



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

February 15, 2023

MEMORANDUM TO:

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

Mark Franke, Acting Deputy Director
Office of Nuclear Material Safety
and Safeguards

Jessica A. Bielecki, Assistant General Counsel for Rulemaking,
Agreement States, and Fee Policy
Office of the General Counsel

John Monninger, Deputy Regional Administrator
Region IV

FROM:

Bethany Cecere, Acting Chief
State Agreement and Liaison Programs Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

A handwritten signature in black ink, appearing to read "Bethany Cecere".

Signed by Cecere, Bethany
on 02/15/23

SUBJECT:

PROPOSED FINAL MASSACHUSETTS AGREEMENT STATE
INTEGRATED MATERIALS PERFORMANCE EVALUATION
PROGRAM REPORT

This memorandum transmits to the Management Review Board (MRB) the proposed final report (Enclosure 1) documenting the Integrated Materials Performance Evaluation Program (IMPEP) review of the Commonwealth of Massachusetts. The IMPEP review was conducted in-person by a team of U.S. Nuclear Regulatory Commission (NRC) and Agreement State technical staff between November 14-18, 2022. In-person inspector accompaniments were completed the week of October 24, 2022. The team's preliminary findings were discussed with representatives of the Commonwealth of Massachusetts on November 18, 2022. The team issued a draft report to Massachusetts on December 21, 2022, for factual comment (NRC's Agencywide Documents Access and Management System Accession Number [ML22347A190](#)). Massachusetts' responded to the draft report by email dated December 21, 2022, from Mr. Joshua E. Daehler, Radioactive Materials Unit Supervisor for the Massachusetts Radiation Control Program ([ML23005A263](#)).

CONTACT: Lisa Forney, Region I
Lisa.Forney@NRC.gov

The team found Massachusetts' performance to be satisfactory for all performance indicators. Additionally, the team did not make any new recommendations, and there were no recommendations from the 2018 IMPEP review for the team to consider.

In accordance with the NRC's Management Directive (MD) 5.6 "Integrated Materials Performance Evaluation Program (IMPEP)," the team recommends that the Massachusetts Agreement State Program be found adequate to protect public health and safety and compatible with NRC's program. Since this is Massachusetts second consecutive IMPEP review in which they were found to be satisfactory for all performance indicators, the team recommends that a periodic meeting take place in approximately 2.5 years with the next IMPEP review to take place in approximately 5 years.

The MRB meeting for Massachusetts' IMPEP review is scheduled to be conducted on March 2, 2023, from 1:00 p.m. to 3:00 p.m. ET, as a hybrid meeting via Microsoft Teams. In accordance with MD 5.6, the meeting is open to the public, and characterized as an NRC Observation Public Meeting. The agenda for the meeting is provided as Enclosure 2.

Enclosures:

1. Massachusetts Agreement State Program IMPEP Review
2. Massachusetts Agreement State Program MRB Meeting Agenda

cc: David Crowley, Chief and Radioactive
Materials Branch Manager
Division of Health Service Regulation,
Radiation Protection Section
Department of Health and Human Services

SUBJECT: MASSACHUSETTS FY2023 PROPOSED FINAL IMPEP REPORT DATE
February 15, 2023

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 RidsOgcMailCenter
 RidsNMSSOD
 RidsRgn1MailCenter Resource
IMPEP.Resource@nrc.gov
Astrainingandtravel.Resource@nrc.gov
 JPriest, Commonwealth of Massachusetts
 JDaehler, Commonwealth of Massachusetts
 KCornelius, OAS Chair Elect

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OFFICE	RIV/DRSS	NMSS/MSST	NMSS/MSST	NMSS/MSST
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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
REVIEW OF THE MASSACHUSETTS AGREEMENT STATE PROGRAM

November 14-18, 2022

PROPOSED FINAL REPORT

EXECUTIVE SUMMARY

The results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Massachusetts Agreement State Program are discussed in this report. The review was conducted on-site from November 14-18, 2022. In-person inspector accompaniments were conducted during the week of October 24, 2022.

The team found Massachusetts' performance to be satisfactory for all seven performance indicators. The team did not make any new recommendations, and there were no recommendations from the 2018 IMPEP review for the team to consider.

Accordingly, the team recommends that the Massachusetts Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. Since this is Massachusetts second consecutive IMPEP review in which they were found to be satisfactory for all performance indicators, the team recommends that a periodic meeting take place in approximately 2.5 years with the next IMPEP review to take place in approximately 5 years.

