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

September 3, 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:

The U.S. Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the evaluation of Agreement State programs. Enclosed for your review is the draft IMPEP report, which documents the results of the Agreement State review held in Massachusetts on July 28 – August 1, 2014. Dr. Janine Katanic was the team leader for the review. The review team's preliminary findings were discussed with you and other members of your staff on the last day of the review. The review team's proposed recommendations are that the Massachusetts Agreement State Program be found adequate, but needs improvement, to protect public health and safety and compatible with 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 recommends that a period of Monitoring be initiated for Massachusetts. Monitoring is an informal process that allows the NRC to maintain an increased level of communication with an Agreement State program. As part of the monitoring process, the NRC would conduct quarterly calls with the appropriate representatives from the Massachusetts Agreement State Program.

The NRC conducts periodic reviews of Agreement State programs to ensure that public health and safety are adequately protected from the potential hazards associated with the use of radioactive materials and that Agreement State programs are compatible with the NRC's program. The process, titled IMPEP, utilizes a team of NRC and Agreement State staff to assess Agreement States' and NRC Regional Offices' radioactive materials programs. All reviews use common criteria in the assessment and place primary emphasis on performance. Three additional areas applicable to your program were identified as non-common performance indicators and are also addressed in the assessment. The final determination of adequacy and compatibility of each Agreement State program, based on the review team's report, is made by a Management Review Board (MRB) composed of NRC managers and an Agreement State program manager who serves as a liaison to the MRB.

In accordance with procedures for implementation of IMPEP, we are providing you with a copy of the review team's draft report for your review and factual comment prior to submitting the report to the MRB. Comments are requested within four weeks from your receipt of this letter. This schedule will permit the issuance of the final report in a timely manner.

The team will review the response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. Our preliminary scheduling places the Massachusetts MRB meeting on October 28, 2014. NRC will provide invitational travel for you or your designee to attend the MRB meeting at NRC Headquarters in Rockville, Maryland. The NRC has videoconferencing capability if it is more convenient for the Commonwealth to participate through this medium. Please contact me if you desire to establish a video conference for the meeting.

If you have any questions regarding the enclosed report, please contact me at (301) 415-2598.

Thank you for your cooperation.

Sincerely,

/RA/

Duncan White, Chief
Agreement State Programs Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Enclosure:
Massachusetts Draft IMPEP Report

cc: Jack Priest, Director
Radiation Control Program

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE MASSACHUSETTS AGREEMENT STATE PROGRAM

July 28 - August 1, 2014

DRAFT 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 recommends 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 recommends 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 strengthening the Commonwealth's incident response program, recommends 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 recommends 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 recommends that a period of Monitoring be initiated for Massachusetts.

The review team further recommends 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 paragraph on the results of the Management Review Board (MRB) meeting will be included in the final report.]

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 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 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 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 this 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 recommends 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 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. 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 recommends 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 Increased Controls. 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. 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 mangement 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 recommends 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 FSME 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 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.

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 Increased Controls 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 Increased Controls, 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 44 of the Program's Increased Controls licenses. The Program committed to review all 44 Increased Controls 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 Increased Controls.

Based on the IMPEP evaluation criteria, the review team recommends 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 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 NRC with those established in the FSME Procedure SA-300 "Reporting Material Events." The program has procedures in place for reporting events to 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 NRC in accordance with the timeframe specified in FSME 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 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. 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 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 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, an onsite inspection was not performed until almost a month after the event. For two other reported medical events reviewed, onsite inspections were not performed, including one that could potentially be related to a generic issue. This was discussed with Program management, and in response, an event report evaluation policy was drafted. 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. For the four medical events reviewed, the Program did not follow the inspection activation guidelines in NRC Management Directive 8.10 or otherwise document why these guidelines were not followed. For three medical events, onsite inspections were not performed, and for one medical event, the inspection was performed almost a month after the event.

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 NRC if it was determined to be 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 recommends 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 FSME, 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 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 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_regamendents.html.

Based on the IMPEP evaluation criteria, the review team recommends 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 Sealed Source and Device (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 recommends 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 recommends 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 recommends 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 recommends 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 recommends 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.

