was thorough and of acceptable technical quality and addressed product integrity under normal and likely accident conditions. Health and safety issues were properly addressed, and the registration clearly summarized the product evaluation. The New Hampshire SS&D reviewers used the NUREG-1556, Volume 3 checklist for the SS&D action to ensure that all health and safety aspects had been adequately addressed. The checklists were signed and dated by the lead reviewer and a concurrence reviewer. The concurrence review provided 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. The team performed an NMED search to verify no relevant incidents were reported.

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 recommends that Maine's performance with respect to the indicator, SS&D Evaluation Program, be found satisfactory.

d. MRB Chair's Determination

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

5.0 SUMMARY

Maine's performance was found to be satisfactory for six of the seven performance indicators: Technical Staffing and Training; Status of Materials Inspection Program; Technical Quality of Inspections; Technical Quality of Licensing Actions; Technical Quality of Incident and Allegation Activities; and SS&D Evaluation Program. The team also found Maine's performance to be satisfactory, but needs improvement for the Legislation, Regulations, and Other Program Elements performance indicator. The finding for the Legislation, Regulations, and Other Program Elements performance indicator remains unchanged from the previous IMPEP review.

The team did not make any recommendations and there were no recommendations from the previous review for the team to consider.

Accordingly, the team recommended, and the MRB Chair agreed, that Maine be found adequate to protect public health and compatible with the NRC's Program. Based on the results of the current IMPEP review, the team recommended and the MRB Chair agreed

that a periodic meeting take place in approximately two years and the next full IMPEP review take place in approximately four years.

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Inspector Accompaniments

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Areas of Responsibility
Sherrie Flaherty, NMSS	Team Leader Technical Quality of Incident and Allegation Activities Inspector Accompaniment
Monica Ford, Region I	Status of Materials Inspection Program Technical Quality of Inspections
Huda Akhavannik, NMSS	Technical Staffing and Training Legislation, Regulations, and Other Program Elements
Daniel Samson, New York	Technical Quality of Licensing Actions Sealed Source and Device Evaluation Program

APPENDIX B

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: 23209
License Type: Industrial Radiography	Priority: 1
Inspection Date: 05/31/2023	Inspector's initials: TH

Management Review Board (MRB) Meeting Participants – October 12, 2023

Management Review Board:

Cathy Haney, MRB Chair, OEDO
Jessica Bielecki, OGC
Robert Lewis, NMSS

Ryan Lantz, RIV
Becki Harisis, the OAS MRB Rep., from the
State of Nebraska

IMPEP Team Members:

Sherrie Flaherty, NMSS
Monica Ford, Region I

Huda Akhavannik, NMSS
Dan Samson, State of New York

State of Maine:

Nathan Saunders, RCPD
Tom Hillman, Inspector

Jim Nizamoff, Inspector

NRC Staff:

Suzanne Dennis, OCM
Jackie Cook, RIV
Ken Erwin, MSST
Monica Ford, RI
Adelaide Giantelli, MSST
Robert Johnson, NMSS
Jeffery Lynch, NMSS
Kathy Modes, MSST

Paul Krohn, Region I
Jessie Quichocho, Region I
Lee Smith, MSST
Soly Soto, OEDO
Kelli Trotter, MSST
Duncan White, MSST
Lisa Forney, RI
Juan Ayala, Region I

Members of the Public:

James Albright, NC
Terrence Apache, UTE Mtn. Ute Tribe
Janice Archuleta, UTE Mtn. Ute Tribe
Louis Brayboy, NC
Gwen Cantsee, UTE Mtn. Ute Tribe

Randy Crowe, NC
Chinwe Ekwuribe, NC
Chelsea Smith, OK
Michael Reid, OK
Jennifer Baugh-Fennell, OK

There were no comments from Members of the Public. The meeting began at approximately 1:00 p.m. (ET) and was adjourned at approximately 1:52 p.m. (ET)