1.0 INTRODUCTION

The Massachusetts Agreement State Program (Massachusetts) review was conducted from November 14-18, 2022, by a team of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Ohio. Team members are identified in Appendix A. In-person inspector accompaniments were conducted during the week of October 24, 2022. The inspector accompaniments are 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 June 16, 2018, to November 18, 2022, were discussed with Massachusetts 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 Massachusetts on October 5, 2022. Massachusetts provided its response to the questionnaire on October 22, 2022. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number [ML22313A143](#).

Massachusetts is administered by the Radiation Control Program which is located within the Bureau of Environmental Health. The Bureau is part of the Department of Public Health. Organization charts for Massachusetts are also available in [ML22313A140](#).

At the time of the review, Massachusetts regulated 383 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) Agreement between the NRC and the Commonwealth of Massachusetts.

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

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on June 15, 2018. The final report is available in [ML18260A311](#). 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
Recommendation: None

Sealed Source and Device (SS&D) Evaluation Program: Satisfactory
Recommendations: None

Overall finding: Adequate to protect public health and safety and compatible with the NRC's program. The 2018 IMPEP team recommended that a periodic meeting be held within 2 years and that a full IMPEP review take place in approximately 4 years.

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 Massachusetts' 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

Massachusetts is comprised of a total of 14 staff members, which includes 10 technical staff members and 4 administrative staff members. Eight of Massachusetts' technical staff members are fully qualified to perform license reviews and radioactive materials inspections across all modalities. This accounts for 12.3 full-time equivalent (FTE) for the radiation control program when fully staffed. Currently there are no vacancies. During the review period, 1 staff member left the program and 1 staff member was hired 147 days later. The vacancy and subsequent replacement had no negative impact on the program as Massachusetts employed an experienced staff member, who quickly became fully qualified in licensing and inspection activities based upon prior experience and available supplemental training.

The training and qualification program established and implemented by Massachusetts is compatible with the NRC's IMC 1248. Massachusetts met and exceeded refresher training requirements for all fully qualified license reviewers and radioactive materials inspectors throughout the entire review period.

c. Evaluation

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

d. MRB Chair's Determination

The final report will include the MRB Chair's determination regarding this indicator.

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 [SA-101](#), "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated Massachusetts' 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

Massachusetts performed a total of 431 inspections during the review period, including 217 Priority 1, 2, 3 and initial inspections. None of the 176 Priority 1, 2, or 3 inspections were conducted overdue, and only 1 of 41 initial inspections was conducted overdue. Overall, less than half a percent of Priority 1, 2, 3 and initial inspections were performed overdue. Massachusetts did not have any overdue inspections at the time of the review, and the only overdue inspection during the review period did not result in any health and safety concerns. Massachusetts inspection frequencies are the same, or in some cases more frequent, than IMC 2800 for similar license types in the program.

A sampling of 27 inspection reports indicated that 3 of the inspection findings were communicated to the licensees beyond Massachusetts’ goal of 30 days after the inspection exit or 45 days after the team inspection exit. In one case, inspection findings were communicated 54 days after the exit, or 9 days late. Findings for the remaining two inspections were affected by the pandemic and communicated to the licensees 65 and 69 days after the exits, respectively. The team noted that Temporary Instruction 003 ([TI-003](#)), “Evaluating the Impacts of the COVID-19 Public Health Emergency as Part of the Integrated Materials Performance Evaluation Program” states, in part, that impacts that are outside the Program’s control, should be noted in the report, but not be considered by the IMPEP team while establishing the overall indicator rating, provided that Massachusetts continues to maintain health, safety, and security. The team confirmed that Massachusetts continued to maintain health, safety, and security during the pandemic. Therefore, the team did not include the timeliness of reporting the two pandemic affected inspections when making the recommendation for this indicator. The team noted that there were no health and safety impacts because of these inspections being communicated to the licensees late.

During this review period, Massachusetts had 69 candidates for reciprocity inspections and performed 18 reciprocity inspections. Massachusetts performed reciprocity inspections for greater than 20 percent of candidates for each year. Specifically, Massachusetts inspected 31 percent of eligible candidates in 2018, 30 percent in 2019, 24 percent in 2020, and 33 percent in 2021. The program also reported performing reciprocity inspections for 18 percent of candidates, as of October 19, 2022. In October 2022, Massachusetts revised their reciprocity procedure to be consistent with the guidance provided in the March 3, 2020, revision of IMC 2800 and are performing these inspections in a risk-informed performance-based manner.

c. Evaluation

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

d. MRB Chair's Determination

The final report will include the MRB Chair's determination regarding this indicator.

