



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

November 14, 2014

Suzanne K. Condon  
Associate Commissioner and Director  
Bureau of Environmental Health  
Department of Public Health  
250 Washington Street, 7th Floor  
Boston, MA 02108

Dear Ms. Condon:

On October 28, 2014, the Management Review Board (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 program adequate to protect public health and safety, but needs improvement, and compatible with the U.S. Nuclear Regulatory Commission's (NRC) program. The MRB directed that a period of Monitoring be initiated for Massachusetts. Monitoring may be used in cases where one or more performance indicators are less than fully satisfactory. Monitoring is an informal process that allows the NRC to maintain an increased level of communication with an Agreement State program.

Section 5.0, page 19, of the enclosed final report contains a summary of the IMPEP team's findings and recommendation. We request your evaluation and response to the recommendation within 30 days from receipt of this letter. Your response to the recommendation should be submitted to Laura A. Dudes, Director, Division of Material Safety, State, Tribal, and Rulemaking Programs. Based on the results of the current IMPEP review, the next full review of the Massachusetts Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled for July 2015.

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,

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Roy P. Zimmerman  
Acting Deputy Executive Director for  
Materials, Waste, Research, State, Tribal and  
Compliance Programs  
Office of the Executive Director for Operations

Enclosure:  
Massachusetts Final IMPEP Report

cc: See next page

cc: Lee Cox, NC  
Organization of Agreement States  
Liaison to the MRB

John M. Priest, Jr., Director  
Radiation Control Program

John Giarrusso, Jr., Chief  
Emergency Management Agency  
State Liaison Office



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

July 28–August 1, 2014

**FINAL REPORT**

Enclosure

## EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Massachusetts Agreement State Program. The review was conducted during the period of July 28–August 1, 2014, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Texas.

Based on the results of this review, the review team recommended, and the Management Review Board (MRB) agreed, that Massachusetts' performance be found satisfactory, but needs improvement, for three of seven indicators: Technical Quality of Inspection Activities, Technical Quality of Licensing Actions, and Technical Quality of Incident and Allegation Activities. The review team recommended, and the MRB agreed, that Massachusetts' performance be found satisfactory for the other indicators reviewed: Technical Staffing and Training, Status of Materials Inspection Program, Sealed Source and Device Evaluation Program, and Compatibility Requirements.

The review team determined that the eight recommendations from previous IMPEP reviews were addressed by the Program and should be closed. The review team made one new recommendation to strengthen the Commonwealth's incident response program. The review team recommended, and the MRB agreed, that the Commonwealth 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.

Overall, the review team recommended, and the MRB agreed, that the Massachusetts Agreement State Program be found adequate to protect public health and safety, but needs improvement, and compatible with the NRC's program. Based on the results of the current IMPEP review, and in accordance with the criteria in NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program," dated February 26, 2004, the review team recommended, and the MRB agreed, that a period of Monitoring be initiated for Massachusetts.

The review team further recommended, and the MRB agreed, that a Periodic meeting be conducted in one year from this review to assess the Commonwealth's progress and efforts taken to address the identified performance issues, and that the next IMPEP review take place in approximately 4 years.

## 1.0 INTRODUCTION

This report presents the results of the review of the Massachusetts Agreement State Program. The review was conducted during the period of July 28–August 1, 2014, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Texas. Team members are identified in Appendix A. The review was conducted in accordance with the “Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy,” published in the *Federal Register* on October 16, 1997, and [NRC Management Directive 5.6](#), “Integrated Materials Performance Evaluation Program (IMPEP),” dated February 26, 2004. Preliminary results of the review, which covered the period from July 17, 2010, to August 1, 2014, were discussed with Massachusetts managers on the last day of the review.

A draft of this report was issued to Massachusetts on September 3, 2014, for factual comment. Massachusetts responded to the findings and conclusions of the review by letter dated September 29, 2014. A copy of the Commonwealth’s response is included as an attachment to this report. The Management Review Board (MRB) met on October 28, 2014, to consider the proposed final report. The MRB found the Massachusetts Agreement State Program adequate to protect public health and safety, but needs improvement, and compatible with the NRC’s program.

The Massachusetts Agreement State Program is administered by the Radiation Control Program (the Program). The Program is part of the Bureau of Environmental Health (the Bureau), within the Department of Public Health. An organization chart for the Program is included in Appendix B.

At the time of the review, the Massachusetts Agreement State Program regulated approximately 444 specific licenses authorizing byproduct, source, and certain special nuclear materials (radioactive materials). The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the Commonwealth of Massachusetts.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Program on February 3, 2014. The Program provided its response to the questionnaire on July 2, 2014. A copy of the questionnaire response may be found in the NRC’s Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML14183B604.

The review team’s general approach for conduct of this review consisted of (1) an examination of the Program’s response to the questionnaire, (2) review of applicable Massachusetts statutes and regulations, (3) an analysis of quantitative information from the Program’s database, (4) technical review of selected regulatory actions, (5) field accompaniments of four of the Program’s inspectors, and (6) interviews with Program staff and managers. The review team evaluated the information gathered against the established criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the Massachusetts Agreement State Program’s performance.

Section 2.0 of this report discusses the Commonwealth's actions in response to recommendations made during previous IMPEP reviews. The results of the current review of the common performance indicators are presented in Section 3.0. The results of the current review of the applicable non-common performance indicators are presented in Section 4.0. The review team's findings and recommendations are summarized in Section 5.0.

## 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on July 16, 2010, the review team made eight recommendations in regard to the Program's performance. The status and determination, which the MRB agreed with, of each recommendation is as follows:

1. "The review team recommends that the Commonwealth pursue adequate funding to support and implement the staffing plan which is needed to meet current program demands as well as the projected increase in workload. (Section 3.1 of the 2006 IMPEP report)"

Status: The Program is funded by licensing and registration fees. The funds are placed into a retained revenue account and the Program is allowed to retain a certain amount of the revenue to meet current Program demands as well as the projected increase in workload. Since the 2010 IMPEP review, the Program has hired additional technical staff to fill the vacancies identified during the previous review. In addition, the Program Director position, which was previously filled with an Acting Director, has been permanently filled. Several technical staff members were promoted during the review period and the vacancies created as a result of those promotions are being addressed by the Program in a timely manner. This recommendation is closed.

2. "The review team recommends that the Commonwealth monitor and maintain accurate information in its database so it can be used by Program management and staff as a reliable planning and tracking tool to ensure that inspections are completed within the required timeframe. (Section 3.2 of the 2010 IMPEP report)"

Status: The review team examined the Program's database and found that the Program maintains accurate information in its database. Program management demonstrated that the database is being utilized as an effective planning and tracking tool. The Program has instituted a system to monitor the database to ensure that inspections are conducted in a timely manner. The Program generates reports to flag routine, initial and Increased Controls (IC) inspections approaching their due dates. Inspection assignments are made at least 90 days in advance of the inspection due date and tickler reports are provided to inspectors on a weekly basis. This recommendation is closed.

3. "The review team recommends that the Commonwealth routinely perform accompaniments of each inspector, at least annually, to ensure quality and consistency in the inspection program. (Section 3.3 of the 2010 IMPEP report)"

Status: The Program performed all but one supervisory accompaniment of inspectors in 2011. The Program performed all supervisory accompaniments of inspectors in 2012 and 2013. One supervisory accompaniment has been completed in 2014 and the

Program is on track to complete the remaining accompaniments by the end of the calendar year. This recommendation is closed.

4. "The review team recommends that the Commonwealth take necessary steps to ensure that all reportable events are submitted and updated to NRC in accordance with FSME Procedure [SA-300](#). (Section 3.5 of the 2002 IMPEP report)"

Status: The review team examined the Program's procedures for tracking events and found that the procedure stresses the importance of determining whether an event is reportable and if so, to make the required notification to NRC in accordance with the specified timeframe in Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300. The Program's procedure also establishes that reportable events are to be entered, updated, and closed in the Nuclear Materials Events Database (NMED) in a timely manner. The review team examined over 50 events that the Program had reported to NRC during the review period and were in NMED, and found that reportable events were being reported to NRC in accordance with the timeframes noted in FSME Procedure SA-300. Where appropriate, updates were made by the Program and events were closed in NMED in a timely manner. The review team also reviewed a sample of events that the Program had identified as not reportable to NRC. Although one non-reported event may potentially be a medical event (see Section 3.5), the other non-reported events reviewed were found to be classified correctly. This recommendation is closed.

5. "The review team recommends that the Commonwealth adopt regulations necessary for compatibility with the required 3-year period. (Section 4.1.2 of the 2006 IMPEP report, modified in the 2010 IMPEP report)"

Status: The review team noted that the Commonwealth had made significant progress in the promulgation of regulations since the last IMPEP review. Specifically, since the 2010 IMPEP review, the Program has submitted 12 final regulation amendments to NRC for review. The Program currently has no overdue regulation amendments. This recommendation is closed.

6. "The review team recommends that the Commonwealth reissue the certificate MA-0555-S-102-S to contain a table indicating radiation levels under maximum loading conditions. (Section 4.2.2 of the 2010 IMPEP report)"

Status: The Program has reissued certificate MA-0555-S-102-S with the appropriate table indicating radiation levels under maximum loading conditions. This recommendation is closed.

