



UNITED STATES
NUCLEAR REGULATORY COMMISSION
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October 11, 2018

Mr. John Priest, Director
Radiation Control Program
Commonwealth of Massachusetts
Department of Public Health
Schrafft Center Suite 1M2A
529 Main Street
Charlestown, MA 02129

Dear Mr. Priest:

On September 13, 2018, the Management Review Board (MRB), which consisted of U.S. Nuclear Regulatory Commission (NRC) senior managers and an Organization of Agreement States Liaison to the MRB, met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Massachusetts Agreement State Program. The MRB found the Massachusetts Agreement State Program adequate to protect public health and safety, and compatible with the NRC's program.

The enclosed final report contains a summary of the IMPEP team's findings (Section 5.0). The team did not make any recommendations regarding program performance and determined that the recommendation from the 2014 IMPEP review should be closed (see Section 2.0). Based on the results of the current IMPEP review, the next full IMPEP review will take place in approximately 4 years, with a periodic meeting in approximately 2 years.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Daniel H. Dorman
Acting Deputy Executive Director for Materials, Waste,
Research, State, Tribal, Compliance, Administration,
and Human Capital Programs
Office of the Executive Director for Operations

Enclosure:
Massachusetts Final IMPEP Report

cc: Augustinus Ong, NH
Organization of Agreement States
Liaison to the MRB



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

JUNE 11-15, 2018

FINAL REPORT

Enclosure

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Massachusetts program. The review was conducted during the period of June 11-15, 2018, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Louisiana.

Based on the results of this review, the Massachusetts Agreement State Program's performance was found to be satisfactory for all the indicators evaluated.

The team did not make any new recommendations and determined that the recommendation from 2014 IMPEP review should be closed. The MRB agreed.

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

1.0 INTRODUCTION

This report presents the results of the review of the Massachusetts Agreement State Program radioactive materials safety program. The review was conducted during the period of June 11-15, 2018, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Louisiana. Team members are identified in Appendix A. The review was conducted in accordance with the "Agreement State Program Policy Statement," published in the *Federal Register* on October 18, 2017 (82 FR 48535), and NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of August 2, 2014, to June 15, 2018, 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 January 29, 2018. Massachusetts provided its response to the questionnaire by e-mail on May 23, 2018. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML18151A555.

A draft of this report was issued to Massachusetts on July 17, 2018, for factual comment (ADAMS Accession Number ML18194A860). Massachusetts responded to the draft report by e-mail dated July 24, 2018, from John M. Priest Jr., Director, Radiation Control Program, Massachusetts Department of Public Health (ADAMS Accession Number ML181214A538). The Management Review Board (MRB) convened on September 13, 2018, to discuss the team's findings.

The Massachusetts Agreement State Program is administered by the Radiation Control Program (the Program) which is located within the Department of Public Health (the Department), Bureau of Environmental Health. Organization charts for the Massachusetts Agreement State Program are available in ADAMS using the Accession Number ML18151A579.

At the time of the review, the Massachusetts Agreement State Program regulated 413 specific licenses authorizing possession and use of radioactive materials. The review focused on the Massachusetts Agreement State Program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the Commonwealth of Massachusetts.

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

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on August 1, 2014. The final report is available in ADAMS (Accession Number ML14301A012). The results of the review and the status of the recommendation are as follows:

Technical Staffing and Training: Satisfactory
Recommendation: None

Status of Materials Inspection Program: Satisfactory
Recommendation: None

Technical Quality of Inspections: Satisfactory but Needs Improvement
Recommendation: None

While there were no formal recommendations made in this area, the 2014 team noted: (1) that the Massachusetts program did not consistently implement its existing procedures for documenting inspection reports; and (2) during inspector accompaniments, inspectors did not consistently identify important health, safety, or security items, specifically with respect to the completeness and thoroughness of the inspection.

In response, Program management developed and implemented a corrective action plan which included providing guidance to the inspection staff regarding the use of existing inspection guidance, including guidance related to inspection documentation, as well as the expectation to use performance-based inspection techniques. Program management set clear expectations for the performance of security-related inspections, and re-inspections of licensees were performed where inspector accompaniments identified technical deficiencies. There was also a renewed management commitment to increased oversight of the Program.

