October 14, 2010

Suzanne Condon, Director
Bureau of Environmental Health
Massachusetts Dept. of Public Health
Schrafft Center, Suite 1M2A
529 Main Street
Charlestown, MA 02129

Dear Ms. Condon:

On September 20, 2010, 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 Agreement State 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 NRC staff to initiate a period of monitoring of the Massachusetts Agreement State Program. Monitoring is an informal process that allows NRC to maintain an increased level of communication with an Agreement State program. As part of the monitoring process, NRC will conduct quarterly calls with the appropriate representatives from the Massachusetts Agreement State Program.

Section 5.0, page 15, of the enclosed final report contains a summary of the IMPEP review team's findings and recommendations. Mr. Robert Gallaghar's letter dated September 9, 2010, adequately discusses the Commonwealth's proposed actions for resolving the review team's recommendations. No further response is requested at this time.

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 2011. During the periodic meeting and at the next IMPEP review, NRC will evaluate the effectiveness of the Commonwealth's response to the review team's recommendations, as well as the overall implementation of your Agreement State program.

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

Sincerely,

/RA Michael F. Weber/

Michael F. Weber
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 w/encl.: Robert Gallaghar, Acting Director
Radiation Control Program

Letter to S. Condon from Michael F. Weber dated:

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE MASSACHUSETTS AGREEMENT STATE PROGRAM

JULY 12-16, 2010

FINAL REPORT

Enclosure

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 12-16, 2010, by a review team composed of technical staff members from the Nuclear Regulatory Commission (NRC) and the State of Ohio. 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 a 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 of May 20, 2006, to July 16, 2010, were discussed with Massachusetts managers on the last day of the review.

A draft of this report was issued to Massachusetts for factual comment on August 16, 2010. The Commonwealth responded by letter dated September 9, 2010, from Robert Gallaghar, Acting Director, Radiation Control Program (the Program). A copy of the Commonwealth's response is included as the Attachment to this report. The Management Review Board (MRB) met on September 20, 2010, 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 NRC's program. The MRB directed NRC staff to initiate a period of monitoring of the Massachusetts Agreement State Program. Monitoring is an informal process that allows NRC to maintain an increased level of communication with an Agreement State program. As part of the monitoring process, NRC will conduct quarterly calls with the appropriate representatives from the Massachusetts Agreement State Program.

The Massachusetts Agreement State Program is administered by the Program, which is located within the Bureau of Environmental Health (the Bureau). The Bureau is located within the Department of Public Health (the Department). Organization charts for the Commonwealth and the Program are included in Appendix B.

At the time of the review, the Massachusetts Agreement State Program regulated approximately 503 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 NRC and the Commonwealth of Massachusetts.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the Program on February 12, 2010. The Program provided a response to the questionnaire on June 25, 2010, and a revised response on July 23, 2010. A copy of the revised questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML102140206.

The review team's general approach for conduct of this review consisted of: (1) examination of Massachusetts' response to the questionnaire, (2) review of applicable Massachusetts statutes and regulations, (3) analysis of quantitative information from the Program's licensing and inspection database, (4) technical review of selected regulatory actions, (5) field accompaniments of three of the Program's inspectors, and (6) interviews with 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 covers the Commonwealth's actions in response to recommendations made during previous reviews. Results of the current review of the common performance indicators are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings and recommendations. Recommendations made by the review team are comments that relate directly to performance by the Commonwealth.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on May 19, 2006, the review team made eight recommendations regarding the Massachusetts Agreement State Program's performance. Two recommendations carried over from the 2002 IMPEP review.

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 review team found that the two vacancies identified during the 2006 IMPEP review have not been filled due to budget constraints. In addition, there have been further decreases in funding for staffing despite increased work duties creating additional demands on existing staff. This issue is discussed in more detail in Section 3.1 of this report. This recommendation remains open.

2. The review team recommends that the Commonwealth address each of the licensing cases where Increased Controls are needed by either issuing license amendments to decrease possession limits or issuing license amendments to include Increased Controls. (Section 3.4 of the 2006 IMPEP report)

   Status: The review team found that the Program has identified and taken appropriate action on those licenses requiring Increased Controls. Furthermore, the Program has a policy in place to use an equivalent version of NRC's Risk-Significant Radioactive Materials Checklist, which aids a license review in determining the applicability of the Increased Controls or other security measures. This recommendation is closed.

3. The review team recommends that the Commonwealth take appropriate and timely follow-up actions commensurate with the potential health and safety significance for all events. (Section 3.5 of the 2006 IMPEP report)

   Status: The review team found that the Program has taken appropriate and timely follow-up actions in its response to radioactive material incidents where a potential health and safety issue exists. 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 Office of

State and Tribal Programs (STP) Procedure SA-300, “Reporting Materials Events.” (Section 3.5 of the 2006 IMPEP report)

Status: The review team found that, although the Program has made progress in reporting events to NRC in accordance with Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300 (formerly STP Procedure SA-300), there has not been a period of sustained performance by the Program with respect to the timeliness of reporting and updating events. This recommendation remains open.

5. The review team recommends that the Commonwealth adopt regulations necessary for compatibility within the required three year time frame and submit alternate forms of legally binding requirements for NRC review following the guidance in FSME Procedure SA-201. (Section 4.1.2 of the 2002 IMPEP report)

   Status: The review team found that the Program submitted legally binding requirements, such as license conditions, for several of the regulation amendments during the review period; however, the Program still has regulation amendments that have not been finalized in the required 3-year period. This recommendation remains open, but has been modified to reflect the Program’s efforts in addressing part of this recommendation. The review team recommends that the Commonwealth adopt regulations necessary for compatibility within the required 3-year period.