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

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Appendix E	Incident Casework Reviews
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APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Janine F. Katanic, FSME	Team Leader Technical Quality of Incident and Allegation Activities Inspector Accompaniments
Stephen Poy, FSME	Sealed Source and Device Evaluation Program Technical Quality of Incident and Allegation Activities
Donna Janda, Region I	Technical Staffing and Training Compatibility Requirements 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 Status of Materials Inspection Program

APPENDIX B

MASSACHUSETTS ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML14183B586

APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1
Licensee: Brigham & Women's Hospital — License No.: 44-0004
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 5/17/11 and 5/19/11 — Inspector: AC

File No.: 2
Licensee: Applus RTD USA, Inc. — License No.: 48-0426
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Date: 1/29/14 and 2/20/14 — Inspector: BP

File No.: 3
Licensee: Tufts Medical Center — License No.: 68-0263
Inspection Type: Special, Unannounced — Priority: 2
Inspection Date: 9/19/12 — 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. — License No.: 42-0650
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 5/2/13 — Inspector: AC

File No.: 5
Licensee: Steward Saint Anne's Hospital Corp. — License No.: 44-0009
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 10/10/12 — Inspector: JS

File No.: 6
Licensee: Medi-Physics, Inc. dba GE Healthcare — License No.: 58-0001
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 9/14/12 — Inspectors: MI

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

File No.: 7
Licensee: Lahey Clinic Foundation License No.: 44-0015
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 4/6/12 Inspectors: MI, MR

File No.: 8
Licensee: Woods Hole Oceanographic Institution License No.: 00-0643
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 11/1/13 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. License No.: 12-8361
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 7/19/11 and 7/21/11 Inspector: JD

File No.: 10
Licensee: Acuren Inspection License No.: 66-0128
Inspection Type: Reciprocity, Unannounced Priority: 1
Inspection Date: 5/7/13 Inspector: AC

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

File No.: 11
Licensee: North Shore Medical Center License No.: 44-0161
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 5/14/14 Inspector: MI

File No.: 12
Licensee: UMass Memorial Health Care License No.: 60-0096
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 3/8-11/11 Inspector: MW

File No.: 13
Licensee: Hallmark Health System, Inc. License No.: 44-0035
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 2/18/11 and 2/22/11 Inspector: MI

File No.: 14
Licensee: Hallmark Health System, Inc. License No.: 44-0035
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 4/2-3/14 Inspector: AC

File No.: 15
Licensee: Eastern Massachusetts Surgery Center License No.: 70-0594
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 5/23/12 Inspector: AC

File No.: 16
Licensee: Sturdy Memorial Hospital License No.: 44-0043
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 06/20/12 Inspector: AC

File No.: 17
Licensee: Brandeis University License No.: 60-0110
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 11/30/12 Inspector: MW

File No.: 18
Licensee: Decommissioning, Decontamination & Environmental Services, LLC License No.: 56-0623
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 01/18/13 Inspector: JS

File No.: 19
Licensee: Mistras Group, Inc. License No.: 16-5591
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 10/22/13 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. License No.: 16-5591
Inspection Type: Special, Unannounced Priority: 1
Inspection Date: 10/22/13 Inspector: MI

File No.: 21
Licensee: Massachusetts Moblie PET, P.C. License No.: 44-0373
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 03/07/14 Inspector: MI

File No.: 22
Licensee: Tufts Medical Center License No.: 68-0263
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 9/19/12 Inspector: JS

File No.: 23
Licensee: North Shore Medical Center License No.: 44-0161
Inspection Type: Special, Unannounced Priority: 3
Inspection Date: 5/14/14 and 5/19/14 Inspector: MI

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: Mistras Group, Inc. License No.: 16-5591
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 5/12/14 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 License No.: 55-0591
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 5/13/14 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 License No.: 44-0161
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 5/14/14 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 License No.: 62-0656
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 5/16/14 Inspector: JS