7. "The review team recommends that the Commonwealth make corrections to registration certificate MA-0166-D-102-B. (Section 4.2.1 of the 2002 IMPEP report and Section 4.2.2 of the 2006 and 2010 IMPEP reports, incorrectly identified as MA-0116-102-B in the 2002 and 2006 IMPEP reports)"

Status: The Program has reissued certificate MA-0166-D-102-B with the appropriate corrections. This recommendation is closed.

8. "The review team recommends that the Commonwealth reissue registration certificate MA-8154-D-803-B with complete text or equivalent form. (Section 4.2.2 of the 2006 IMPEP report, modified in the 2010 IMPEP report)"

Status: The Program has reissued certificate MA-8154-D-803-B, to include a cover page of the corrected registration certificate for NR-143-D-103-B and the inactivated certificate MA-8154-D-803-B. This recommendation is closed.

### 3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review 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

Considerations central to the evaluation of this indicator include the Program's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Program's questionnaire response relative to the indicator, interviewed managers and staff, reviewed job descriptions and training records, and considered any workload backlogs.

The Program is currently managed by the Program Director, the Radioactive Materials Unit Supervisor (Unit Supervisor), the Licensing Supervisor, and the Inspection Supervisor. The Radioactive Materials Unit is responsible for materials licensing, inspection, compliance, sealed source and device evaluation, regulation development, and emergency response activities. At the time of the review, in addition to the supervisory positions noted, there were four technical staff members with varying degrees of involvement in the radioactive materials program, to include, as appropriate: materials inspection, materials licensing, and sealed source and device evaluations. In addition, the Planning/Monitoring Unit Supervisor and the Nonionizing/Industrial X-Ray/Accelerator Unit Supervisor also perform radioactive materials licensing and inspections as part of their current duties. The Program devotes approximately 10.2 full-time equivalents (FTE) to radioactive materials licensing and inspection activities, including administrative and supervisory duties.

During the review period, the Program experienced the following personnel changes: the previous Unit Supervisor retired in May 2011; one technical staff member resigned in April 2012; the Deputy Director, who was functioning as the Acting Director, resigned in November 2012 (an Interim Director was then assigned as Program Director until the permanent Director was hired); three technical staff members were promoted to supervisory positions within the Program, including the Unit Supervisor position (filled in December 2011); two technical staff members were hired in January 2011 and May 2013, respectively; and a permanent Program Director was hired in March 2014. Three positions were vacant at the time of this review: two full-time technical staff positions and a Deputy Director position. The Program is in the process of filling the two technical positions, which have been vacant since February 2014 and June 2014, respectively, due to the promotion of two technical staff members to supervisory positions. The Director anticipates filling the Deputy Director position, which has

been vacant since November 2012, during the third quarter of 2014. The review team did not identify any backlogs in licensing or inspections due to the vacancies. The review team determined that staffing levels were adequate for the Agreement State program and comparable to other programs of similar scope and complexity.

The Program has a documented training plan for technical staff that is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1248, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." Staff members are assigned increasingly complex duties as they progress through the qualification process. Currently, the Program has two technical staff members undergoing the qualification process. Based on a review of qualification journals, the review team determined that the Program adequately documents each staff member's qualification status. The review team concluded that the Program's training program is adequate to carry out its regulatory duties and noted that Massachusetts management supports the Program's training program.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Massachusetts' performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

### 3.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, inspections of Priority 1, 2, and 3 licensees, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation was based on the Program's questionnaire response relative to this indicator, data gathered from the Program's licensing and inspection database, examination of completed inspection casework, and interviews with Program management and staff.

The review team verified that the Program's inspection frequencies for all types of radioactive material licenses are at least as frequent as similar license types listed in NRC IMC 2800, "Materials Inspection Program." The Program currently conducts inspections of eight licensees more frequently than prescribed in IMC 2800, including four multi-site medical broad scope facilities which are inspected annually, rather than the 2 year inspection frequency prescribed by IMC 2800. It was noted that the Program is conducting Increased Controls (IC) inspections in conjunction with the routine health and safety inspections.

The review team determined that the Program conducted 162 Priority 1, 2, and 3 inspections during the review period, based on the inspection frequencies established in IMC 2800. The Program identified in its response to the questionnaire, and the review team verified, that a total of five of these inspections were conducted overdue by more than 25 percent of the inspection frequency prescribed in IMC 2800. There were no Priority 1, 2, and 3 inspections overdue at the time of the review.

The Program performed 68 initial inspections during the review period, one of which was conducted overdue. As described in IMC 2800, initial inspections should be conducted within 12 months of license issuance. There was one initial inspection which was overdue at the time of review due to the fact that the licensed material was on a ship out at sea and not available for

inspection. The ship had recently returned to shore and the Program was planning to schedule and conduct the inspection in the near future. The Program, in its response to the draft report, indicated the inspection was completed on August 13, 2014. Overall, the review team calculated that the Program performed three percent of its inspections (Priority 1, 2, 3, and Initials) overdue during the review period.

The review team evaluated the Program's timeliness in providing inspection findings to licensees. A review of inspection reports and printouts from the Program's database determined that inspection findings were generally issued within 30 days of inspection completion, with very few exceptions.

During the review period, the Program granted 65 reciprocity requests for Priority 1, 2, and 3 licensees. The review team determined that during each year of the review period, the Program exceeded the NRC's criteria found in IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20," of inspecting 20 percent of candidate licensees operating under reciprocity in each of the four years covered by the review period.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Massachusetts' performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

### 3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 23 radioactive materials inspections conducted during the review period. The casework reviewed included inspections conducted by six current Program staff and one former Program staff member and covered inspections of various license types, including: academic broad scope, medical broad scope, research and development, high dose rate remote afterloader, industrial radiography, gamma knife, nuclear pharmacy, mobile nuclear medicine, reciprocity, and IC. Appendix C lists the inspection casework files reviewed, with case-specific comments, as well as the results of the inspector accompaniments.

Based on the evaluation of casework, the review team found that most inspection reports were thorough, complete, and consistent, with sufficient documentation to ensure that a licensee's performance with respect to health and safety was acceptable. The documentation supported violations, recommendations made to licensees, the effectiveness of licensee corrective actions taken to resolve previous violations, and discussions held with licensees during exit interviews. The review team noted that a few inspection reports were missing items such as a description of licensed activities. Additionally, of the casework files reviewed, five inspection reports from four different inspectors had sections that were left blank and did not provide a written description of some functional or program areas reviewed or otherwise indicate that these areas were not inspected. The Program's Inspection Procedures describe in the section "Instructions for Inspection Reports," that the inspection report should at least include, but is not limited to, a description of licensed activities, scope of the inspection, and the functional or program areas inspected. For the casework files reviewed, it appeared that the Program was not consistently implementing its procedures for documenting inspection reports. The review team considered making a specific recommendation in this area but did not propose one because the Program

already has procedures in place for both the content and completion of inspection reports and for supervisory review of inspection reports. This was discussed with Program management who acknowledged that steps would be taken to consistently implement the current inspection report documentation procedures.

The inspection procedures utilized by the Program are consistent with the inspection guidance outlined in IMC 2800. Following each inspection, the inspector briefs a supervisor regarding the inspection. An inspection report is then completed by the inspector and reviewed and signed by a supervisor. The Program issues to the licensee, either a letter indicating a clear inspection or a Notice of Violation (NOV), in letter format, which details the results of the inspection. When the Program issues a NOV, the licensee is required to provide a written corrective action plan, based on the violations cited, within 10 days. The review team determined that the inspection findings were appropriate and prompt regulatory actions were taken, as necessary. Inspection findings were clearly stated and documented in the reports and sent to the licensees with the appropriate letter detailing the results of the inspection.

The Program has a policy for supervisors to accompany all staff performing radioactive materials inspections on an annual basis. All supervisory accompaniments of inspectors were performed annually during the review period with the exception of one missed inspector accompaniment in 2011. The supervisors performing accompaniments prepare reports that document the areas covered during the accompaniments as well as the supervisor's review of the resulting inspection report.

The review team noted that the Program has an adequate supply of survey instruments to support its inspection program, as well as responding to incidents. Appropriate, calibrated survey instrumentation, such as Geiger-Mueller (GM) meters, scintillation detectors, ion chambers and micro-R meters, was observed to be available. The Program also has neutron detectors and other survey and analysis equipment to support the inspection program at the State Laboratory. Instruments are calibrated annually by an approved vendor.

The review team accompanied four Program inspectors during four inspections the week of May 12-16, 2014. The Program inspectors were accompanied during inspections of the following types of licensees: industrial radiography, production facility (cyclotron), medical use with written directives required, self-shielded irradiator, and research and development. The inspector accompaniments, with specific comments, are identified in Appendix C.