6. The team recommends that the Commonwealth make corrections to registration certificate MA-0166-D-102-B (this was incorrectly listed as MA-0116-102-B in the 2002 and 2006 reports). (Section 4.2.1 of the 2002 IMPEP report)

   Status: The review team found that the Program has gathered the information necessary to make the corrections but has not issued the corrected registration certificate. This recommendation remains open.

7. The review team recommends that the Commonwealth develop and document a set of formal qualification requirements for sealed source and device (SS&D) reviewers. (Section 4.2.1 of the 2006 IMPEP report)

   Status: The review team found that the reviewer qualification requirements were incorporated into the Program’s Licensing Procedures document. The Program’s qualification procedures for SS&D reviews are consistent with the qualification requirements for SS&D reviewers in NRC’s Inspection Manual Chapter (IMC) 1246, “Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area.” This recommendation is closed.

8. The review team recommends that the Commonwealth issue inactivated registration certificates in the future with full text and reissue the shortened certificates with full text, if practicable. If the Commonwealth wishes to continue the practice of short forms, then the review team recommends that the registration certificate, which is referenced in the short text, be attached to the inactivated registration. (Section 4.2.2 of the 2006 IMPEP report)

Status: The review team found that newly issued inactivation certificates were found to be complete with the full text. One of the two 2006 SS&D casework certificates (MA-1059-S-905-S) was for a duplicate model number registration and was not reissued as there is a current registration. The second case work certificate (MA-8154-D-803-B) has not been reissued. This recommendation remains open with respect to the reissuance of registration certificate MA-8154-D-803-B with the complete text and has been modified accordingly. The review team recommends that the Commonwealth reissue registration certificate MA-8154-D-803-B with the complete text or equivalent form.

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

Issues 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.

When fully staffed, the Massachusetts Agreement State Program is composed of the Radioactive Materials Program Director and technical and administrative staff in the Radioactive Materials Unit (Unit). A supervisor heads the Unit. Technical staff members perform both inspection and licensing duties, and respond to incidents and allegations. Based on information provided by the Program, the review team estimated that the Program currently expends approximately 12.5 full-time equivalents (FTE) to administer the Agreement State program.

During the review period the Program experienced the following personnel changes: the Program Director retired from the Agreement State program, a clerical staffer was reassigned outside of the Unit and a technical staffer who performed part-time licensing/inspection duties was transferred to the Environmental Laboratory within the Massachusetts Radiation Control Program. One technical staff member was hired into the Unit during the review period. At the time of the review, the Bureau still had two full-time technical vacancies that existed at the 2006 IMPEP review, a part-time technical vacancy, and a clerical vacancy. The Program Director position became vacant in October 2009 and a technical staffer was promoted to the Acting Program Director position. The vacancies in the Program have forced staff to take on additional duties to try to maintain the Program's increasing workload. The review team identified the vacancies as an underlying cause of the Program's performance weaknesses, such as overdue inspections and inconsistencies/inadequacies in the files and databases, discussed in later sections of this report.

As stated in Section 2.0, the Program still has not been able to fill the two vacant technical positions that existed during the 2006 IMPEP review due to budget constraints. The Program is

allowed to retain a certain percentage of the revenue from its annual licensing fees and is capped at that point. Excess revenue is deposited in the Commonwealth's general fund. Without an increase in this cap the Program does not have the funding to fill the vacant positions. In addition, the Acting Director expressed concern that the current staff will be tasked with additional duties resulting from the transfers of the personnel mentioned above. The review team is concerned that this increased workload demand will adversely affect performance under the Agreement with NRC; therefore, the review team kept open the recommendation from the 2006 IMPEP review on pursuing adequate funding in order to fill the technical vacancies, because the Program's current staffing level is not sufficient to carry out all of its regulatory duties in a timely manner.

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 IMC 1246. The Program uses on-the-job training, such as inspector accompaniments, to supplement formal coursework. Staff members are typically assigned increasingly complex duties as they progress through the qualification process. Staff members are authorized to perform regulatory duties independently after demonstrating competency. The Unit Supervisor signs off on all staff qualifications at the recommendation of the appropriate senior advisor. The review team noted that the Acting Program Director encourages and supports training opportunities based on program needs. The Unit Supervisor has instituted better tracking and documentation of staff training history and experience. The review team noted that the most recently hired technical staff member was progressing through the Program's qualification process. The review team concluded that the Program's training is adequate to carry out its regulatory duties.

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, but needs improvement.

3.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, overdue inspections, 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 database, examination of completed inspection casework, and interviews with managers and staff members.

The review team verified that the Program's inspection frequencies for all types of radioactive materials licenses are at least the same frequency as those listed in NRC's IMC 2800, "Materials Inspection Program." The Program conducts inspections of four multi-site medical broadscope facilities more frequently than it is prescribed in IMC 2800. These four medical broadscope facilities are inspected annually, whereas IMC 2800 prescribes a 2-year inspection frequency. In addition, the Program is conducting Increased Controls inspections in conjunction with the routine health and safety inspections.