The 2018 team noted that the deficiencies identified in this indicator during the 2014 review had been corrected and that sustained performance over this review period had been demonstrated. See Section 3.3 for additional details.

Technical Quality of Licensing Actions: Satisfactory but Needs Improvement
Recommendation: None

While there were no formal recommendations made in this area, the 2014 team noted several deficiencies including: (1) not consistently including maximum possession limits on licenses in accordance with NRC requirements; (2) not consistently using specific license conditions addressing additional safety considerations for certain models of irradiators in accordance with the NRC Order issued on July 3, 1984; (3) not consistently reviewing enforcement and inspection history during the license renewal process, or not properly documenting the enforcement history review when completed; (4) using superseded licensing guidance which did not contain current regulatory references or updated

risk-informed licensing approaches for medical licensing; and (5) using a license condition for Increased Controls and Fingerprinting Order licenses that had not been previously approved by the NRC.

In response, the Program made changes across the licensing program. These included: reviewing all licenses subject to NRC requirements to ensure that maximum possession limits were placed on the affected licenses and addressed during all future licensing actions; adding the standard license condition to and then issuing corrected licenses to those licensees who had been subject to the NRC Order issued on July 3, 1984; revising its current licensing procedures to ensure that license reviewers were reviewing enforcement and inspection history during the license renewal process, as well as properly documenting those reviews; revising its licensing procedures to ensure that current licensing guidance was used during licensing actions; and reviewing all Increased Controls and Fingerprinting Order licenses to identify those licenses that contained the license condition not approved by the NRC, replacing that condition with the license condition which had been approved by the NRC, and issuing corrected licenses to those affected licensees.

The 2018 team noted that the deficiencies identified in this indicator during the 2014 review had been corrected and that sustained performance over this review period had been demonstrated. See Section 3.4 for additional details.

Technical Quality of Incident and Allegation Activities: Satisfactory but Needs Improvement

While there were no formal recommendations made in this area, the 2014 team noted several deficiencies including: (1) weaknesses in the Program's responses to reported incidents, including inconsistent coordination, consistency, and thoroughness; (2) not consistently using identified guidance documents which direct the Program's actions when assessing an event to determine its level of response; (3) failing to identify deficiencies in licensee-provided information when assessing and closing out an event; and (4) relying on licensee conclusions for medical events rather than performing independent evaluations of an event.

In response, the Program made multiple changes to the manner in which events are evaluated, reviewed, and closed. These included: developing and implementing a procedure and event evaluation form to ensure that staff consistently use appropriate guidance documents when determining the level of response to an event, including the scope and timeframe of the Program's response, as well as to aid staff in providing timely evaluation of reported events; instituting a policy to clarify event close-out expectations when evaluating licensee-provided information against the associated regulatory reporting requirements; and changing the Program's approach to evaluating licensee conclusions for medical events to include a programmatic review and evaluation of the event.

The 2018 team noted that the deficiencies identified in this indicator during the 2014 review had been corrected and that sustained performance over this review period had been demonstrated. See Section 3.5 for additional details.

One recommendation was issued by the team for the Program's evaluation and implementation and is identified below:

Recommendation: "The review team recommends that the Commonwealth strengthen its incident response program and take measures to ensure that the Program's evaluation of events is thorough, complete, properly documented to facilitate future follow-up, and undergoes appropriate management review prior to closeout." (Section 3.5 of the 2014 IMPEP report)

Status: The review team examined Massachusetts' incident response program and found that inspectors assigned to follow up on each event worked closely with management to ensure that actions taken in response to incidents were thorough and comprehensive, and that inspectors' reports were complete and properly documented. Documentation of each incident reviewed by the team was found to be complete, demonstrated a thorough review of the incident, and contained clear descriptions of any findings to facilitate future follow-up. A tracking sheet included with each incident file documented the reviewer assignment, priority for response, and timely and appropriate management review of the response prior to close-out of the event. This recommendation is closed.