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 Massachusetts' 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 26 inspection reports, and interviewed inspectors involved in materials inspections conducted during the review period. The team reviewed casework for inspections conducted by eight of Massachusetts' inspectors, which included one former and seven current staff members. The casework reviewed comprised medical, industrial, commercial, academic, research, and service provider licenses.

A team member accompanied four inspectors the week of October 24, 2022. Inspectors were well prepared for the inspections and utilized Massachusetts inspection procedures that were compatible with NRC inspection procedures.

The Program implemented changes to the inspection program because of the pandemic, primarily for medical facilities, directed at health and safety of program and licensee staff. While these changes sometimes extended the total time necessary to complete the inspection, none of the affected inspections were conducted outside the prescribed time frames.

During this review period, all inspectors were accompanied by a supervisor on an annual basis, until 2020. As a result of the pandemic and in accordance with [TI-003](#),

Massachusetts changed to a bi-annual accompaniment frequency for calendar years 2020, 2021, and 2022 due to restrictions at licensees' facilities. Since that change, all inspectors were accompanied under the new frequency. [TI-003](#) states in part, that if supervisory accompaniments of all qualified inspectors may not be able to be performed in each calendar year due to the pandemic, then the IMPEP team should not consider this impact while establishing the overall indicator rating provided that Massachusetts continues to maintain health, safety, and security. The team confirmed that Massachusetts continued to maintain health, safety, and security during the pandemic. Therefore, the team concluded that Massachusetts approach to supervisory accompaniments was acceptable.

The team found that the consistency and quality of Massachusetts' inspection reports, regardless of the staff member performing the inspection, or the type of licensee inspected, was particularly noteworthy. In addition to referencing the appropriate sections of Massachusetts regulations, inspectors included a detailed narrative of the licensee's facilities, equipment, and procedures as part of the inspection record. The information provided in the inspection reports facilitates good communication with management during record reviews and ensures future inspectors can easily track changes from the previous inspections.

c. Evaluation

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

d. MRB Chair's Determination

The final report will include the MRB Chair's determination regarding this indicator.

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 the Massachusetts' 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 Massachusetts' 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* (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, Massachusetts performed 1,196 radioactive materials licensing actions. The team evaluated 22 of those licensing actions. The licensing actions selected for review included 5 new applications, 8 amendments, 7 renewals, 1 termination, and 1 denial. The team evaluated casework which included the following license types and actions: broad scope, medical diagnostic and therapeutic, accelerator, commercial manufacturing and distribution, industrial radiography, research and development, academic, nuclear pharmacy, gauges, service providers, decommissioning actions, financial assurance, and bankruptcy. The casework sample represented work from one former and seven current license reviewers.

The team noted that the current versions of the Checklist to Provide a Basis for Confidence that Radioactive Materials Will be Used as Specified on the Application (Pre-Licensing Guidance) in addition to the RSRM Checklist were used appropriately. Massachusetts adapted the NRC's checklists and included the essential elements. Massachusetts conducted pre-licensing site visits for all unknown entities in accordance with the pre-licensing checklist. Massachusetts maintains a policy that any licensee at a new location that will possess Category 1 or 2 quantities of radioactive material is also required to implement increased security measures before the licensee will be authorized to possess the radioactive material.

Massachusetts used a quality control approach in its materials licensing program. Each licensing action receives a full peer review. All actions received final signature from the Program Director before being issued. In addition, Massachusetts developed a spreadsheet to assist in determining the amount of financial assurance required based on the possession limit of radioactive material on the license. The team noted that the peer reviews in addition to the consistent uses of checklists while completing licensing actions helped to ensure the technical quality of the action.

c. Evaluation

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

d. MRB Chair's Determination

The final report will include the MRB Chair's determination regarding this indicator.

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 Massachusetts' 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, 61 incidents were reported to the NMED database by Massachusetts. Of those incidents, there were 20 events related to the loss of radioactive material in transit due to the transportation carriers. In most of these cases, the material was found. Shipments that were completely lost were of low health and safety significance due to the small quantities and short-lived radioactive material present. The team evaluated 19 radioactive materials incidents which included 6 events involving lost or stolen radioactive material, 3 potential overexposures, 5 medical events, 2 pertaining to damaged equipment, and 3 reports of leaking sources. Massachusetts dispatched inspectors for on-site follow-up for 12 of the cases reviewed.

When notified of an incident, management and staff met 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. These determinations are made based on both the circumstances and the health and safety significance of the incident. The team found that Massachusetts' evaluation of incident notifications and its response to those incidents were thorough, well balanced, complete, and comprehensive.