The Program conducted a total of 164 Priority 1, 2, and 3 (high priority) inspections during the review period. The Program identified in its response to the questionnaire, and the review team verified, that a total of 24 high priority inspections were conducted overdue by more than 25 percent of the inspection frequency prescribed by IMC 2800. The review team verified that no high priority inspections were overdue at the time of the review. The review team also evaluated the Program's timeliness for conducting initial inspections. The Program conducted 73 initial inspections, of which 23 were conducted overdue. Initial inspections are to be conducted within 12 months after license issuance, as prescribed by IMC 2800. The overdue inspections ranged from a few days to 24 months overdue. The review team verified that no initial inspections were overdue at the time of the review. Overall, the review team calculated that the Program performed 19 percent of its Priority 1, 2, 3, and initial inspections overdue during the review period. In addition, the team found that many of the entries into the database were inaccurate thereby providing flawed results.

In investigating the underlying causes of the number of overdue inspections, the review team found that inspections were assigned in a timely manner using the inspection and licensing database, which generates printouts of upcoming inspection due dates; however, the Program managers did not follow up on the performance of these inspections.

The review team evaluated the Program's timeliness of issuance of inspection reports. The Program has a policy of issuing the inspection findings to licensees within 30 days from the date of the inspection. The review team examined the Program's database printouts and inspection files and determined that inspection findings were usually issued within 30 days of inspection completion.

In reviewing the Program's performance of reciprocity inspections, the review team found that the Program granted 54 reciprocity requests for Priority 1, 2, and 3 licensees during the review period. The review team determined that the Program inspected 20 percent of the candidate reciprocity licensees in accordance with IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20," in each year of the review period, except 2008. In 2008, the Program inspected only 2 of the 13 candidates for that year. The Program self-identified an incorrect priority code that was assigned to several reciprocity licensees during that year. The Program corrected the priority code assigned to each of the reciprocity licensees and was able to meet the 20 percent criterion in subsequent years of the review period.

The review team recommends that the Commonwealth monitor and maintain accurate information in its inspection 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.

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, but needs improvement.

3.3 Technical Quality of Inspections

The review team evaluated inspection reports, enforcement documentation, and inspection field notes and interviewed the responsible inspectors for 17 radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by eight inspectors and covered a wide variety of inspection types. These included medical broadscope, diagnostic nuclear medicine, gamma knife, industrial radiography, waste disposal/processing, academic broadscope, research and development broadscope, and self-shielded irradiator. The casework included initial, routine, follow-up, reciprocity, and Increased Controls inspections. Appendix C lists the inspection casework files reviewed, with case-specific comments.

Based on the evaluation of casework, the review team determined that inspections covered all aspects of the licensees' radiation safety and security programs. The review team noted that the inspections covered the Increased Controls, fingerprinting, and the National Source Tracking System requirements, when appropriate. The review team found that inspection reports were thorough, complete, consistent, and of high quality with sufficient documentation to ensure that licensees' performances with respect to health, safety, and security were acceptable. Inspection report documentation supported violations, recommendations made to licensees, and unresolved safety issues.

While on site, the review team evaluated the Program's handling and storing of sensitive documents. According to the Acting Program Director, the Program has statutory authority to withhold certain documents related to security matters, such as Increased Controls issues. For example, letters and/or tie-down documents containing security-related information are maintained in a locked cabinet and are not released to the public. The Program cannot mark documents, such as materials licenses, as sensitive information based only on the maximum possession limits listed on the license. Information related to physical security must also be present on the document in order to withhold it from public release. An exception to this policy is that the Program withholds all documents with Increased Controls-related issues. These documents have a security header to notify the reader of the presence of security-related information. In addition, the Program has the authority to redact security-related information from Freedom of Information Act requests. The review team concluded that the Program's policies and practices for sensitive information are adequate.

The Acting Program Director and senior inspection staff perform supervisory inspection accompaniments. The review team noted that, during the review period, supervisory accompaniments were not performed for any inspector on an annual basis. Several inspectors were not accompanied by a supervisor over a period of 3 consecutive years. The Unit Supervisor noted that there were several reasons for the inconsistency in annual accompaniments, including not maintaining a list or tracking system for completion of the accompaniments, staffing shortages which led to prioritization of other duties, and Program management changes. 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.

The review team accompanied three of the Program's inspectors during the period of June 8-10, 2010. The facilities inspected included an industrial radiography licensee and diagnostic

nuclear medicine licensees. The inspector accompaniments are listed in Appendix C. The inspectors demonstrated performance-based inspection techniques and knowledge of the regulations. The inspectors were well trained, prepared for the inspections, and thorough in their audits of the licensees' radiation safety and security programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspectors held entrance and exit meetings with the appropriate level of licensee management. The review team determined that the inspections were adequate to assess radiological health, safety, and security at the licensed facilities.

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.

3.4 Technical Quality of Licensing Actions

The review team examined 25 completed licensing casework files and interviewed 5 of 6 license reviewers as well as the Coordinator for Materials Licensing. 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, security requirements, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate correspondence, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer or supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included 2 new licenses, 8 renewals, 8 amendments, 3 license terminations, and 4 reciprocity requests. Casework reviewed included a cross-section of license types including: a service provider, industrial radiography, broadscope and limited medical, decommissioning, storage only, research and development and gamma knife. A listing of the licensing casework reviewed, with case-specific comments, can be found in Appendix D.

The review team found that the licensing actions were complete, consistent, and of high quality with health, safety, and security issues properly addressed. License tie-down conditions were stated clearly, and were generally backed by information contained in the file.

The Program renews licenses every 5 years. The review team noted that most licensing actions were promptly acted upon, usually within 30 days of receipt. During the 2006 IMPEP, the review team noted that eight renewals were pending for more than 1 year; however, at the time of this review, the review team noted that of the 15 renewals currently in house only one had been pending for 11 months. This review of this action was active, and the team did not find any safety-significant impact on this licensee's program due to the length of time of this pending renewal.