Inspectors were found to be well prepared for the inspections. During each of the accompaniments, the inspectors utilized appropriate and calibrated radiation survey instrumentation. Where appropriate, the inspectors verified the licensee's inventory with the data maintained in the National Source Tracking System (NSTS). However, as noted below, the team found that three inspectors did not identify some items important to health and safety or security with respect to completeness and thoroughness of the inspection, and technical quality. The three inspectors lacked familiarity with or misunderstood some requirements related to the health and safety or security of the materials being inspected. As an example, an inspector reviewing records related to patient release criteria was not familiar with the related regulations or guidance for these activities. During three of the inspections, inspectors were noted to have a strong reliance on the previous inspection record, and tended to ask leading questions, rather than independently verifying licensee

compliance with requirements. Inspectors tended to “trust” licensee performance rather than interview personnel, ask for demonstrations, or verify information. During one inspection of security-related items, the inspector asked a licensee employee if anything had changed since the last inspection, and when the licensee noted that it had not, that portion of the inspection was concluded without any verification of compliance or interviews with other appropriate licensee personnel. When the review team member asked the inspector why the items were not verified, the inspector explained that if the items were inspected during a previous inspection and found to be in compliance that they did not need to be reviewed again during subsequent inspections.

At the conclusion of each accompaniment, the review team member provided specific performance observations to each inspector. Additionally, the review team member briefed Program management regarding the specific concerns identified. The review team member noted specific concerns related to one inspection that was not adequate to assess the security of licensed materials. The review team member discussed the specific areas in which potentially important security concerns were not inspected, including potential vulnerabilities in the physical security of licensed material as well as access control deficiencies. In response, Program management developed a corrective action plan which included providing additional guidance to the inspection staff and performing a re-inspection of the subject licensee. The additional guidance to the inspection staff outlined Program management expectations for certain security-related inspections. All inspectors were also reminded by Program management of its inspection guidance to use a performance-based approach and to directly observe work activities, conduct interviews with licensee personnel, ask for demonstrations, and review selected records. The re-inspection of the subject licensee was conducted the next business day and was performed by the inspector, the Unit Supervisor, and the Program Director. The inspection identified serious deficiencies in the licensee’s security program and resulted in the Program issuing a Confirmatory Action Letter to the licensee to correct the identified deficiencies.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Massachusetts’ performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory, but needs improvement.

#### 3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 29 specific licensing actions. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of inspection and enforcement history, use of pre-licensing guidance and conduct of pre-licensing visits, and peer/supervisory review.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included: 6 new licenses, 8 renewals, 3 decommissioning or termination actions, and 12 amendments. Files

reviewed included a cross-section of license types, including: broad scope, medical diagnostic and therapy including high dose rate remote afterloader, temporary/permanent implant brachytherapy, etc., industrial radiography, research and development, nuclear pharmacy, portable gauges, manufacturers and distributors, and self-shielded irradiators. The casework sample represented technical reviews performed by nine current and one former Program staff member. A list of the licensing casework evaluated, with case-specific comments, is provided in Appendix D.

Overall, the review team found that most licensing actions were thorough, complete, consistent, and of high quality with health, safety, and security issues properly addressed. Deficiency letters clearly stated regulatory positions, were used properly, and identified substantive deficiencies in the licensees' and applicants' submittals. With a few exceptions noted below and in Appendix D, license reviewers used the Program's licensing guides and/or NRC NUREG-1556 series licensing guidance documents, policies, checklists, and standard license conditions specific to the type of licensing actions to ensure consistency in licenses. Terminated licensing actions were well documented, showing appropriate transfer and survey records. For medical licenses, the Program's review of preceptor attestations was found to be thorough.

Each licensing action is assigned a primary and secondary reviewer and completed licenses are signed by the Program Director. New licensing requests are also reviewed by the Unit Supervisor following the primary and secondary review. Licenses are issued for a five-year period under a timely renewal system.

The team noted consistent use of the security and risk significant material check lists (pre-licensing guidance) for every licensing action. The Program performs pre-licensing checks of all licensing actions, including new applications, amendments, and transfers of control. The Program's pre-licensing review methods incorporate the essential elements of NRC's revised pre-licensing guidance to provide a basis of confidence that the applicant will use requested radioactive materials as intended. All new license applicants receive a pre-licensing site visit which includes an evaluation of the applicant's radiation safety and security programs prior to license issuance.

The review team found that some licensing casework reviewed was inconsistent in risk significant areas with respect to safety and security of radioactive material. The specific areas involved include: maximum possession limits, use of license conditions for certain devices, review of enforcement and inspection history during renewals, use of superseded licensing guidance, and use of a non-NRC approved legally binding requirement. Specifically, three of the casework files reviewed did not specify maximum possession limits for radioactive materials as requested by Office of Nuclear Material Safety and Safeguards (NMSS) letter RCPD-10-007, "Requesting Implementation of a Policy on Maximum Possession Limits for Radioactive Material Licenses," dated June 21, 2010. During the casework file review, the review team identified that two of the Program's radiography licenses did not specify maximum possession limits for radiographic sources and also identified one broad scope license that did not specify a maximum possession limit for a sealed source. This was discussed with the Program, and in response, the Program reviewed the licenses for its other two industrial radiography licenses and determined that these licenses also did not have maximum possession limits. For radiography licenses, the Program had been following an older licensing template that had not

been revised to address maximum possession limits. For the broad scope license, the lack of a possession limit for a sealed source appeared to be isolated. The Program informed the review team that they would contact the identified licensees to obtain the necessary information regarding amounts of radioactive material possessed, and issue corrected copies of the licenses with maximum possession limits specified. The Program, during the MRB meeting, indicated that it added the possession limits and issued corrected copies to the identified licenses.

The team also noted that a license authorizing possession and use of a certain model of irradiator did not contain the license condition addressing safe use of the irradiator. The additional safety considerations for the specific model of irradiator are found in Standard License Condition 75, from NUREG-1556, Volume 20, "Consolidated Guidance About Materials Licenses: Guidance About Administrative Licensing Procedures," and were developed in accordance with the Order issued by NRC on July 3, 1984. This was discussed with the Program, who was able to show the review team that the license conditions were alternately described in an earlier tie-down condition to the license. In an effort to determine whether this was an isolated occurrence, the team identified that the Program had nine licensees that authorized possession and use of the certain model of irradiator. The team reviewed the other eight licenses for the specific license condition. Although the other eight licenses are not addressed in the casework in Appendix D, the review team identified that two of the eight licenses did not contain the license condition or alternately did not clearly describe the safety considerations in tie-down conditions to the license. The Unit Supervisor stated that the identified licensees had the additional safety considerations in place for the irradiator. It appeared to be an oversight that the license conditions were not listed on the licenses or otherwise clearly specified in the tie-downs to the licenses. The Program stated that they would add the standard license condition to all three of the identified licenses that did not contain the condition and issue corrected copies of the licenses. The Program, in its response to the draft report, indicated that it added the standard license condition and issued corrected copies to all three of the identified licenses.

Additionally, the Program was inconsistently reviewing inspection and enforcement history during the license renewal process. Some license reviewers indicated that they reviewed the inspection and enforcement history during license renewals but do not maintain the documentation of the review. Other license reviewers indicated that they do not review the inspection and enforcement history during license renewals. The Program's licensing procedures do not describe the need to perform a review of the inspection and enforcement history during license renewals. The Program agreed to review its current licensing procedures and develop and implement a plan to ensure that license reviewers are reviewing inspection and enforcement history during license renewals.

The Program encouraged licensees and applicants to utilize the licensing guidance in the NRC NUREG-1556 series, "Consolidated Guidance about Materials Licenses," for their submittals. For almost all types of licensing actions reviewed, the NUREG-1556 series was being utilized. However, the review team found that for medical licensees, there were some cases where licensees were still submitting licensing information to the Program utilizing the guidance in NRC Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs." The licensing guidance in NRC Regulatory Guide 10.8 is outdated and was superseded with the publication of NUREG-1556, Volume 9, "Consolidated Guidance about

Materials Licenses: Program-Specific Guidance about Medical Use Licenses,” dated January 2003. The Program’s licensing procedures allow license reviewers to review and accept licensing actions using the guidance in NRC Regulatory Guide 10.8 although it does not contain current regulatory references or updated risk-informed licensing approaches. The Program agreed to review its licensing procedures and revisit its practice of accepting medical licensing actions based on superseded licensing guidance.

The review team examined the Program’s licensing practices regarding the IC and Fingerprinting Orders. The Program had previously submitted to the NRC for review and compatibility determination, two legally binding requirements (license conditions) for implementing: (1) the IC, and (2) Fingerprinting requirements. The review team noted that some of the subject licenses contained the two NRC reviewed and approved license conditions. However, three licenses contained a different, single license condition that had not been submitted to the NRC for compatibility review and approval. The Program had developed this single license condition in an effort to consolidate the two previously used and approved license conditions. This consolidated license condition had not been submitted to NRC for review. Review of this license condition (legally binding requirement) for compatibility to NRC regulations was outside the scope of the team’s review. The review team identified three licenses that contained the unapproved license condition but did not review all 42 of the Program’s IC licenses. The Program committed to review all 42 IC licenses, identify the licenses that contain the license condition that had not been submitted to NRC for review and compatibility determination, replace it with the license conditions that have been approved by the NRC, and issue corrected copies of the licenses.

The review team strongly considered making specific performance recommendations regarding the areas of maximum possession limits, use of license conditions for certain devices, review of enforcement and inspection history during renewals, use of superseded licensing guidance, and use of a non-NRC approved legally binding requirement. However, because of the strong Program management commitments made during the review, and actions taken to begin to address these identified performance concerns, the review team determined that specific performance recommendations were not necessary.