Compatibility Requirements: Satisfactory
Recommendation: None

Sealed Source and Device Evaluation Program: Satisfactory
Recommendation: None

Overall finding: Adequate to protect public health and safety, but needs improvement, and compatible with the NRC's program.

The review team also recommended, and the MRB agreed, that a period of Monitoring be initiated for Massachusetts. Leading up to the 2018 review, the Program continued to be on Monitoring.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the NRC regional and Agreement State radioactive materials programs. These indicators are: (1) Technical Staffing and Training; (2) Status of Materials Inspection Program; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

The ability to conduct effective licensing and inspection programs is largely dependent on having a sufficient number of experienced, knowledgeable, well-trained technical personnel. Under certain conditions, staff turnover could have an adverse effect on the implementation of these programs, and could affect public health and safety. Apparent trends in staffing must be explored. Review of staffing also requires consideration and

evaluation of the levels of training and qualification. The evaluation standard measures the overall quality of training available to, and taken by, materials program personnel.

a. Scope

The team used the guidance in State Agreements procedure SA-103, "Reviewing the Common Performance Indicator: Technical Staffing and Training," and evaluated Massachusetts' performance with respect to the following performance indicator objectives:

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Agreement State training and qualification program is equivalent to NRC Inspection Manual Chapter (IMC) 1248, "Formal Qualifications Program for Federal and State Material and Environmental Management Programs."
- Qualification criteria for new technical staff are established and are followed or qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing of the licensing and inspection programs.
- Management is committed to training and staff qualification.
- Individuals performing materials licensing and inspection activities are adequately qualified and trained to perform their duties.
- License reviewers and inspectors are trained and qualified in a reasonable period of time.

b. Discussion

The Massachusetts Agreement State Program is comprised of 11 technical staff members, including supervisors, which equals 9.2 full time equivalents for the radioactive materials program when fully staffed. This includes a Director, as well as clerical and billing staff. At the time of the review, there were no vacancies. During the review period, three staff members left the program and five staff members were hired. On average, positions were vacant from 7 to 9 months. All employees hired during this review period have science degrees with three having a master of science. Massachusetts has a training and qualification program compatible with the NRC's IMC 1248.

Department management is very supportive of the training program. The five most recent hires have attended a combined 50 NRC training courses since September 2014. Continuing education is promoted and tracked by the Materials Unit Supervisor. The training qualification record that is used to track milestones directed toward qualification is comprehensive and includes in-house training, on the job instruction, and formal courses. A mentoring program has been implemented where senior inspectors or license reviewers provide on the job training for more junior employees.

c. Evaluation

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

d. MRB Decision

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

3.2 Status of Materials Inspection Program

Periodic inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety practices. The frequency of inspections is specified in IMC 2800, "Materials Inspection Program," and is dependent on the amount and kind of material, the type of operation licensed, and the results of previous inspections. There must be a capability for maintaining and retrieving statistical data on the status of the inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated 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 frequency prescribed in IMC 2800.
- Candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 1220, "Processing of NRC Form 241, Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters, and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20."
- Deviations from inspection schedules are normally coordinated between technical staff and management.
- There is a plan to perform any overdue inspections and reschedule any missed or deferred inspections; or a basis has been established for not performing any overdue inspections or rescheduling any missed or deferred inspections.
- Inspection findings are communicated to licensees in a timely manner (30 calendar days, or 45 days for a team inspection, as specified in IMC 0610, "Nuclear Material Safety and Safeguards Inspection Reports").

b. Discussion

Massachusetts' inspection frequencies are the same for similar license types found in the NRC's IMC 2800. Massachusetts has implemented an inspection "stretch" goal that is more restrictive than NRC's. Assigned inspections are performed no later than 10 percent beyond the Program's due date as opposed to the NRC's current policy of no later than 50 percent beyond the Program's due date. The Program performed 151 Priority 1, 2, and 3 inspections and 48 initial inspections over the review period, none of which were conducted overdue by NRC's standards.