All licensing actions are peer reviewed by a primary and secondary license reviewer and the Licensing Supervisor. The Acting Director or designee signs all licensing documents. The

program uses a variety of licensing guidance, which includes the NRC NUREG-1556 Series, "Consolidated Guide About Materials Licenses," and the NUREG-1757 Series, "Consolidated Decommissioning Guidance," as well as Program guidance and information on the internet.

The review team evaluated financial assurance and decommissioning activities conducted in the Program. The review team found that decommissioning actions were well documented from the initiating action to final surveys, materials disposition, and termination of the license. No potentially significant health and safety issues were identified. The review team found that actions terminating licenses were well documented, included the appropriate material survey records, and contained documentation of proper disposal or transfer or radioactive material, as appropriate.

The review team determined through interviews with Program managers and staff that the Program does not routinely verify that licensees conducting business in Massachusetts under reciprocity have the proper security conditions on their license. The Program had a number of radiographers enter the Commonwealth under reciprocity during the review period. Radiographers typically possess materials in quantities of concern that meet the criteria for implementation of the Increased Controls. The review team determined that the Program's reciprocity reviewer only verifies that the out-of-State license has not expired. The review team discussed with Program managers and staff the importance of examining the reciprocity licensees' licenses for the presence of the appropriate security conditions.

The review team assessed the Programs' implementation of the pre-licensing guidance. The Program has implemented the essential elements of NRC's pre-licensing guidance issued on September 22, 2008, and transmitted to the Agreement States via Office of Federal and State Materials and Environmental Management Programs (FSME) Letter RCPD-08-020, "Requesting Implementation of the Checklist to Provide a Basis for Confidence That Radioactive Material Will Be Used as Specified on a License and the Checklist for Risk-significant Radioactive Material."

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.

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 response to the questionnaire relative to this indicator, evaluated selected incidents reported for Massachusetts in the Nuclear Material Events Database (NMED) against those contained in the Program's files, and evaluated the casework for 10 of the 60 reported radioactive materials incidents. A listing of the casework examined can be found in Appendix E. The review team also evaluated the Program's response to five allegations involving radioactive materials received during the review period, including two allegations that NRC referred to the Commonwealth.

The Event Coordinator has primary responsibility for oversight of all incidents and allegations. The initial response and followup to incidents and allegations involving radioactive materials are coordinated with the Program Director, Unit Supervisor, and Coordinator for Materials Licensing.

A combined written procedure exists for handling all incidents and allegations. If an inspection is warranted, Program management is notified and an inspector is assigned to handle the event. The Program conducts on-site investigations for all incidents that present a potential or actual hazard to public health and safety. Prior to dispatching responders to the site, Program management is advised of the planned response. The Program assigns each incident and allegation an individual docket number and maintains a local database for tracking the status of all incidents and allegations. If an incident meets the reporting requirements established in FSME Procedure SA-300, the Program notifies the NRC Headquarters Operations Center. If the investigation is complex and extends over a period of time, the Program updates the respective NMED record, using the NMED software.

The incidents selected for review included the following categories: possible overexposure, lost or stolen radioactive material, medical, transportation, and contamination. The review team determined that the Program's responses to incidents were thorough, complete, and comprehensive. Initial responses were prompt and well coordinated, and the level of effort was commensurate with the health and safety significance of the incident. The Program dispatched inspectors for on-site investigations when appropriate and took suitable enforcement and follow-up actions. When no immediate threat was present and the Program determined that the licensee had qualified, competent individuals investigating the incident, the Program generally responded by telephone with subsequent review of the licensee's written report or an on-site follow up at a later date.

The 2006 IMPEP review team identified that the Program was not reporting significant or routine events in a timely manner as requested in FSME (formerly STP) Procedure SA-300 and kept open a recommendation from the 2002 IMPEP review that the Commonwealth take necessary steps to ensure that all reportable events are submitted and updated to NRC in accordance with SA-300. Prior to the on-site portion of this review, the review team queried NMED and identified 51 NRC reportable events for Massachusetts over the review period. During the on-site review, the review team evaluated the timeliness of reporting these events to the NRC Headquarters Operations Center and determined that five events were not reported to NRC in a timely manner. In addition, the review team identified that timely followup information was not provided for nine events that are still open in NMED. The review team discussed the issue of reporting events and providing updates in a timely manner with Program managers and the Event Coordinator. Program managers indicated that several of the events involved loss/theft of radioactive material and were left open in NMED because there is no new information regarding these events and the Program staff has not determined the events to be closed. Although the review team found that progress has been made in reporting events to the NRC in accordance with FSME Procedure SA-300, there has not been a period of sustained Program performance regarding timeliness of reporting and updating events to warrant closing the recommendation from the 2006 IMPEP review. Therefore, the recommendation from the 2006 IMPEP report remains open.

In evaluating the effectiveness of the Program's response to allegations, the review team evaluated the completed casework for five allegations, including two that NRC referred to the Commonwealth. The review team concluded that the Program consistently took prompt and appropriate action in response to 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 allegers of the conclusion of their

investigation. The review team determined that the Program adequately protected the identity of allegers.

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.

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. NRC's Agreement with Massachusetts does not relinquish regulatory authority for a uranium recovery program; therefore, only the first three 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 and staff 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 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, which would affect the Agreement State program or its authority, was passed since the last review.

4.1.2 Program Elements Required for Compatibility

The Commonwealth 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 materials.