The review team examined the Program’s implementation of its procedure for the control of security-related sensitive information. Prior to July 25, 2014, the Program did not have a written procedure in place for handling security-related documents; however, certain security-related files were being maintained in locked file cabinets. Prior to the review, the Program identified that they did not have a written policy for the control of sensitive information and on July 25, 2014, issued a written policy. This policy addresses a more comprehensive approach to the identification, marking, transmission, control, and handling of documents that contain sensitive information related to licensees subject to the IC.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Massachusetts’ performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory, but needs improvement.

### 3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Program's actions in responding to incidents and allegations, the review team examined the Program's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Massachusetts in NMED against those contained in the Program's files, and evaluated the casework for nine radioactive materials incidents. A listing of the casework examined, with case-specific comments, can be found in Appendix E. The review team also evaluated the Program's response to six allegations involving radioactive materials, including two that the NRC referred to the Commonwealth during the review period. Note that this section addresses the Program's response to routine materials incidents and allegations; the Program's response to incidents and allegations related to the Sealed Source & Device (SS&D) evaluation program are discussed in Section 4.2.3.

The incidents/events selected for review included the following categories: medical event, lost radioactive material, contamination, dose to embryo/fetus, and exceeded effluent constraint. The review team compared the Program's reporting of events to the NRC with those established in the NMSS Procedure SA-300 "Reporting Material Events." The program has procedures in place for reporting events to the NRC and for entering events into NMED. The review team examined the Program's procedures for tracking events and found that the procedure stresses the importance of determining whether an event is reportable and, if so, to make the required notification to the NRC in accordance with the timeframe specified in NMSS Procedure SA-300. The Program's procedure also establishes that reportable events are to be entered, updated, and closed in NMED in a timely manner. The review team examined over 50 events that the Program had reported to the NRC during the review period and were in NMED, and found that reportable events were being reported to the NRC in accordance with the timeframes noted in NMSS Procedure SA-300. Where appropriate, updates were made by the Program and events were closed in NMED in a timely manner. The review team also reviewed a sample of events that the Program had identified as not reportable to the NRC. With one potential exception described below, the other non-reported events reviewed were found to be classified correctly and did not meet the reportability thresholds.

The review team's evaluation of selected incident case files found that the Program's responses to reported incidents were not well coordinated, not consistent, and in some cases, not thorough. When the Program was notified of an event, there was a prompt response to determine whether the event is reportable, and if so, to make the report to the NRC in a timely manner. The event was then assigned to a reviewer; however, there was no systematic approach to determine the scope and level of effort of the Program's response. There was no process to systematically evaluate reported events and make a determination as to whether an onsite response was warranted regarding the safety or security significance of an event, and if so, the time frame and scope of the response. As a result, the Program's response to events was often not commensurate with the potential health and safety significance of the event. As an example, the Program performed an onsite inspection for a low health and safety significance issue related to a lost generally licensed static eliminator that contained radioactive material below the reporting thresholds. On the other hand, for a medical event that resulted in an Abnormal Occurrence, a potentially high health and safety significant event, an onsite inspection was not performed until almost a month after the event. The Program's lack of a systematic approach to determine what type of response was warranted for reported events was discussed with Program management. To address the review team's observation, an event

report evaluation policy was drafted by the Program. The draft policy is intended to provide guidance to the Program in providing a timely evaluation of reported events to help determine the appropriate scope and time frame of the Program's response. The Program Director planned to obtain additional feedback from the Program staff prior to finalizing and implementing the policy.

The Program's inspection procedure describes that special inspections involving medical events will be performed using the guidance in NRC Management Directive 8.10, "NRC Medical Event Assessment Program," (now titled "NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility") and that other special inspections will be performed using the guidance in NRC Inspection Procedure 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing." Both of these documents provide procedures and guidance for responding to and documenting events involving materials licensees. The review team found that the Program staff did not routinely refer to either of these documents for guidance regarding the conduct of event response activities. These guidelines do not require that onsite inspections be performed for events but rather provide guidance to be used in determining whether an onsite inspection is warranted or whether the event can be followed up during the next routine inspection, by a review of a licensee event report, or other appropriate actions. For the events reported to the Program that were reviewed by the team, these guidelines were not reviewed by the Program. As a result, the Program did not follow the inspection activation guidelines or otherwise document a rationale for its event response decisions, whether that be to conduct an onsite inspection or to review a licensee report.

For those events where the Program did not perform an onsite response, the Program responded to events by reviewing licensee written reports which are required by regulation to be submitted to the Program. For two of the events reviewed, the Program did not identify that the licensee written reports did not contain all of the information required by regulation. If the information required to be provided in licensee written reports is not contained in the reports, the Program's evaluation of the event may be based on incomplete or inadequate information. This was discussed with Program management, and in response, a policy was developed and issued regarding event report closeout expectations. The policy describes the Program Director's expectations that Program staff should review licensee written event reports against the associated regulatory reporting requirements. In addition, the Program was preparing an Information Notice to be sent to all medical licensees reminding them of the need to include all necessary and required information when submitting written reports related to medical events.

A review of the selected incident files indicated that, especially concerning medical events, the Program's review and analysis of the event was not thorough and relied on the licensee's conclusions rather than performing an independent evaluation of the event that included a determination of the contributing factors and root causes. Medical event files did not consistently contain adequate information needed for the Program to evaluate the effectiveness of the licensee's corrective actions to prevent recurrence, identify any generic issues, or determine whether events were isolated or programmatic. Completed and closed event files were reviewed by the Program's event coordinator but did not routinely undergo Program management review. The review team found that event files often contained the initial event information and email correspondence between the Program and the licensee regarding the event, but did not often contain the Program's documented analysis or evaluation of the event. For potential or actual medical events, the circumstances of such events are often sufficiently

complex to render email communication regarding technical questions and details of the event to be ineffective. As noted earlier, one of the non-reported events reviewed involved a high dose remote afterloader brachytherapy procedure where the applicator was not fully inserted for the first two fractions. Based on the written information provided by the licensee, the Program concluded that the event was not a reportable medical event. However, the information provided by the licensee in the event file did not contain complete information regarding the procedure and the final treatment record that would have been necessary to make a determination as to whether or not a medical event occurred. It is unclear from the specific incident file whether the individual received the prescribed dose to the intended treatment site and/or whether there was dose to unintended tissue. The lack of information in the particular case file was discussed with Program management, who indicated that a plan would be developed to obtain additional information regarding the case, and a report would be made to the NRC if it was determined to be a medical event. During the MRB meeting, the Program reported that it had completed its review of the case and determined that it was not a medical event.

As noted, Program management was responsive in commencing efforts to address issues related to event response coordination and licensee written report review. The review team believes that these efforts will enhance the Program's event response but determined that additional efforts are necessary to strengthen and enhance the quality of event response. 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.

In evaluating the effectiveness of the Program's response to allegations, the review team evaluated the completed casework for six allegations, including two that the NRC referred to the Commonwealth during the review period. The Program responds to allegations in accordance with its procedure for the management of allegations. The procedures describe the receipt, processing, and completion of reviews of allegations. The review team concluded that the Program consistently took prompt and appropriate action in response to the concerns raised. The review team noted that the Program thoroughly documented the investigations and retained all necessary documentation to appropriately close the allegations. The Program notified the concerned individuals of the conclusion of its investigation. The review team determined that the Program adequately protected the identity of the concerned individuals.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Massachusetts' performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory, but needs improvement.

#### 4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State Programs: (1) Compatibility Requirements, (2) Sealed Source and Device Evaluation Program, (3) Low-level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. All four non-common performance indicators applied to this review.

#### 4.1 Compatibility Requirements

To assess Massachusetts' status with respect to this performance indicator, the review team examined the Program's response to the questionnaire relative to this indicator, reviewed Massachusetts' State Regulation Status Data Sheet (SRS) as maintained by NMSS, and conducted interviews with managers responsible for this program area.

##### 4.1.1 Legislation

Massachusetts became an Agreement State on March 19, 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 of Public Health is designated as the Commonwealth's radiation control agency. The review team noted that no new legislation was passed during the review period which would affect the Agreement State program or its authority. Massachusetts regulations are not subject to sunset review.

##### 4.1.2 Program Elements Required for Compatibility

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 nine months to complete. The Program Director noted that additional support for rulemaking activities has been identified for future regulation development.