Initial inspections of new licenses were performed within 12 months of license issuance. Each year of the review period, Massachusetts performed greater than 20 percent of candidate reciprocity inspections, with percentages ranging from 28 percent for 2014 to 54 percent for 2016.

Of the 23 inspection files reviewed, inspection findings were conveyed to licensees greater than 30 days after the inspection in only two instances. The late documentation was conveyed to the licensee in 45 and 60 days, respectively, after the completion of the inspection. In both cases, the delays were a result of transmission of findings around the holidays and the travel schedule of the manager.

c. Evaluation

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

d. MRB Decision

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

3.3 Technical Quality of Inspections

Inspections, both routine and reactive, provide assurance that licensee activities are carried out in a safe and secure manner. Accompaniments of inspectors performing inspections, and the critical evaluation of inspection records, are used to assess the technical quality of an Agreement State's inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated 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 consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated the inspection reports and enforcement documentation, and interviewed inspectors involved in materials inspections conducted during the review period. The casework reviewed included 23 inspections conducted by 11 of Massachusetts' inspectors and covered medical, industrial, commercial, academic, research, service, security, and reciprocity licenses.

The team found that inspection documents were thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed. Inspection findings were clearly communicated to the licensee and violations were written with a direct link to a regulation or license condition. Inspection documentation received timely management review with no reviews taking longer than 30 days to complete. In the casework reviewed, every inspection addressed previously identified open items and violations.

A team member accompanied six program inspectors during the weeks of March 19-23 and May 21-24, 2018. No performance issues were noted during the inspector accompaniments. The inspectors were well-prepared and thorough, and assessed the impact of licensed activities on health, safety, and security. Inspector accompaniments are identified in Appendix B.

Supervisory accompaniments for each of the materials inspectors were performed in each year of the review period by the Materials Unit Supervisor. The accompaniments were well documented and the supervisor discussed the results of the evaluation with each employee.

The team verified that the Program maintains a wide variety of appropriately calibrated survey instruments to support the inspection program, and to respond to radioactive materials incidents and emergency situations. Detection instruments are available for gamma, beta, and alpha, as well as dose rates. The Program had several portable multi-channel analyzers for assessing and identifying unknown sources. The team conducted a random instrumentation check and all meters were calibrated. A senior staff member manages the instrumentation program and assures that the calibrations are tracked and staggered so that appropriated instrumentation is available.

c. Evaluation

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

d. MRB Decision

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

3.4 Technical Quality of Licensing Actions

The quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, as well as security. An assessment of licensing procedures, actual implementation of those procedures, and documentation of communications and associated actions between the 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 State Agreements procedure 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., financial assurance, increased controls, pre-licensing guidance).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and can be inspected.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.

- Applicable guidance documents are available to reviewers and are followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).
- Licensing practices for risk-significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

b. Discussion

During the review period, Massachusetts performed 954 radioactive materials licensing actions. The team evaluated 23 of those licensing actions. The licensing actions selected for review included four new applications, nine amendments, seven renewals and three terminations. The team evaluated casework which included the following license types and actions: broad scope, medical diagnostic and therapy, accelerator, commercial manufacturing and distribution, industrial radiography, research and development, academic, nuclear pharmacy, self-shielded irradiators, service providers, decommissioning actions, financial assurance, and bankruptcies. The casework sample represented work from 12 license reviewers.

The team found that licensing actions were well documented. Each completed licensing action was peer reviewed before submission to the Program Director for signature. The team noted that the incorporation of a licensing action peer review process has led to consistently high quality products.

The team evaluated the pre-licensing guidance and the pre-licensing site visit aspect of the new license application process. The Program conducted pre-licensing site visits for all unknown entities in accordance with the pre-licensing checklist. The Program issued a license once the applicant had adequate facilities and equipment, as well as a qualified radiation safety officer and materials users. In addition, the Program did not issue licenses to new applicants with licensed radioactive material quantity equal to or exceeding Category 2 quantities unless the applicant had implemented increased security measures in accordance with Massachusetts' requirement, which is compatible to NRC's. Moreover, the Program maintains a policy that any licensee at a new location that will possess Category 2 quantities and above of radioactive material is also required to implement increased security measures before the location will be authorized to possess the Category 2 quantities and above in the license.