APPENDIX D

LICENSE CASEWORK REVIEWS

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

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

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

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

File No.: 4
Licensee: Brandeis University — License No.: 60-0110
Type of Action: Renewal — Amendment No.: 09
Date Issued: 4/10/14 — 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 — License No.: 42-0650
Type of Action: Amendment — Amendment No.: 01
Date Issued: 4/11/13 — License Reviewer: MI

File No.: 6
Licensee: Massachusetts General Hospital — License No.: 62-0656
Type of Action: New — Amendment No.: 0
Date Issued: 9/3/11 — 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 License No.: 60-0088
Type of Action: Amendment Amendment No.: 21
Date Issued: 1/20/11 License Reviewer: AC

File No.: 8
Licensee: Boston Medical Research License No.: 13-7482
Type of Action: Termination Amendment No.: 05
Date Issued: 6/18/13 License Reviewer: BP

File No.: 9
Licensee: PETNET Solutions, Inc. License No.: 41-0296
Type of Action: Renewal Amendment No.: 15
Date Issued: 5/4/11 License Reviewer: AC

File No.: 10
Licensee: MikRon License No.: 56-0673
Type of Action: New Amendment No.: 00
Date Issued: 10/31/12 License Reviewer: AC

File No.: 11
Licensee: Si-REL, LLC License No.: 48-0668
Type of Action: New Amendment No.: 00
Date Issued: 5/1/2012 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 License No.: 48-0668
Type of Action: Amendment Amendment No.: 01
Date Issued: 3/7/13 License Reviewer: JS

Comment:
See File No. 11

File No.: 13
Licensee: PerkinElmer Health Sciences License No.: 00-3200
Type of Action: Amendment Amendment No.: 33
Date Issued: 11/10/10 License Reviewer: JD

File No.: 14
Licensee: OSI Electronics License No.: 55-0663
Type of Action: New Amendment No.: 00
Date Issued: 2/10/12 License Reviewer: JS

File No.: 15
Licensee: GSR Environmental License No.: 48-0659
Type of Action: New Amendment No.: 00
Date Issued: 11/17/10 License Reviewer: MR

File No.: 16
Licensee: Tran, Vendy License No.: 49-0665
Type of Action: New Amendment No.: 00
Date Issued: 2/21/12 License Reviewer: BP

File No.: 17
Licensee: Geotechnical Consultants, Inc. License No.: 48-0334
Type of Action: Amendment Amendment No.: 04
Date Issued: 8/11/10 License Reviewer: MR

File No.: 18
Licensee: Mistras Group, Inc. License No.: 16-5591
Type of Action: Renewal Amendment No.: 16
Date Issued: 8/11/11 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. License No.: 67-0452
Type of Action: Amendment Amendment No.: 06
Date Issued: 09/14/11 License Reviewer: MI

File No.: 20
Licensee: Prima Care, P.C. License No.: 67-0452
Type of Action: Renewal Amendment No.: 08
Date Issued: 12/11/13 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 License No.: 49-0577
Type of Action: Amendment Amendment No.: 02
Date Issued: 12/20/13 License Reviewer: MW

File No.: 22
Licensee: Steward Holy Family Hospital, Inc. dba Holy Family License No.: 44-0032
Type of Action: Amendment Amendment No.: 23
Date Issued: 2/19/14 License Reviewer: ES

File No.: 23
Licensee: UMass/Memorial Health Care License No.: 60-0096
Type of Action: Renewal Amendment No.: 29
Date Issued: 12/6/12 License Reviewer: AC

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

File No.: 24
Licensee: Geleota Associates, Inc. License No.: 49-0084
Type of Action: Termination Amendment No.: 05
Date Issued: 8/1/13 License Reviewer: AC

File No.: 25
Licensee: Milford Regional Medical Center License No.: 44-0009
Type of Action: Renewal Amendment No.: 15
Date Issued: 1/10/13 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 License No.: 60-0037
Type of Action: Renewal Amendment No.: 16
Date Issued: 3/4/14 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 License No.: 48-0574
Type of Action: Renewal Amendment No.: 03
Date Issued: 8/13/13 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 License No.: 44-0062
Type of Action: Amendment Amendment No.: 24
Date Issued: 2/24/14 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 License No.: 48-0426
Type of Action: Amendment Amendment No.: 07
Date Issued: 1/24/14 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 — License No.: 60-0096
Date of Incident: 3/5/14 — NMED No.: 140127
Investigation Date: 3/17/14 — 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 — License No.: G0350
Date of Incident: unknown — NMED No.: 130506
Investigation Date: 10/15/13 — 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. — License No.: 12-8361
Date of Incident: 2/1/12 — NMED No.: 120136
Investigation Date: 2/2/12 — Type of Incident: Contamination
Type of Investigation: Review licensee report/Site