The review team examined the Program's rulemaking process. Regulations are drafted by the Program, reviewed by Program managers and staff, and are then sent to NRC for a compatibility review. The Program evaluates any NRC compatibility comments and revises the regulations, as necessary. 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 time required for the Department Commissioner to review and, if necessary, edit this memorandum can take several months. The regulations are then presented to the Commonwealth's Department of Public Health

Council (PHC) who approves the publication of regulations for public comments. A notice that regulations are available for public comments is published in two newspapers and in the *Massachusetts Register* for public review and comment. If requested, the public comment period may be extended, which consequently, extends the time for promulgation. Any comments received by the public are evaluated through comment analysis by the Program staff, and the regulations are revised, as necessary. The amount of time to complete the comment analysis varies, but usually takes several months. The revised regulations are reviewed by Program managers and are submitted to PHC for promulgation. Once PHC approves the regulations for promulgation, the Program's legal counsel submits regulations 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 NRC for a compatibility review as final regulations.

The review team noted the Program preferred to present PHC a regulation package with significant changes and include in those packages any minor amendments NRC had issued. The review team explained that this practice may compromise the ability of the Commonwealth to adopt regulations within the required 3-year period in accordance with current NRC policy.

At the time of this review, four amendments were reviewed as proposed regulations, but were considered overdue, because they were not adopted and effective by the required implementation date. NRC reviewed these proposed regulations and submitted comments on three of the four regulations. The Commonwealth has promulgated these regulations and will submit them to NRC for final review. The four amendments identified overdue at the time of the review are the following:

- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697), that was required for Agreement State adoption by October 1, 2007.

- "Security Requirements for Portable Gauges Containing Byproduct Material," 10 CFR Part 30 amendment (70 FR 2001), that was required for Agreement State adoption by July 11, 2008.

- "Medical Use of Byproduct Material - Recognition of Specialty Boards," 10 CFR Part 35 amendment (70 FR 16336, 71 FR 1926), that was required for Agreement State adoption by April 29, 2008.

- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40 and 70 amendment (71 FR 15005), that was required for Agreement State adoption by March 27, 2009.

The review team identified the following regulation amendments that the Program will need to address in upcoming rulemakings or by adopting alternate legally binding requirements:

- "Medical Use of Byproduct Material – Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 amendment (72 FR 45147, 54207), that is due for Agreement State adoption by October 29, 2010.

- "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 is due for Agreement State adoption by December 17, 2010.

- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendment (72 FR 55864), that is due for Agreement State adoption by November 30, 2010.

- "Occupational Dose Records, Labeling Containers and Total Effective Dose Equivalent," 10 CFR Parts 19 and 20 amendment (72 FR 68043), that is due for Agreement State adoption by February 15, 2011.

- "Medical Use of Byproduct Material – Authorized User Clarification," 10 CFR Part 35 amendment (74 FR 33901), that is due for Agreement State adoption by September 28, 2012.

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, but needs improvement.

4.2 Sealed Source and Device Evaluation Program

In reviewing this indicator, the review team used three subelements to evaluate the Program's performance regarding the sealed source and device (SS&D) evaluation program. These subelements 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 evaluated SS&D staff training records, certain reported incidents involving products authorized in Massachusetts SS&D sheets, the use of guidance documents and procedures, and interviewed the staff currently conducting SS&D evaluations.

4.2.1 Technical Staffing and Training

SS&D evaluation responsibilities are distributed between two reviewers. They were the only active SS&D reviewers during the review period.

The Program has four reviewers who are qualified to perform safety evaluations of SS&D applications. No new reviewers were added during the review period. All have science degrees and have attended 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 review team determined that the SS&D staffing level and technical qualifications for the current staff were adequate.

4.2.2 Technical Quality of the Product Evaluation Program

The review team evaluated 18 of the 112 SS&D evaluation amendments, inactivations, new registrations, and reactivations. The reviewers alternate between being the initial reviewer, with the other as the concurrence reviewer. 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, with the case-specific comments, 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 team 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 Massachusetts rules. The review team verified that these documents were available and used appropriately in performing SS&D reviews.

One issue was identified in registration number MA-0555-S-102-S in that the certificate registration section "External Radiation Levels" identified the radiation levels per microgram of californium-252 instead of the maximum loading of 116.9 micrograms (64.11 mCi) as indicated in the current version of NUREG 1556, Volume 3. The safety significance is that a license reviewer or inspector could misread the table of radiation levels and significantly underestimate the radiation levels. 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.

The review team determined that the Program performed evaluations based on sound conservative assumptions to ensure 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

Seven incidents related to SS&D defects involving sources or devices registered by the Commonwealth of Massachusetts were reported during the review period. (Six of the incidents were related to a specific component assembly manufacturing lot.) The review team found that the Program's response to incidents was prompt, taking into consideration the health and safety or security significance of the event. Program staff was aware of the need to look at such incidents as potentially generic in nature with possible wide-ranging effects.

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, 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, 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. There are no plans for a commercial LLRW disposal facility in Massachusetts. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, the review team found Massachusetts' performance to be satisfactory for four of the seven performance indicators reviewed, and satisfactory, but needs improvement for the following three performance indicators: Technical Staffing and Training, Status of Materials Inspection Program, and Compatibility Requirements. The review team made three recommendations regarding program performance by the Commonwealth and kept open five recommendations from previous reviews. 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 NRC's program. Based on the results of the current IMPEP review, the review team recommended, and the MRB agreed, that the Massachusetts Agreement State Program be placed on Monitoring, with a periodic meeting held in approximately 1 year to assess the Program's progress in addressing the open recommendations. The review team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately 4 years.