Events that could impact public health and safety were evaluated by the staff, their supervisor, Events Coordinator, and the Director. Significant events as determined by the Director or responsible Radiation Control Program Supervisor were subjected to additional review by a Challenge Board chaired by the Director. The purpose of the

Challenge Board review was to ensure the event had been fully assessed, sufficient corrective actions to prevent recurrence had been implemented, and event closure documentation was completed.

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

During the review period, 21 allegations were received by Massachusetts. The team evaluated 11 allegations, including 4 allegations that the NRC referred to the Commonwealth, during the review period.

All allegations were evaluated by the staff, their supervisor, and the Allegations Coordinator. Massachusetts' goal was to resolve allegations within 30 days of receipt which the team observed was met. Before the closure of any allegation case, the case was reviewed and approved by the supervisor and/or Allegations Coordinator, and the Director.

c. Evaluation

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

d. MRB Chair's Determination

The final report will include the MRB Chair's determination regarding this indicator.

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 the Uranium Recovery Program; therefore, only the first 3 non-common performance indicators applied to this review: (1) Legislation, Regulations, and Other Program Elements; (2) SS&D Evaluation; and (3) LLRW.

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 Web site 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 Massachusetts’ 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](#), “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, 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

Massachusetts became an Agreement State on March 21, 1997. Massachusetts’ current effective statutory authority is contained in the Massachusetts General Law Chapters 111 and 111H. The Department of Public Health is designated as the Commonwealth’s radiation control agency. The review team noted no legislation affecting the radiation control program was passed during the review period.

Massachusetts’s administrative rulemaking process usually takes approximately 12 months from drafting to finalizing a rule. The public, NRC, other agencies, and potentially impacted licensees and registrants are offered an opportunity to comment during the process. Comments are considered and incorporated, as appropriate, before the regulations are finalized and approved by the Director of the Bureau of Environmental Health. The team noted that the Commonwealth’s rules and regulations are not subject to “sunset” laws.

On November 10, 2022, six regulation amendment packages were submitted during the review period including one revised final regulation amendment to address NRC comments from November 2, 2018. Of the regulation amendments submitted, three were submitted in a timely manner and three were impacted by the pandemic. Three regulation amendments were overdue by approximately two to nine months. Part of

Massachusetts's process for maintaining compatibility between NRC and Radiation Control Program regulations involved a delay in process involving:

- Reviewed draft material including changes based on comments from NRC will be sent to the Massachusetts Department of Public Health Legal Office for review, comment, and approval, then revised, accordingly; and
- Radiation Control Program, in coordination with the Legal Office, will draft a memo to the Public Health Council (PHC) on the proposed amendments. The draft PHC memo will be sent to the Director of the Bureau of Environmental Health for review and approval.

The Commonwealth's process normally takes 12 months, but due to the pandemic, this process took 18 months. [TI-003](#) states, in part, that the State's legislative process for adopting NRC regulations may be delayed or adversely affected due to the pandemic and should not affect the overall rating for this indicator, provided that Massachusetts continues to maintain health, safety, and security. The team confirmed that Massachusetts continued to maintain health, safety, and security during the pandemic and did not factor this into the overall rating for this indicator.

During this review period, the following three amendments were overdue, but were adopted on October 14, 2022:

- "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," 10 CFR Parts 30, 32, and 35 amendment (83 FR 33046), that was due for Agreement State adoption by January 14, 2022.
- "Miscellaneous Corrections – Organizational Changes," 10 CFR Parts 37, 40, 70, and 71 amendment (83 FR 57231), that was due for Agreement State adoption by December 21, 2021.
- "Miscellaneous Corrections," 10 CFR Parts 1, 2, 34, 37, 50, 71, 73, and 140 amendment (83 FR 30285), that was due for Agreement State adoption by July 30, 2022.

Massachusetts implemented the adoption of other program elements which included, licensing guidance, inspection guidance, and new or revised medical guidance during this review period.

c. Evaluation

The team determined that, during the review period, Massachusetts met the performance indicator objectives listed in Section 4.1.a. Based on the criteria in MD 5.6, the team recommends that Massachusetts' performance with respect to the indicator, Legislation, Regulations, and Other Program Elements, be found satisfactory.

d. MRB Chair's Determination

The final report will include the MRB Chair's determination regarding this indicator.

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: Sealed Source and Device Evaluation Program,” and evaluated Massachusetts’ 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

Massachusetts has four staff qualified to perform SS&D reviews, which equates to 1.1 FTE total. There were no vacancies and no new SS&D staff members hired or no staff that left during the review period. Massachusetts has a training program equivalent to IMC 1248, Appendix D. The team determined that individuals performing SS&D evaluation activities were adequately qualified and trained to perform their duties.