During the review period, the Program submitted 12 final regulation amendments to the NRC for review: 1 final regulation amendment to replace a previously approved license condition; 1 final regulation amendment which is due in 2015; and 10 final amendments that were overdue for State adoption at the time of submission. Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally-binding requirements no later than three years after they become effective. The NRC's compatibility review resulted in three comments, which will need to be addressed by the State in upcoming rulemaking activities. The following 10 amendments were overdue when submitted to the NRC:

- “Financial Assurance for Materials Licensees,” 10 CFR Parts 30, 40 and 70 amendment (68 FR 57327), that was due for Agreement State adoption on December 3, 2006. (RATS ID 2003-1)
- “Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments,” 10 CFR Part 71 amendment (69 FR 3697), that was due for Agreement State adoption on October 1, 2007. (RATS ID 2004-1)
- “Security Requirements for Portable Gauges Containing Byproduct Material,” 10 CFR Part 30 amendment (70 FR 2001), that was due for Agreement State adoption on July 11, 2008. (RATS ID 2005-1)
- “Medical Use of Byproduct Material – Recognition of Specialty Boards,” 10 CFR Part 35 amendment (70 FR 16336; 71 FR 1926), that was due for Agreement State adoption on April 29, 2008. (RATS ID 2005-2)
- “Minor Amendments,” 10 CFR Parts 20, 30, 32, 35, 40 and 70 amendment (71 FR 15005), that was due for Agreement State adoption on March 27, 2009. (RATS ID 2006-1)
- “Medical Use of Byproduct Material – Minor Corrections and Clarifications,” 10 CFR Parts 32 and 35 amendment (72 FR 45147, 54207), that was due for Agreement State adoption on October 29, 2010. (RATS ID 2007-1)
- “Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements,” 10 CFR Parts 30, 31, 32, and 150 amendment (72 FR 58473), that was due for Agreement State adoption on December 17, 2010. (RATS ID 2007-2)
- “Requirements for Expanded Definition of Byproduct Material,” 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendment (72 FR 55864), that was due for Agreement State adoption on November 30, 2010. (RATS ID 2007-3)
- “Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent,” 10 CFR Parts 19 and 20 amendment (72 FR 68043), that was due for Agreement State adoption on February 15, 2011. (RATS ID 2008-1)
- “Medical Use of Byproduct Material – Authorized User Clarification,” 10 CFR Part 35 amendment (74 FR 33901), that was due for Agreement State adoption on September 28, 2012. (RATS ID 2009-1)

The review team noted that the Commonwealth had made significant process in the promulgation of regulations since the last IMPEP review and currently has no overdue regulation amendments. A complete list of regulation amendments can be found on the NRC website at the following address: [http://nrc-stp.ornl.gov/rss\\_regamendments.html](http://nrc-stp.ornl.gov/rss_regamendments.html).

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Massachusetts' performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

#### 4.2 Sealed Source and Device Evaluation Program

In reviewing this indicator, the review team used three sub-elements to evaluate the Program's performance regarding the SS&D evaluation program. These sub-elements were (1) Technical Staffing and Training, (2) Technical Quality of the Product Evaluation Program, and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

In assessing the Massachusetts SS&D evaluation activities, the review team examined the information provided in response to the IMPEP questionnaire and evaluated the SS&D registry sheets and supporting documents processed during the review period. The team also reviewed certain reported incidents involving products authorized in Massachusetts SS&D sheets, the use of guidance and procedures, and interviewed the staff currently conducting SS&D evaluations.

##### 4.2.1. Technical Staffing and Training

At the time of the review, the Program had four reviewers who were qualified to perform safety evaluations of SS&D applications. However, the Program's SS&D evaluation responsibilities were distributed between three active reviewers with the fourth individual not currently involved in SS&D reviews. All have science degrees and have attended the NRC's SS&D Workshop. The review team interviewed staff members involved in the reviews and determined that they were familiar with the procedures used in the evaluation of a source/device and had access to applicable reference documents. The Program sent one individual to the NRC SS&D Workshop held in 2014. The Program plans to fill an open staff vacancy in the near future and indicated that this individual may be trained to perform SS&D safety evaluations. The review team determined that the Program's staffing and training with respect to SS&D evaluations is adequate, based on the Program's current SS&D workload.

##### 4.2.2 Technical Quality of the Product Evaluation Program

The Program completed 61 SS&D evaluation actions during the review period, including amendments, inactivations, new registrations, and corrections. The review team evaluated 17 of the 61 SS&D evaluation actions. The cases selected for review were representative of the Program's licensees and types of sources and devices evaluated. A list of SS&D casework examined can be found in Appendix F.

In assessing the Program's SS&D evaluation activities, the review team examined information contained in the Program's response to the IMPEP questionnaire for this indicator and interviewed Program staff and managers. The review confirmed that the Program follows the recommended guidance from NRC's SS&D workshop, NUREG-1556 Series guidance, applicable and pertinent American National Standards Institute standards, ISO-9001, and relevant Massachusetts rules. The review team verified that these documents were available and were used appropriately in performing SS&D reviews.

The review team determined that the Program performed evaluations based on sound conservative assumptions to ensure that public health and safety was adequately protected. Deficiency letters clearly stated regulatory positions and all health and safety issues were addressed. The review team determined that product evaluations were thorough, complete, consistent, and adequately addressed the integrity of the products during use and in the event of accidents.

#### 4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

During the review period, there were six reported incidents related to SS&D defects involving sources or devices registered by the Commonwealth of Massachusetts. All six reported incidents were reviewed by the review team. The review team found that the Program's response to the reported incidents was prompt, taking into consideration the health and safety or security significance of the incident. Program staff was aware of the need to evaluate such incidents as potentially generic in nature with possible wide-ranging effects.

The Program received one allegation during the review period related to an unregistered sealed source in use in Massachusetts. The allegation was provided to the Program by another Agreement State. The review team determined that the response by the Program to the allegation was prompt and that the Program took appropriate action in response to the concerns raised. The review team noted that the Program thoroughly documented the investigation and retained all necessary documentation to close the allegation.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Massachusetts' performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found 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 Program's questionnaire response indicated that a Program Coordinator performs low-level radioactive waste fee and survey collection activities. The review 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. Although the review team followed up on the information provided in the questionnaire, a review of this indicator was not performed.

## 5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, the review team recommended, and the MRB agreed, that Massachusetts' performance be found satisfactory, but needs improvement, for the indicators Technical Quality of Inspection Activities, Technical Quality of Licensing Actions, and Technical Quality of Incident and Allegation Activities. The review team found Massachusetts' performance to be satisfactory for the other indicators reviewed. The review team made one recommendation regarding the performance of the Commonwealth. As noted in Section 2.0, the review team determined that the eight recommendations from previous IMPEP reports were addressed by the Program and should be closed.

Overall, the review team recommended, and the MRB agreed, that the Massachusetts Agreement State Program be found adequate to protect public health and safety, but needs improvement, and compatible with the NRC's program. Based on the results of the current IMPEP review, and in accordance with the criteria in NRC Management Directive 5.6, the review team recommended, and the MRB agreed, that a period of Monitoring be initiated for Massachusetts. Monitoring may be used in cases where one or more performance indicators are less than fully satisfactory. Monitoring is an informal process that allows the NRC to maintain an increased level of communication with an Agreement State program.

The review team further recommended, and the MRB agreed, that a Periodic Meeting be conducted in 1 year from this review to assess the Commonwealth's progress and efforts taken to address the identified performance issues, and that the next IMPEP review take place in approximately 4 years.

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

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)

## LIST OF APPENDICES

|            |   |
|------------|---|
| Appendix A | IMPEP Review Team Members               |
| Appendix B | Massachusetts Organization Charts       |
| Appendix C | Inspection Casework Reviews             |
| Appendix D | License Casework Reviews                |
| Appendix E | Incident Casework Reviews               |
| Appendix F | Sealed Source & Device Casework Reviews |

## APPENDIX A

### IMPEP REVIEW TEAM MEMBERS

| <b>Name</b>                 | <b>Area of Responsibility</b>   |
|-----------------------------|---|
| Janine F. Katanic, NMSS     | Team Leader<br>Technical Quality of Incident and Allegation<br>Activities<br>Inspector Accompaniments     |
| Stephen Poy, NMSS           | Sealed Source and Device Evaluation Program<br>Technical Quality of Incident and Allegation<br>Activities |
| Donna Janda, Region I       | Technical Staffing and Training<br>Compatibility Requirements<br>Technical Quality of Inspections         |
| Farrah Gaskins, Region I    | Technical Quality of Licensing Actions  |
| Michelle Simmons, Region IV | Technical Quality of Licensing Actions  |
| Vanessa Danese, Texas       | Technical Quality of Inspections<br>Status of Materials Inspection Program                                |

APPENDIX B

MASSACHUSETTS ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML14183B586

Department of Public Health  
 Center for Environmental Health  
 Radiation Control Program  
 June 16, 2014

John M. Priest, Jr.  
 Director  
 4510-0615 PM VII  
 00058724

Vacant  
 Environmental Engineer IV  
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HR & BUDGET UNIT

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 Program Coordinator III  
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ENVIRONMENTAL UNIT

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 Env. Engineer III  
 4510-0600 Gr. 23B  
 00004792

GENERAL

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RADIOACTIVE MATERIALS

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 4510-0615 Gr. 27A  
 00038171

NIR / INDUSTRIAL

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 4510-0615 Gr. 13  
 00221137