Below are the recommendations, as mentioned earlier in this report, for evaluation and implementation, as appropriate, by the Commonwealth:

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)

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)

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)

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)

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

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)

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

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

LIST OF APPENDIXES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Michelle Beardsley, FSME	Team Leader Technical Staffing and Training
Leira Cuadrado, FSME	Status of Materials Inspection Program Compatibility Requirements
Donna Janda, Region I	Technical Quality of Inspections Technical Quality of Incident and Allegation Activities Inspector Accompaniments
James Mullauer, Region III	Technical Quality of Licensing Actions
Karl Von Ahn, Ohio	Sealed Source and Device Evaluation Program

APPENDIX B

MASSACHUSETTS ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML102170078

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Massachusetts Institute of Technology — License No.: 60-0094
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Dates: 10/4-6/06 — Inspector: AC

File No.: 2
Licensee: Massachusetts General Hospital — License No.: 60-0055
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Dates: 3/3-6/09 — Inspector: AC

File No.: 3
Licensee: Tufts New England Medical Center — License No.: 68-0263
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 4/3/08 — Inspector: AC

File No.: 4
Licensee: UMass Memorial Health Alliance Leominster Campus — License No.: 44-0191
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 3/6/07 — Inspector: RG

Comment:
The Program conducted the inspection 4 months overdue.

File No.: 5
Licensee: Philotechnics — License No.: 56-0543
Inspection Type: Initial, Announced — Priority: 2
Inspection Date: 4/7/08 — Inspector: BP

Comment:
The Program conducted the inspection 18 months overdue.

File No.: 6
Licensee: ABC Testing, Inc. — License No.: 19-7781
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Date: 6/25/08 — Inspector: AC

File No.: 7
Licensee: Children's Hospital Boston — License No.: 60-0137
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Dates: 12/15-17/08 — Inspector: TC

File No.: 8
Licensee: University of Massachusetts/Lowell — License No.: 60-0049
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Dates: 2/10-11/09 — Inspector: AC

File No.: 9
Licensee: Thermo EGS Gauging, Inc. — License No.: 20-6751
Inspection Type: Routine, Unannounced — Priority: 5
Inspection Dates: 1/26/10, 2/2/10 — Inspectors: JD, JS

File No.: 10
Licensee: Caritas Good Samaritan Medical Center — License No.: 44-0023
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 2/28/07 — Inspector: JS

File No.: 11
Licensee: Tufts Medical Center — License No.: 68-0263
Inspection Type: Special, Announced — Priority: 2
Inspection Dates: 4/3/08, 5/2/08, 12/30/08 — Inspector: TC

File No.: 12
Licensee: Tufts Medical Center — License No.: 68-0263
Inspection Type: Followup, Unannounced — Priority: 2
Inspection Date: 6/29/10 — Inspector: JS

File No.: 13
Licensee: Quality Assurance Lab — License No.: 48-0426
Inspection Type: Special, Announced — Priority: 1
Inspection Date: 6/9/09 — Inspector: BP

File No.: 14
Licensee: Northshore Medical Center — License No.: 44-0161
Inspection Type: Followup, Unannounced — Priority: 3
Inspection Dates: 1/28/09, 7/21/09, 1/22/10 — Inspector: MW

File No.: 15
Licensee: Baystate Health — License No.: 01-4127
Inspection Type: Special, Announced — Priority: 2
Inspection Date: 5/12/09 — Inspector: BP

File No.: 16
Licensee: Caritas St. Elizabeth's Medical Center — License No.: 00-6345
Inspection Type: Followup/Special, Announced — Priority: 5
Inspection Date: 7/30/08 — Inspector: MW

File No.: 17
Licensee: MDS Nordion License No.: 66-0021
Inspection Type: Reciprocity, Unannounced Priority: 2
Inspection Dates: 3/2-3/10 Inspectors: AC, MI

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: ABC Testing, Inc. License No.: 19-7781
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 6/8/10 Inspector: TC

Accompaniment No.: 2
Licensee: Beverly Hospital License No.: 60-0052
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 6/9/10 Inspector: MW

Accompaniment No.: 3
Licensee: Joslin Diabetes Center, Inc. License No.: 15-2661
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 6/10/10 Inspector: AC

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Quality Inspection Services, Inc. NRC License No.: 31-30187-01
Type of Action: Reciprocity Amendment No.: 12
Date Issued: 6/3/10 License Reviewer: MI

File No.: 2
Licensee: Eyegate Pharmaceuticals, Inc. License No.: 33-0549
Type of Action: New Amendment No.: N/A
Dates Issued: 2/12/07 License Reviewer: BP

File No.: 3
Licensee: Eyegate Pharmaceuticals, Inc. License No.: 33-0549
Type of Action: Termination Amendment No.: 01
Dates Issued: 6/11/08 License Reviewer: BP

File No.: 4
Licensee: Nobel Hospital License No.: 16-1811
Type of Action: Renewal Amendment No.: 20
Date Issued: 7/9/07 License Reviewer: AC

File No.: 5
Licensee: University of Massachusetts Memorial Hospital License No.: 44-0063
Type of Action: Renewal Amendment No.: 15
Date Issued: 7/24/09 License Reviewers: AC, BP

File No.: 6
Licensee: Milton Hospital License No.: 44-0050
Type of Action: Amendment Amendment No.: 11
Date Issued: 11/30/09 License Reviewers: BP, AC

File No.: 7
Licensee: Smith College License No.: 01-4621
Type of Action: Renewal Amendment No.: 24
Date Issued: 2/1/10 License Reviewers: AC, MI