c. Evaluation

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

d. MRB Decision

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

3.5 Technical Quality of Incident and Allegation Activities

The quality, thoroughness, and timeliness of response to incidents and allegations of safety concerns can have a direct bearing on public health and safety. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal and external coordination, and investigative and followup actions, are a significant indicator of the overall quality of the incident response and allegation programs.

a. Scope

The team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated Massachusetts' performance with respect to the following performance indicator objectives:

- Incident response, investigation, and allegation procedures are in place and followed.
- Response actions are appropriate, well-coordinated, and timely.
- On-site responses are performed when incidents have potential health, safety, or security significance.
- Appropriate followup actions are taken to ensure prompt compliance by licensees.
- Followup inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the Nuclear Material Events Database (NMED).
- Allegations are investigated in a prompt, appropriate manner.
- Concerned individuals are notified of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

During the review period, 37 incidents were reported to the NMED database by Massachusetts. The team selected 14 events to evaluate. The casework reviewed included: seven lost/stolen radioactive materials events; one potential fetal overexposure; two medical events; three leaking source events, two of which that were also categorized as damaged equipment events; and one contamination event. The team found that inspectors properly evaluated each event, interviewed involved individuals, and thoroughly documented their findings. Enforcement actions were taken where appropriate.

The team found that when an event is reported to the Program, it is evaluated to determine its health and safety significance and what the appropriate response should be. That response can range anywhere from responding immediately to reviewing the event during the next inspection. The Program responded immediately to each incident that it determined had potential health and safety significance, including dispatching inspectors for onsite follow up for six of the cases reviewed. The team also found that the Program responded to events in accordance with their established procedure.

The team evaluated the Program's reporting of events to the NRC's Headquarters Operations Officer (HOO). The team noted that in each case evaluated where HOO notification was required, the Program reported all events within the required timeframe. Incidents were also appropriately reported to the NMED.

During the review period, 14 allegations were received by Massachusetts. The team evaluated 11 of the allegations, including four allegations referred by NRC. All of the allegations reviewed were appropriately closed, concerned individuals were notified of the actions taken, and alleged identities were protected.

c. Evaluation

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

d. MRB Decision

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

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements; (2) Sealed Source and Device (SS&D) Evaluation Program; (3) Low-Level Radioactive Waste Disposal (LLRW) Program; and (4) Uranium Recovery Program. The NRC's Agreement with Massachusetts retains regulatory authority for a low-level radioactive waste disposal program and a uranium recovery program; therefore, only the first two non-common performance indicators applied to this review.

4.1 Compatibility Requirements

State statutes should authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health, safety, and security. The State must be authorized through its legal authority to license, inspect, and enforce legally binding requirements, such as regulations and licenses.

NRC regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted in a time frame so that the effective date of the State requirement is not later than 3 years after the effective date of the NRC's final rule. Other program elements, as defined in Appendix A of State Agreements procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements," that have been designated as necessary for maintenance of an adequate and compatible program, should be adopted and implemented by an Agreement State within 6 months following NRC designation.

a. Scope

The team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," and evaluated 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, as amended.
- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were adopted no later than 3 years after the effective date of the NRC regulation.
- Other program elements, as defined in SA-200 that have been designated as necessary for maintenance of an adequate and compatible program, have been adopted and implemented within 6 months of NRC designation.
- The State statutes authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement.
- The State is authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses.
- Sunset requirements, if any, do not negatively impact the effectiveness of the State's regulations.

b. Discussion

The Commonwealth of Massachusetts became an Agreement State on March 21, 1997. The authority under which the Program administers the Agreement is located in Massachusetts General Law Chapter 111H and Chapter 111. The statute authorizing the Governor to enter into the Agreement is contained in Chapter 111H, and the statute under which the Program operates is in Chapter 111. The Department is designated as the Commonwealth's radiation control agency. The review team noted that no legislation which would affect the Agreement State program or its authority was passed during the review period. Massachusetts regulations are not subject to sunset review.