Lisa Hebert  
 Tech. Radon Specialist  
 4510-9248 Gr. 21D  
 00061315

Donald Buckley  
 Env. Engineer III  
 4510-0615 Gr. 23B  
 00013005

Michael Lawler  
 Forensic Scientist III  
 4510-0100 Gr. 24  
 00238354

Vacant  
 Env. Engineer III  
 4510-0615 Gr. 23B  
 00000469

Kenneth Treagde  
 Env. Engineer IV  
 4510-0615 Gr. 25  
 00034341

Medwell Hill  
 Env. Engineer II  
 4510-0600 Gr. 25  
 00238702

Kaitlin Haverly  
 Accountant I  
 4510-0600 Gr. 07  
 00010463

Stefanie Santora  
 Adm'n. Assistant I  
 4510-5048 Gr. 07  
 00172126

William Sellers  
 PC I  
 4510-0625 Grade 10  
 00023238

Jeanne Brodenck  
 Env. Engineer III  
 4510-9014 Gr. 23B  
 00032797

John Sumaras  
 Env. Engineer III  
 4510-0615 Gr. 23B  
 00046232

Doug Cullen  
 Env. Engineer III  
 4510-0615 Gr. 23B  
 00017063

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Irene Farina  
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 4510-0615 Gr. 09  
 0014874

Earl Caution  
 Env. Health Insp. II  
 4510-0900 Gr. 12  
 00016608

Marie Ward  
 Env. Engineer III  
 4510-0600 Gr. 23B  
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Joe Chodorowsky  
 Program Coordinator II  
 4510-0600 Gr. 12  
 00004912

Ed Salomon  
 Env. Engineer III  
 4510-0615 Gr. 23B  
 00016248

Bruce Packard  
 Env. Engineer III  
 4510-0615 Gr. 23B  
 00046757

Anthony Carpenito  
 Env. Engineer IV  
 4510-0615 Gr. 25  
 00016528

Marc DeIorenzo  
 Clerk III  
 4510-9012 Gr. 11  
 00012556

Paul Daly  
 Clerk III  
 4510-0615 Gr. 11  
 00014095

Vacant  
 Env. Engineer III  
 4510-0615 Gr. 23B  
 00004548

Vacant  
 Env. Engineer III  
 4510-0615 Gr. 23B  
 00029232

Vacant  
 Env. Engineer III  
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 00004548

Judy Garbati  
 Clerk IV  
 4510-0615 Gr. 13  
 00138600

Director, RCP

## APPENDIX C

### INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1

Licensee: Brigham & Women's Hospital  
Inspection Type: Routine, Unannounced  
Inspection Date: 5/17/11 and 5/19/11

License No.: 44-0004  
Priority: 2  
Inspector: AC

File No.: 2

Licensee: Applus RTD USA, Inc.  
Inspection Type: Routine, Unannounced  
Inspection Date: 1/29/14 and 2/20/14

License No.: 48-0426  
Priority: 1  
Inspector: BP

File No.: 3

Licensee: Tufts Medical Center  
Inspection Type: Special, Unannounced  
Inspection Date: 9/19/12

License No.: 68-0263  
Priority: 2  
Inspector: JS

Comment: The inspection report did not address certain functional or program areas or otherwise identify them as "not inspected."

File No.: 4

Licensee: PETNET Solutions, Inc.  
Inspection Type: Routine, Unannounced  
Inspection Date: 5/2/13

License No.: 42-0650  
Priority: 2  
Inspector: AC

File No.: 5

Licensee: Steward Saint Anne's Hospital Corp.  
Inspection Type: Routine, Unannounced  
Inspection Date: 10/10/12

License No.: 44-0009  
Priority: 2  
Inspector: JS

File No.: 6

Licensee: Medi-Physics, Inc. dba GE Healthcare  
Inspection Type: Routine, Unannounced  
Inspection Date: 9/14/12

License No.: 58-0001  
Priority: 2  
Inspectors: MI

Comment: Inspector's observations of licensee activities were not described in the inspection report.

File No.: 7

Licensee: Lahey Clinic Foundation  
Inspection Type: Routine, Unannounced  
Inspection Date: 4/6/12

License No.: 44-0015  
Priority: 2  
Inspectors: MI, MR

File No.: 8

Licensee: Woods Hole Oceanographic Institution  
Inspection Type: Routine, Unannounced  
Inspection Date: 11/1/13

License No.: 00-0643  
Priority: 3  
Inspector: BP

Comment: The inspection report did not include a description of licensed activities and did not address certain functional or program areas or otherwise identify them as "not inspected." Inspector's observations of licensee activities were not described in the inspection report.

File No.: 9

Licensee: QSA Global, Inc.  
Inspection Type: Routine, Unannounced  
Inspection Date: 7/19/11 and 7/21/11

License No.: 12-8361  
Priority: 2  
Inspector: JD

File No.: 10

Licensee: Acuren Inspection  
Inspection Type: Reciprocity, Unannounced  
Inspection Date: 5/7/13

License No.: 66-0128  
Priority: 1  
Inspector: AC

Comment: Inspector's observations of licensee activities were not described in the inspection report.

File No.: 11

Licensee: North Shore Medical Center  
Inspection Type: Routine, Unannounced  
Inspection Date: 5/14/14

License No.: 44-0161  
Priority: 3  
Inspector: MI

File No.: 12

Licensee: UMass Memorial Health Care  
Inspection Type: Routine, Unannounced  
Inspection Date: 3/8-11/11

License No.: 60-0096  
Priority: 2  
Inspector: MW

File No.: 13

Licensee: Hallmark Health System, Inc.  
Inspection Type: Routine, Unannounced  
Inspection Date: 2/18/11 and 2/22/11

License No.: 44-0035  
Priority: 3  
Inspector: MI

File No.: 14

Licensee: Hallmark Health System, Inc.  
Inspection Type: Routine, Unannounced  
Inspection Date: 4/2-3/14

License No.: 44-0035  
Priority: 3  
Inspector: AC

File No.: 15

Licensee: Eastern Massachusetts Surgery Center  
Inspection Type: Routine, Unannounced  
Inspection Date: 5/23/12

License No.: 70-0594  
Priority: 3  
Inspector: AC

File No.: 16

Licensee: Sturdy Memorial Hospital  
Inspection Type: Routine, Unannounced  
Inspection Date: 6/20/12

License No.: 44-0043  
Priority: 3  
Inspector: AC

File No.: 17

Licensee: Brandeis University  
Inspection Type: Routine, Announced  
Inspection Date: 11/30/12

License No.: 60-0110  
Priority: 3  
Inspector: MW

File No.: 18

Licensee: Decommissioning, Decontamination &  
Environmental Services, LLC  
Inspection Type: Routine, Unannounced  
Inspection Date: 1/18/13

License No.: 56-0623  
Priority: 2  
Inspector: JS

File No.: 19

Licensee: Mistras Group, Inc.  
Inspection Type: Routine, Unannounced  
Inspection Date: 10/22/13

License No.: 16-5591  
Priority: 1  
Inspector: MI

Comment: The inspection report did not contain information on licensee's scope of work and did not address certain functional or program areas or otherwise identify them as "not inspected." Inspector's observations of licensee activities were not described in the inspection report.

File No.: 20

Licensee: Mistras Group, Inc.  
Inspection Type: Special, Unannounced  
Inspection Date: 10/22/13

License No.: 16-5591  
Priority: 1  
Inspector: MI

File No.: 21

Licensee: Massachusetts Moblie PET, P.C.  
Inspection Type: Routine, Unannounced  
Inspection Date: 3/07/14

License No.: 44-0373  
Priority: 3  
Inspector: MI

File No.: 22

Licensee: Tufts Medical Center  
Inspection Type: Routine, Unannounced  
Inspection Date: 9/19/12

License No.: 68-0263  
Priority: 2  
Inspector: JS

File No.: 23

Licensee: North Shore Medical Center  
Inspection Type: Special, Unannounced  
Inspection Date: 5/14/14 and 5/19/14

License No.: 44-0161  
Priority: 3  
Inspector: MI

### INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1

Licensee: Mistras Group, Inc.  
Inspection Type: Routine, Unannounced  
Inspection Date: 5/12/14

License No.: 16-5591  
Priority: 1  
Inspectors: AC

Comments:

- 1) The inspector misunderstood some requirements related to health and safety and security of the licensed activities being inspected.
- 2) The inspector did not clearly state regulatory requirements to the licensee regarding non-compliances.

Accompaniment No.: 2

Licensee: Semprus Biosciences Corporation  
Inspection Type: Routine, Unannounced  
Inspection Date: 5/13/14

License No.: 55-0591  
Priority: 5  
Inspector: DC

Comments:

- 1) The inspector lacked familiarity with some requirements related to the health and safety of the licensed activities being inspected.
- 2) The inspector did not verify compliance or adequately inspect some programmatic areas related to the health and safety of the licensed activities being inspected.

Accompaniment No.: 3

Licensee: North Shore Medical Center  
Inspection Type: Routine, Unannounced  
Inspection Date: 5/14/14

License No.: 44-0161  
Priority: 3  
Inspector: MI

Comments:

- 1) The inspector lacked familiarity or misunderstood some requirements related to the health and safety and security of the licensed activities being inspected.
- 2) The inspector did not verify compliance with certain security related requirements.