File No.: 8
Licensee: Spaulding Rehabilitation Hospital License No.: 44-0064
Type of Action: Termination Amendment No.: 5
Date Issued: 10/22/07 License Reviewers: BP, AC

File No.: 9
Licensee: Norfolk County Cardiology Associates
Type of Action: New
Date Issued: 3/31/10
License No.: 67-0285
Amendment No.: 3
License Reviewers: AC, MI

File No.: 10
Licensee: Tufts New England Medical Center
Type of Action: Amendment
Date Issued: 5/5/08
License No.: 68-0263
Amendment No.: 4
License Reviewers: AC, KI

File No.: 11
Licensee: Williams College
Types of Action: Renewal
Dates Issued: 4/16/08
License No.: 04-0284
Amendment No.: 9
License Reviewers: JS, MI

File No.: 12
Licensee: Boston College
Types of Action: Renewal
Dates Issued: 5/19/09
License No.: 00-6427
Amendment No.: 13
License Reviewers: AC, MI

File No.: 13
Licensee: Beth Israel Deaconess Medical Center
Type of Action: Amendment
Date Issued: 9/11/08
License No.: 60-0432
Amendment No.: 10
License Reviewers: MI, AC, KD

File No.: 14
Licensee: M/A - Com
Type of Action: Termination
Date Issued: 10/22/07
License No.: 48-0405
Amendment No.: 4
License Reviewer: JD

File No.: 15
Licensee: Entergy Nuclear Op., Inc.
Type of Action: Renewal
Date Issued: 3/6/09
License No.: 07-6262
Amendment No.: 15
License Reviewer: AC, MI

File No.: 16
Licensee: Beth Israel Deaconess Medical Center
Type of Action: Amendment
Date Issued: 6/11/08
License No.: 60-0432
Amendment No.: 9
License Reviewer: MI, AC

File No.: 17
Licensee: MDS Nordion
Type of Action: Reciprocity
Date Issued: 12/1/09
NRC License No.: 54-28275-01
Amendment No.: N/A
License Reviewer: MI

File No.: 18
Licensee: H & H X-ray Services, Inc. NRC License No.: 17-19236-01
Type of Action: Reciprocity Amendment No.: 26
Date Issued: 11/12/09 License Reviewer: MI

File No.: 19
Licensee: Conam Inspection License No.: 16-5591
Type of Action: Amendment Amendment No.: 15
Date Issued: 8/18/09 License Reviewer: JD

File No.: 20
Licensee: Easter Massachusetts Surgery Center, LLC License No.: 70-0594
Type of Action: Amendment Amendment No.: 2
Date Issued: 1/12/10 License Reviewers: TC, JD

File No.: 21
Licensee: Varian Medical Systems NRC License No.: 45-30957-01
Type of Action: Reciprocity Amendment No.: N/A
Date Issued: 12/22/09 License Reviewer: MI

File No.: 22
Licensee: ABC Testing License No.: 19-7781
Type of Action: Amendment Amendment No.: 10
Date Issued: 10/28/07 License Reviewer: AC

File No.: 23
Licensee: Neutron Products, Inc. Maryland License No.: 31-025-03
Type of Action: Reciprocity Amendment No.: N/A
Date Issued: 4/18/07 License Reviewer: MI

File No.: 24
Licensee: Decontamination, Decommissioning & Environmental Services, Inc. License No.: 56-0623
Type of Action: New Amendment No: N/A
Date Issued: 6/4/10 License Reviewer: BP

File No.: 25
Licensee: ABC Testing License No.: 19-7781
Type of Action: Renewal Amendment No. : 11
Date issued: 7/2/10 License Reviewer: JS

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Cardinal Health — License No.: 42-0146
Date of Incident: 3/18/09 — NMED No.: 090394
Investigation Dates: 3/18 – 7/13/09 — Type of Incident: Transportation
Types of Investigation: Telephone, Licensee Report

File No.: 2
Licensee: Cambridge Isotopes Lab/Ontario Power — License No.: N/A
Date of Incident: 6/28/07 — NMED No.: 070401
Investigation Dates: 6/29 – 8/22/07 — Type of Incident: Lost/Stolen/Abandoned RAM
Type of Investigation: Telephone

File No.: 3
Licensee: Solo Cup Company — General License No.: G0285
Date of Incident: 10/29/07 — NMED No.: 070683
Investigation Dates: 10/29/07, 11/29/07 — Type of Incident: Lost/Stolen/Abandoned RAM
Type of Investigation: Site

File No.: 4
Licensee: Geotechnical Consultants — License No.: 48-0334
Date of Incident: 11/6/08 — NMED No.: 080777
Investigation Date: 11/7/08 — Type of Incident: Lost/Stolen/Abandoned RAM
Type of Investigation: Telephone

File No.: 5
Licensee: Thyro-Cat — License No.: 44-0550
Date of Incident: 6/13/07 — NMED No.: 070376
Investigation Date: 6/20/07 — Type of Incident: Contamination
Type of Investigation: Site

File No.: 6
Licensee: Brigham & Women's Hospital — License No.: 44-0004
Date of Incident: 6/30/09 — NMED No.: 090575
Investigation Date: 8/27/09 — Type of Incident: Possible Overexposure
Type of Investigation: Telephone, Licensee Report

File No.: 7
Licensee: Massachusetts General Hospital — License No.: 60-0055
Date of Incident: 2/10/10 — NMED No.: 100071
Investigation Date: 2/25/10 — Type of Incident: Medical
Type of Investigation: Telephone, Licensee Report