The Commonwealth's regulations for the Program are located in Title 105 of the Code of Massachusetts Regulations Section 120, and apply to ionizing radiation, whether emitted from radionuclides or devices. Massachusetts requires a license for possession and use of radioactive material.

The review team examined the Program's rulemaking process. Regulations are drafted by the Program, reviewed by Program managers and staff, and then sent to the NRC for a compatibility review. After addressing any compatibility comments, the regulations are then reviewed by the Program's legal counsel. A memorandum containing the regulations, revised to reflect legal counsel comments, is presented to the Department Commissioner for review. The regulations are then presented to the Commonwealth's Public Health Council (PHC), which meets monthly and approves the proposed regulations for public comment. Once comments are addressed, the revised regulations are submitted to the PHC for promulgation. After PHC approval, the final regulations are submitted to the Secretary of the Commonwealth, who establishes an effective date for the regulations. A copy of the final promulgated regulations is then sent to the NRC for a compatibility review as final regulations. The rulemaking process takes approximately 9 months to complete.

During the review period, the Program submitted three final amendments that were overdue for State adoption at the time of submission to the NRC:

- "Licenses, Certifications, and Approvals for Materials Licensees," 10 CFR Parts 30, 36, 39, 40, 70 and 150 amendment (76 FR 56951), that was due for Agreement State adoption on November 14, 2014. (RATS ID 2011-2)
- "Advance Notification of Native American Tribes of Transportation of Certain Types of Nuclear Waste," 10 CFR Part 71 amendment (77 FR 34194), that was due for Agreement State adoption on August 10, 2015. (RATS ID 2012-2)
- "Technical Corrections," 10 CFR Parts 30, 34, 40 and 71 amendment (77 FR 39899), that was due for Agreement State adoption on August 6, 2015. (RATS ID 2012-3)

An additional three amendments were overdue at the time of the review:

- "Decommissioning Planning," 10 CFR Parts 20, 30, 40 and 70 amendment (76 FR 35512), that was due for Agreement State adoption on December 17, 2015. (RATS ID 2011-1)
- "Requirements for Distribution of Byproduct Material," 10 CFR Parts 30, 31, 32, 40 and 70 amendment (77 FR 43666), that was due for Agreement State adoption on October 23, 2015. (RATS ID 2012-4)

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

These amendments were overdue for several reasons including the promulgation of higher priority regulations outside the Program and Program management prioritizing resources to hire and train staff. The first two amendments were submitted to the NRC as proposed regulations for compatibility review nearly 1 year after the rules were due for adoption. The third was submitted as a proposed regulation approximately 1 month after the rule was due for adoption. Program management indicated that all regulations would be updated by the time of the September 13, 2018, Management Review Board meeting.

c. Evaluation

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

- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were, in some cases, adopted later than 3 years after the effective date of the NRC regulation.

Although all regulations were up-to-date at the time of the MRB meeting, during the review period the Program submitted three final amendments that were overdue for State adoption when submitted to the NRC. Additionally, three amendments were overdue at the time of the review. These amendments went overdue for a variety of reasons; some the Program had control over and others where it did not. Those issues have now been resolved

Based on the criteria in MD 5.6, the team recommended that Massachusetts’ performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

d. MRB Decision

The MRB agreed with the team’s recommendation and found Massachusetts’ performance with respect to this indicator to be satisfactory.

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

Adequate technical evaluations of SS&D designs are essential to ensure that SS&Ds will maintain their integrity and that the design is adequate to protect public health and safety. NUREG-1556, Volume 3, “Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration,” provides information on conducting SS&D reviews and establishes useful guidance for teams. Under this guidance, three sub elements: Technical Staffing and Training, Technical Quality of the Product Evaluation Program, and Evaluation of Defects and Incidents

Regarding SS&D's, are evaluated to determine if the SS&D program is satisfactory. Agreement States with authority for SS&D evaluation programs who are not performing SS&D reviews are required to commit in writing to having an SS&D evaluation program in place before performing evaluations.

a. Scope

The team used the guidance in State Agreements procedure SA-108, "Reviewing the Non-Common Performance Indicator: Sealed Source and Device Evaluation Program," and evaluated 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

At the time of the review, the Program had four staff qualified to perform SS&D evaluations with no vacancies. During the review period, one of the SS&D staff members retired from the Program and two new staff were hired as replacements.