File No.: 4
Licensee: Metan Marine, USA — License No.: G0673
Date of Incident: unknown — NMED No.: N/A
Investigation Date: 3/19/14 — Type of Incident: Lost RAM
Type of Investigation: Site

File No.: 5
Licensee: PETNET Solutions, Inc. License No.: 42-0650
Date of Incident: 4/29/13 NMED No.: 130237
Investigation Date: 4/30/13 Type of Incident: Exceed effluent constraint
Type of Investigation: Review licensee report

File No.: 6
Licensee: St. Anne's Hospital License No.: 44-0009
Date of Incident: 7/28/10 NMED No.: N/A
Investigation Date: 8/6/10 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 License No.: 68-0263
Date of Incident: 5/17/13 NMED No.: 140313
Investigation Date: 6/12/13 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 License No.: 44-0004
Date of Incident: 5/3/11 NMED No.: 110348
Investigation Date: 7/22/11 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 License No.: 44-0060
Date of Incident: 2/16/11 NMED No.: N/A
Investigation Date: 5/26/11 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 — SS&D Type: (N) Ion Generators
Applicant Name: Bruker Detection Corp. — Type of Action: Amendment
Date issued: 3/7/11 — SS&D Reviewers: JS, JD

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

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

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

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

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

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

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

File No.: 9
Registry No.: MA-1287-D-103-B SS&D Type: (E) Beta Gauges
Applicant Name: Thermo EGS Gauging, Inc. Type of Action: New
Date issued: 7/22/10 SS&D Reviewers: JS, JD

File No.: 10
Registry No.: MA-8232-D-801-G SS&D Type: (N) Ion Generators
Applicant Name: Sionex Corp. Type of Action: Inactivation
Date issued: 6/20/11 SS&D Reviewers: JS, JD

File No.: 11
Registry No.: MA-0555-S-807-S SS&D Type: (H) General Neutron Source App
Applicant Name: Industrial Nuclear Company, Inc. Type of Action: Inactivation
Date issued: 4/8/11 SS&D Reviewers: JS, JD

File No.: 12
Registry No.: MA-1059-D-946-S SS&D Type: (H) General Neutron Source App
Applicant Name: QSA Global, Inc. Type of Action: Inactivation
Date issued: 9/11/12 SS&D Reviewers: JS, JD

File No.: 13
Registry No.: MA-0573-D-103-B SS&D Type: (U) X-Ray Fluorescence
Applicant Name: Radiation Monitoring Device, Inc. Type of Action: Amendment
Date issued: 6/20/14 SS&D Reviewers: JS, KT

File No.: 14
Registry No.: MA-1383-D-101-B SS&D Type: (U) X-Ray Fluorescence
Applicant Name: Protec Instrument Corp. Type of Action: New
Date issued: 6/23/14 SS&D Reviewers: JS, KT

File No.: 15
Registry No.: MA-1059-D-370-S SS&D Type: (A) Industrial Radiography
Applicant Name: QSA Global, Inc. Type of Action: Amendment
Date issued: 1/31/14 SS&D Reviewers: JS, KD

File No.: 16
Registry No.: MA-1059-D-369-S SS&D Type: (A) Industrial Radiography
Applicant Name: QSA Global, Inc. Type of Action: Amendment
Date issued: 12/6/13 SS&D Reviewers: JS, KT

File No.: 17
Registry No.: MA-1287-D-801-B SS&D Type: (E) Beta Gauges
Applicant Name: Thermo EGS Gauging, Inc. Type of Action: New
Date issued: 9/2/10 SS&D Reviewers: JS, JD