Accompaniment No.: 4

Licensee: Massachusetts General Hospital  
Inspection Type: Routine, Unannounced  
Inspection Date: 5/16/14

License No.: 62-0656  
Priority: 2  
Inspector: JS

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1  
Licensee: Massachusetts General Hospital  
Type of Action: Termination  
Date Issued: 10/17/12  
License No.: 42-0343  
Amendment No.: 04  
License Reviewer: JS

File No.: 2  
Licensee: IBA Molecular North America  
Type of Action: Amendment  
Date Issued: 6/20/14  
License No.: 42-0473  
Amendment No.: 09  
License Reviewer: ES

File No.: 3  
Licensee: Boston College  
Type of Action: Amendment  
Date Issued: 8/27/13  
License No.: 00-6427  
Amendment No.: 15  
License Reviewer: BP

File No.: 4  
Licensee: Brandeis University  
Type of Action: Renewal  
Date Issued: 4/10/14  
License No.: 60-0110  
Amendment No.: 09  
License Reviewer: DC

Comments:

- 1) The additional safety considerations for a specific model of irradiator (Standard License Condition 75, from NUREG-1556, Volume 20, "Consolidated Guidance About Materials Licenses: Guidance About Administrative Licensing Procedures") were not included in the license conditions but were alternately addressed in a tie-down letter on the license.
- 2) The license did not have a maximum possession limit for a sealed source listed on the license.
- 3) Inspection and enforcement history review was not performed during the license renewal process.

File No.: 5  
Licensee: PETNET Solutions  
Type of Action: Amendment  
Date Issued: 4/11/13  
License No.: 42-0650  
Amendment No.: 01  
License Reviewer: MI

File No.: 6

Licensee: Massachusetts General Hospital

Type of Action: New

Date Issued: 9/3/11

License No.: 62-0656

Amendment No.: 00

License Reviewer: JD

Comment: The Program did not obtain financial assurance for this license although required. This licensee has three separate licenses with the Program and financial assurance has recently been submitted to the Program during the renewal of another license. The financial assurance documents were still under review by the Program but appeared to address and include the financial assurance requirements for this license.

File No.: 7

Licensee: Lantheus Medical Imaging

Type of Action: Amendment

Date Issued: 1/20/11

License No.: 60-0088

Amendment No.: 21

License Reviewer: AC

File No.: 8

Licensee: Boston Medical Research

Type of Action: Termination

Date Issued: 6/18/13

License No.: 13-7482

Amendment No.: 05

License Reviewer: BP

File No.: 9

Licensee: PETNET Solutions, Inc.

Type of Action: Renewal

Date Issued: 5/4/11

License No.: 41-0296

Amendment No.: 15

License Reviewer: AC

File No.: 10

Licensee: MikRon

Type of Action: New

Date Issued: 10/31/12

License No.: 56-0673

Amendment No.: 00

License Reviewer: AC

File No.: 11

Licensee: Si-REL, LLC

Type of Action: New

Date Issued: 5/1/2012

License No.: 48-0668

Amendment No.: 00

License Reviewer: JS

Comment: The license utilized a legally binding requirement (license condition) that had not been submitted to the NRC for review and compatibility determination.

File No.: 12

Licensee: Si-REL, LLC

Type of Action: Amendment

Date Issued: 3/7/13

License No.: 48-0668

Amendment No.: 01

License Reviewer: JS

Comment:

See File No. 11

File No.: 13

Licensee: PerkinElmer Health Sciences  
Type of Action: Amendment  
Date Issued: 11/10/10

License No.: 00-3200  
Amendment No.: 33  
License Reviewer: JD

File No.: 14

Licensee: OSI Electronics  
Type of Action: New  
Date Issued: 2/10/12

License No.: 55-0663  
Amendment No.: 00  
License Reviewer: JS

File No.: 15

Licensee: GSR Environmental  
Type of Action: New  
Date Issued: 11/17/10

License No.: 48-0659  
Amendment No.: 00  
License Reviewer: MR

File No.: 16

Licensee: Tran, Vendy  
Type of Action: New  
Date Issued: 2/21/12

License No.: 49-0665  
Amendment No.: 00  
License Reviewer: BP

File No.: 17

Licensee: Geotechnical Consultants, Inc.  
Type of Action: Amendment  
Date Issued: 8/11/10

License No.: 48-0334  
Amendment No.: 04  
License Reviewer: MR

File No.: 18

Licensee: Mistras Group, Inc.  
Type of Action: Renewal  
Date Issued: 8/11/11

License No.: 16-5591  
Amendment No.: 16  
License Reviewer: MI

Comments:

- 1) The license did not have a maximum possession limit for sealed sources listed on the license.
- 2) Inspection and enforcement history review was not documented during the license renewal process.

File No.: 19

Licensee: Prima Care, P.C.  
Type of Action: Amendment  
Date Issued: 9/14/11

License No.: 67-0452  
Amendment No.: 06  
License Reviewer: MI

File No.: 20

Licensee: Prima Care, P.C.

Type of Action: Renewal

Date Issued: 12/11/13

License No.: 67-0452

Amendment No.: 08

License Reviewer: MI

Comments:

- 1) The licensee committed to follow medical licensing guidance that has been superseded.
- 2) Inspection and enforcement history review was not documented during the license renewal process.

File No.: 21

Licensee: Anderson, Craig

Type of Action: Amendment

Date Issued: 12/20/13

License No.: 49-0577

Amendment No.: 02

License Reviewer: MW

File No.: 22

Licensee: Steward Holy Family Hospital, Inc. dba Holy Family

Type of Action: Amendment

Date Issued: 2/19/14

License No.: 44-0032

Amendment No.: 23

License Reviewer: ES

File No.: 23

Licensee: UMass/Memorial Health Care

Type of Action: Renewal

Date Issued: 12/6/12

License No.: 60-0096

Amendment No.: 29

License Reviewer: AC

Comment: Inspection and enforcement history review was not documented during the license renewal process.

File No.: 24

Licensee: Geleota Associates, Inc.

Type of Action: Termination

Date Issued: 8/1/13

License No.: 49-0084

Amendment No.: 05

License Reviewer: AC

File No.: 25

Licensee: Milford Regional Medical Center

Type of Action: Renewal

Date Issued: 1/10/13

License No.: 44-0009

Amendment No.: 15

License Reviewer: AC

Comments:

- 1) The licensee committed to follow medical licensing guidance that has been superseded.
- 2) Inspection and enforcement history review was not documented during the license renewal process.

File No.: 26

Licensee: Dana-Farber Cancer Institute

Type of Action: Renewal

Date Issued: 3/4/14

License No.: 60-0037

Amendment No.: 16

License Reviewer: DC

Comments:

- 1) The licensee committed to follow medical licensing guidance that has been superseded.
- 2) Inspection and enforcement history was not performed review during the license renewal process.

File No.: 27

Licensee: Microsemi Corporation

Type of Action: Renewal

Date Issued: 8/13/13

License No.: 48-0574

Amendment No.: 03

License Reviewer: AC

Comment: The license utilized a legally binding requirement (license condition) that had not been submitted to the NRC for review and compatibility determination.

File No.: 28

Licensee: Boston University Medical Center

Type of Action: Amendment

Date Issued: 2/24/14

License No.: 44-0062

Amendment No.: 24

License Reviewer: KT

Comment: The license utilized a legally binding requirement (license condition) that had not been submitted to the NRC for review and compatibility determination.

File No.: 29

Licensee: Applus RTD dba Quality Assurance Laboratory

Type of Action: Amendment

Date Issued: 1/24/14

License No.: 48-0426

Amendment No.: 07

License Reviewer: DC

Comment: The license did not have a maximum possession limit for sealed sources listed on the license.

## APPENDIX E

### INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1

Licensee: UMass Memorial Health Care

Date of Incident: 3/5/14

Investigation Date: 3/17/14

License No.: 60-0096

NMED No.: 140127

Type of Incident: Medical Event

Type of Investigation: Review licensee report

Comments:

- 1) The Program did not follow its inspection activation guidelines or otherwise document a rationale for not conducting an onsite inspection.
- 2) The inspector did not identify that the license's 15-day written report did not contain all of the information required by regulation.
- 3) The inspector did not identify incorrect information in the licensee's report regarding the amount of yttrium-90 drawn up into the system.
- 4) The Program's investigation was not sufficient to identify if the incident was the result of a generic issue.

File No.: 2

Licensee: LTI Smart Glass

Date of Incident: unknown

Investigation Date: 10/15/13

License No.: G0350

NMED No.: 130506

Type of Incident: Lost RAM

Type of Investigation: Review licensee report

Comments:

- 1) The inspector did not identify that the license's 30-day written report did not contain all of the information required by regulation.
- 2) On 11/5/13, the Unit Supervisor requested that an on-site inspection be performed, but the inspection had not been performed as of the date of the review.

File No.: 3

Licensee: QSA Global, Inc.

Date of Incident: 2/1/12

Investigation Date: 2/2/12

License No.: 12-8361

NMED No.: 120136

Type of Incident: Contamination

Type of Investigation: Review licensee report/Site

File No.: 4

Licensee: Metan Marine, USA

Date of Incident: unknown

Investigation Date: 3/19/14

License No.: G0673

NMED No.: N/A

Type of Incident: Lost RAM

Type of Investigation: Site

File No.: 5

Licensee: PETNET Solutions, Inc.