The team noted that, over the review period, the Program was able to successfully plan for this retirement knowing in advance that their senior SS&D reviewer was going to

retire. The Program was able to contract with the retired individual to return and train the two new staff members. The retired reviewer worked with the Program for 2 years, until both new staff members were fully qualified.

Massachusetts has a training program equivalent to NRC training requirements listed in the NRC's IMC 1248, Appendix D.

Technical Quality of the Product Evaluation

Massachusetts has 58 SS&D registrations from 13 licensees. The Program completed 86 SS&D actions during the review period, which included 46 amendments, 10 new applications, 26 inactivations, and four corrected sheets. The team evaluated 71 of these actions and found that the registration sheets were complete, thorough and of acceptable technical quality.

Evaluation of Defects and Incidents Regarding SS&Ds

The team evaluated one incident reported from another State during the review period involving a Massachusetts-registered nuclear gauge.

The Program evaluated the device which had a failure of the shutter to remain open. The evaluation revealed that Loctite (an adhesive) had not been used for two screws to hold a magnet in the correct position to maintain the shutters in an open position. The Program required the distributor to notify all facilities that had purchased the gauge to be aware of this potential problem and what to inspect. This was determined to be a manufacturing quality control concern and not a design error. The device manufacturer retrained the targeted assembly workers about applying Loctite to the two screws during assembly. The Program determined that this concern was corrected.

c. Evaluation

The team determined that, during the review period, Massachusetts met the performance indicator objectives listed in Section 4.2.a., and recommended that, based on the criteria in MD 5.6, Massachusetts' performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

d. MRB Decision

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

4.3 Low-level Radioactive Waste Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement," to allow a State to seek an amendment for the regulation of low-level radioactive waste (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.

The Commonwealth 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. The team did, however, follow up on the Program's questionnaire response, which indicated that a Program Coordinator performs low-level radioactive waste fee and survey collection activities. The team discussed the referenced fees and activities with the Program. The Program collects fees from the Commonwealth's Class A low-level waste generators, and these fees are deposited into a Massachusetts low-level waste fund. This money is used by the Commonwealth to monitor the low-level waste activities of the generators licensed by the Program. The generators work with a low-level waste processor to dispose of their material.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Massachusetts' performance was found to be satisfactory for all performance indicators reviewed. The team did not make any recommendations regarding program performance and determined that the recommendation from the 2014 IMPEP review should be closed. The MRB agreed.

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

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Inspection Accompaniments

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Areas of Responsibility
Randy Erickson, Region IV	Team Leader Status of Materials Inspection Program Compatibility Requirements
John Miller, Region I	Technical Staffing and Training Technical Quality of Inspections
Shawn Seeley, Region I	Technical Quality of Licensing Actions Inspector Accompaniments
Darren Piccirillo, Region III	Status of Materials Inspection Program (assist Erickson)
Geoffrey Warren, Region III	Technical Quality of Inspections Technical Quality of Incident and Allegation Activities
James Pate, LA	Sealed Source & Device Evaluation Program

APPENDIX B

INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: 44-0020
License Type: Medical Written Directive	Priority: 3
Inspection Date: 3/19/18	Inspector: HH

Accompaniment No.: 2	License No.: 60-0095
License Type: Broad Medical	Priority: 2
Inspection Date: 3/20-21/18	Inspector: TC / BL

Accompaniment No.: 3	License No.: 42-0690
License Type: Distribution License	Priority: 2
Inspection Date: 5/21/18	Inspector: BP

Accompaniment No.: 4	License No.: 19-7781
License Type: Industrial Radiography (TJS)	Priority: 1
Inspection Date: 5/22/18	Inspector: SM

Accompaniment No.: 5	License No.: 30-A131
License Type: SS Irradiator	Priority: 5
Inspection Date: 5/23/18	Inspector: ES