Technical Quality of the Product Evaluation

Massachusetts has 18 SS&D licensees and 73 SS&D certificates. Massachusetts processed 59 actions during the review period. These included 3 new actions, 6 inactivations, and 50 amendments. The team evaluated 23 SS&D actions and found that the evaluations were adequate, complete, and consistent with the guidance.

Evaluation of Defects and Incidents Regarding SS&Ds

The team evaluated 11 incidents involving Massachusetts SS&D registered products during the review period. These incidents were investigated in accordance with the Massachusetts' Incident and Allegation Procedure. None of the incidents were related to manufacturing or design of the sources/devices manufactured or distributed by a licensee with a SS&D registered by Massachusetts. The team determined that there were no generic defects that affected the safety of these devices.

c. Evaluation

The team determined that, during the review period, Massachusetts met the performance indicator objectives listed in Section 4.2.a. Based on the criteria in MD 5.6, the team recommends that Massachusetts's performance with respect to the indicator, SS&D Evaluation Program, be found satisfactory.

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

4.3 LLRW Disposal Program

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

Massachusetts does not have a LLRW disposal facility (i.e., it is not a host State) and is not required to have a program for licensing a disposal facility until such time as it becomes a host State. Therefore, the team did not review this indicator.

5.0 SUMMARY

Massachusetts' performance was found to be satisfactory for all seven performance indicators reviewed.

The team did not make any recommendations.

Accordingly, the team recommends that Massachusetts be found adequate to protect public health and safety and compatible with the NRC's program. Since this is Massachusetts second consecutive IMPEP review in which they were found to be satisfactory for all performance indicators, the team recommends that a periodic meeting take place in approximately 2.5 years with the next IMPEP review to take place in approximately 5 years.

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Inspector Accompaniments

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Areas of Responsibility
Jacqueline D. Cook, Region IV	Team Leader Legislation, Regulations and Other Program Elements
Lisa A. Forney, Region I	Team Leader in Training Technical Staffing and Training Inspector Accompaniments
Robert Johnson, NMSS	Status of the Materials Inspection Program
Stephen James, OH	Technical Quality of Inspections
Farrah Gaskins, Region I	Technical Quality of Licensing Actions
Frank Tran, Region III	Technical Quality of Incident and Allegation Activities
Stephen Poy, NMSS	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.: 44-0191
License Type: Nuclear Medicine	Priority: 3
Inspection Date: 10/24/2022	Inspector's initials: EC

Accompaniment No.: 2	License No.:12-8361
License Type: Manufacturing & Distribution Broad Scope	Priority: 2
Inspection Date: 10/25/2022	Inspector's initials: BL, AC

Accompaniment No.: 3	License No.: 44-0164
License Type: HDR, Nuclear Medicine	Priority: 2
Inspection Date: 10/26/2022	Inspector's initials: CW

Accompaniment No.: 4	License No.: 19-0672
License Type: Industrial Radiography	Priority: 1
Inspection Date: 10/27/2022	Inspector's initials: SM

**Massachusetts Agreement State Program Management Review Board Meeting Agenda
March 2, 2023, 1:00 p.m. – 3:00 p.m. (ET), via Microsoft Teams**

1. Meeting Convened.
 - a. Announcement of NRC Public Observation Meeting.
 - b. Introduction of MRB members, review team members, Agreement State representatives, and other participants.
 - c. Request for members of the public to identify themselves and their affiliation.
2. MRB Chair Convenes the Business Portion of the Meeting.
 - a. Consideration of the Agreement State's IMPEP Report.
 - b. Presentation of Performance Indicator Findings for the Agreement State's Program and Discussion:
 - i. Technical Staffing and Training
 - ii. Status of Materials Inspection Program
 - iii. Technical Quality of Inspections
 - iv. Technical Quality of Licensing Actions
 - v. Technical Quality of Incident and Allegation Activities
 - vi. Legislation, Regulations, and Other Program Elements
 - vii. Sealed Source and Device Evaluation Program
 - c. IMPEP Team Recommendations.
 - d. MRB Consultation/Comments on Issuance of Report.
 - e. Request for comments from the Agreement State representatives, MRB Members, and IMPEP team members.
 - f. Overall MRB Chair Determination.
3. MRB Chair Closes the Business Portion of the Meeting
4. Questions or comments from members of the public.
5. Meeting adjournment.