Date of Incident: 4/29/13

Investigation Date: 4/30/13

License No.: 42-0650

NMED No.: 130237

Type of Incident: Exceed effluent constraint  
Type of Investigation: Review licensee report

File No.: 6

Licensee: St. Anne's Hospital

Date of Incident: 7/28/10

Investigation Date: 8/6/10

License No.: 44-0009

NMED No.: N/A

Type of Incident: Medical event  
Type of Investigation: Review licensee report

Comments:

- 1) The Program did not follow its inspection activation guidelines or otherwise document a rationale for not conducting an onsite inspection.
- 2) The Program concluded that the event was not a medical event; however, the information contained in the incident file was not sufficient to draw that conclusion, and was based, in part, on incomplete information regarding all of the fractional treatments delivered.
- 3) The Program's investigation was not sufficient to identify if the prescribed dose was delivered to the intended treatment site or if there was dose to unintended tissue.

File No.: 7

Licensee: Tufts Medical Center

Date of Incident: 5/17/13

Investigation Date: 6/12/13

License No.: 68-0263

NMED No.: 140313

Type of Incident: Medical Event  
Type of Investigation: Review licensee report/Site

Comments:

- 1) The Program did not follow its inspection activation guidelines or otherwise document a rationale for conducting an onsite inspection 26 days after the event, which was an Abnormal Occurrence.
- 2) The special inspection did not review licensee corrective actions to determine if they were effective in preventing a recurrence of the incident, and did not verify whether the incident was isolated or programmatic.

File No.: 8

Licensee: Brigham & Women's Hospital

Date of Incident: 5/3/11

Investigation Date: 7/22/11

License No.: 44-0004

NMED No.: 110348

Type of Incident: Medical Event

Type of Investigation: Review licensee report

Comments:

- 1) The Program did not follow its inspection activation guidelines or otherwise document a rationale for not conducting an onsite inspection.
- 2) The Program's investigation did not verify that only certain treatment sites were planned incorrectly although several other sites were treated with the same type of applicator.
- 3) The Program's investigation did not evaluate the licensee's procedures for administrations requiring a written directive.

File No.: 9

Licensee: Lowell General Hospital

Date of Incident: 2/16/11

Investigation Date: 5/26/11

License No.: 44-0060

NMED No.: N/A

Type of Incident: Dose to embryo/fetus

Type of Investigation: Review licensee report/Site

APPENDIX F

SEALED SOURCE & DEVICE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1  
Registry No.: MA-1101-D-103-B  
Applicant Name: Bruker Detection Corp.  
Date issued: 3/7/11  
SS&D Type: (N) Ion Generators  
Type of Action: Amendment  
SS&D Reviewers: JS, JD

File No.: 2  
Registry No.: MA-1059-D-334-S  
Applicant Name: QSA Global, Inc.  
Date issued: 10/5/12  
SS&D Type: (A) Industrial Radiography  
Type of Action: Amendment  
SS&D Reviewers: JS, JD

File No.: 3  
Registry No.: MA-0573-D-103-B  
Applicant Name: Radiation Monitoring Device, Inc.  
Date issued: 6/20/14  
SS&D Type: (U) X-Ray Fluorescence  
Type of Action: Amendment  
SS&D Reviewers: JS, KT

File No.: 4  
Registry No.: MA-1287-D-103-B  
Applicant Name: Thermo EGS Gauging, Inc.  
Date issued: 7/22/10  
SS&D Type: (E) Beta Gauges  
Type of Action: Correction  
SS&D Reviewers: JS, JD

File No.: 5  
Registry No.: MA-1229-D-101-S  
Applicant Name: Sirtex Wilmington, LLC  
Date issued: 12/10/12  
SS&D Type: (AF) Other Medical Uses  
Type of Action: Correction  
SS&D Reviewers: JS, JD

File No.: 6  
Registry No.: MA-1340-D-101-G  
Applicant Name: Charles Stark Draper Lab, Inc.  
Date issued: 4/14/11  
SS&D Type: (N) Ion Generators  
Type of Action: New  
SS&D Reviewers: JS, JD

File No.: 7  
Registry No.: MA-1059-D-377-S  
Applicant Name: QSA Global, Inc.  
Date issued: 4/17/14  
SS&D Type: (A) Industrial Radiography  
Type of Action: New  
SS&D Reviewers: JS, KT

File No.: 8  
Registry No.: MA-1287-D-802-B  
Applicant Name: Thermo EGS Gauging, Inc.  
Date issued: 9/2/10  
SS&D Type: (D) Gamma Gauges  
Type of Action: Inactivation  
SS&D Reviewers: JS, JD

File No.: 9

Registry No.: MA-1287-D-103-B  
Applicant Name: Thermo EGS Gauging, Inc.  
Date issued: 7/22/10

SS&D Type: (E) Beta Gauges  
Type of Action: New  
SS&D Reviewers: JS, JD

File No.: 10

Registry No.: MA-8232-D-801-G  
Applicant Name: Sionex Corp.  
Date issued: 6/20/11

SS&D Type: (N) Ion Generators  
Type of Action: Inactivation  
SS&D Reviewers: JS, JD

File No.: 11

Registry No.: MA-0555-S-807-S  
Applicant Name: Industrial Nuclear Company, Inc.  
Date issued: 4/8/11

SS&D Type: (H) General Neutron Source App  
Type of Action: Inactivation  
SS&D Reviewers: JS, JD

File No.: 12

Registry No.: MA-1059-D-946-S  
Applicant Name: QSA Global, Inc.  
Date issued: 9/11/12

SS&D Type: (H) General Neutron Source App  
Type of Action: Inactivation  
SS&D Reviewers: JS, JD

File No.: 13

Registry No.: MA-0573-D-103-B  
Applicant Name: Radiation Monitoring Device, Inc.  
Date issued: 6/20/14

SS&D Type: (U) X-Ray Fluorescence  
Type of Action: Amendment  
SS&D Reviewers: JS, KT

File No.: 14

Registry No.: MA-1383-D-101-B  
Applicant Name: Protec Instrument Corp.  
Date issued: 6/23/14

SS&D Type: (U) X-Ray Fluorescence  
Type of Action: New  
SS&D Reviewers: JS, KT

File No.: 15

Registry No.: MA-1059-D-370-S  
Applicant Name: QSA Global, Inc.  
Date issued: 1/31/14

SS&D Type: (A) Industrial Radiography  
Type of Action: Amendment  
SS&D Reviewers: JS, KD

File No.: 16

Registry No.: MA-1059-D-369-S  
Applicant Name: QSA Global, Inc.  
Date issued: 12/6/13

SS&D Type: (A) Industrial Radiography  
Type of Action: Amendment  
SS&D Reviewers: JS, KT

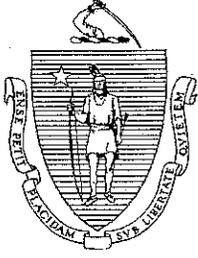
File No.: 17

Registry No.: MA-1287-D-801-B  
Applicant Name: Thermo EGS Gauging, Inc.  
Date issued: 9/2/10

SS&D Type: (E) Beta Gauges  
Type of Action: New  
SS&D Reviewers: JS, JD

ATTACHMENT

September 29, 2014 Letter from John M. Priest, Jr.  
Massachusetts Response to the Draft Report  
ADAMS Accession No.: ML14275A005



DEVAL L. PATRICK  
GOVERNOR

JOHN W. POLANOWICZ  
SECRETARY

CHERYL BARTLETT, RN  
COMMISSIONER

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September 29, 2014

Duncan White, Chief  
Agreement State Program Branch  
Division of Materials Safety and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs  
United States Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

**RE: NRC Letter dated September 3, 2014 with  
2014 IMPEP Draft Report**

Dear Mr. White:

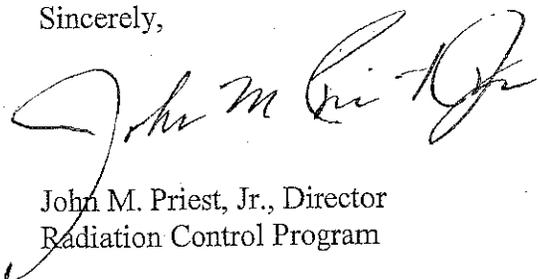
This letter refers to your letter dated September 3, 2014 requesting for factual comment upon the IMPEP (Integrated Materials Performance Evaluation Program) review Draft Report included with your letter.

We recommend for the following corrections to the Report:

1. Section 3.2, 4<sup>th</sup> paragraph; Change "The ship had recently returned to shore and the Program was planning to schedule the inspection in the near future." to "The ship had recently returned to shore and the Program completed the inspection on August 13, 2014."
2. Section 3.4, 7<sup>th</sup> paragraph; Replace last sentence "The Program stated that they would add the standard license condition to all three of the identified licenses that did not contain the condition and issue corrected copies of the licenses." with "The Program added the standard license condition to all three of the identified licenses that did not contain the condition and issued corrected copies of the licenses."
3. Section 3.4, 10<sup>th</sup> paragraph; Change the two instances of "44" to "42". There are 42 Massachusetts licensees subject to increased controls.

Thank you for your cooperation in this matter.

Sincerely,

A handwritten signature in cursive script, reading "John M. Priest, Jr.", written in black ink.

John M. Priest, Jr., Director  
Radiation Control Program

cc: Suzanne K. Condon