File No.: 8
Licensee: QSA Global, Inc.
Date of Incident: 8/20/08
Investigation Date: 8/22/08
License No.: 12-8361
NMED No.: 080492
Type of Incident: Possible Overexposure
Type of Investigation: Site

File No.: 9
Licensee: QSA Global, Inc.
Date of Incident: 12/18/07
Investigation Date: 12/21/07
License No.: 12-8361
NMED No.: 080005
Type of Incident: Lost/Stolen/Abandoned RAM
Type of Investigation: Site

File No.: 10
Licensee: Quaker Fabric Corp.
Date of Incident: 5/19/09
Investigation Date: 5/21 – 6/24/09
General License No.: G0122
NMED No.: 090505
Type of Incident: Lost/Stolen/Abandoned RAM
Type of Investigation: Site

APPENDIX F

SEALED SOURCE AND DEVICE (SS&D) CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Registry No.: MA-1233-D-101-G
Manufacturer: Sionex Corporation
Date Issued: 4/26/10
SS&D Type: (N) Ion Generators, Chromatography
Model Nos.: SVAC Series micro Analyzer, micro Analyzer-1, micro Analyzer-2, micro Analyzer V2.0
Type of Action: Amendment
SS&D Reviewers: JD, JS

File No.: 2
Registry No.: MA-1059-S-191-S
Manufacturer: QSA Global, Inc
Date Issued: 4/1/10
SS&D Type: (F) Well Logging Source
Model No.: CDC.CYn series
Type of Action: Amendment
SS&D Reviewers: JS, JD

File No.: 3
Registry No.: MA-1287-D-105-B
Manufacturer: Thermo EGS Gauging
Date Issued: 2/17/10
SS&D Type: (E) Beta Gauge
Model Nos.: SCL-77A, SCL-1C
Type of Action: Amendment
SS&D Reviewers: JD, JS

File No.: 4
Registry No.: MA-1059-D-114-S
Manufacturer: QSA Global, Inc
Date Issued: 9/17/09
SS&D Type: (Y) Calibrators
Model No.: 773
Type of Action: Amendment
SS&D Reviewers: JD, JS

File No.: 5
Registry No.: MA-1059-D-930-S
Manufacturer: QSA Global, Inc
Date Issued: 5/19/09
SS&D Type: (A) Industrial Radiography
Model No.: 650L source changer
Type of Action: Inactivation
SS&D Reviewers: JS, JD

File No.: 6
Registry No.: MA-1059-D-365-S
Manufacturer: QSA Global, Inc
Date Issued: 1/28/09
SS&D Type: (A) Industrial Radiography
Model No.: 989
Type of Action: New
SS&D Reviewers: JD, JS

File No.: 7
Registry No.: MA-1101-D-801-G
Manufacturer: Bruker Detection Corp.
Date Issued: 3/6/09
SS&D Type: (N) Ion Generator, Chromatography
Model No.: RAID System Series
Type of Action: Inactivation
SS&D Reviewers: JS, JD

File No.: 8
Registry No.: MA-1159-D-102-B
Manufacturer: Thermo Niton Analyzers
Date Issued: 8/30/07
SS&D Type: (U) X-ray Fluorescence
Model No.: XL3p series
Type of Action: New
SS&D Reviewers: JS, JD

File No.: 9
Registry No.: MA-0555-S-102-S
Manufacturer: Industrial Nuclear Corp
Date Issued: 8/3/07
SS&D Type: (H) General Neuron Source
Model No.: HK252M41 Series
Type of Action: New
SS&D Reviewers: JS, JD

Comments:
a) In the registration certificate section “External Radiation Levels”, the table listed radiation profiles on a per microgram (0.536 mCi) basis instead of the customary maximum activity.
b) The maximum loading of the sealed source is 116.9 micrograms (64.11 mCi).
c) Since a user of the registration certificate could potentially misread the radiation levels, the review team recommends that the program reissue this registration certificate to include a dose profile from the maximum source loading.

File No.: 10
Registry No.: MA-1059-D-364-S
Manufacturer: QSA Global, Inc
Date Issued: 9/21/06
SS&D Type: (AA) Manual Brachytherapy
Model No.: R2.3 (Sr-90 eye applicator)
Type of Action: New
SS&D Reviewers: JS, JD

File No.: 11
Registry No.: MA-1059-S-215-S
Manufacturer: QSA Global, Inc
Date Issued: 1/22/07
SS&D Type: (Y) Calibrator
Model No.: SIC.L9
Type of Action: Reactivation
SS&D Reviewers: JS, JD

File No.: 12
Registry No.: MA-0573-D-103-B
Manufacturer: RMD Instruments
Date Issued: 7/2/07
SS&D Type: (U) X-ray Fluorescence
Model Nos.: LPA-1, LPA-1B, LTR1000
Type of Action: Amendment
SS&D Reviewers: JS, JD

File No.: 13
Registry No.: MA-1059-S-359-S
Manufacturer: QSA Global, Inc
Date Issued: 8/1/07
SS&D Type: (X) Medical Reference Source
Model Nos.: 1000C series, 1000R series
Type of Action: Amendment
SS&D Reviewers: JS, JD

File No.: 14
Registry No.: MA-219-D-813-S
Manufacturer: Pharmalucence, Inc
Date Issued: 8/1/08

SS&D Type: (J) Gamma Irradiator, Category 1
Model No.: IBL-437C
Type of Action: Inactivation
SS&D Reviewers: JD, JS

ATTACHMENT

September 9, 2010 Letter from Robert Gallaghar
Massachusetts Response to the Draft Report
and
NRC's comment resolution document

ADAMS Accession No.: ML102580885