June 20, 2006

Ms. Suzanne K. Condon
Associate Commissioner
Center for 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 program review held in Massachusetts on May 15-19, 2006. I was the team leader for the review. The review team's preliminary findings were discussed with you and 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 to protect public health and safety and compatible with NRC's program.

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 NRC's program. The process, titled IMPEP, employs a team of NRC and Agreement State staff to assess both Agreement State and NRC Regional Office radioactive materials programs. All reviews use common criteria in the assessment and place primary emphasis on performance. Three additional areas have been 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, will be 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 draft team report for your review and 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 that will be responsive to your needs.

The team will review your 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 in the week of July 31, 2006. I will coordinate with you to establish the date for the MRB review of the Massachusetts report. NRC will provide invitational travel for you or your designee to attend the MRB meeting. NRC has video conferencing capability if it is more convenient for the State 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/
Kevin Hsueh, Team Leader
Health Physicist
Office of State and Tribal Programs

Enclosure:
As stated

cc: Robert J. Walker, Director
Radiation Control Program
Department of Public Health

Cristine McCombs, Director
Massachusetts Emergency Management Agency
State Liaison Officer

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF MASSACHUSETTS AGREEMENT STATE PROGRAM

May 15-19, 2006

DRAFT REPORT

U.S. Nuclear Regulatory Commission

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 May 15-19, 2006, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Maine. 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 the February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of June 29, 2002 to May 19, 2006, were discussed with Massachusetts management on the last day of the review.

The Massachusetts Agreement State Program is administered by the Radiation Control Program (the Program) located within the Center for Environmental Health (the Center). The Center is located within the Department of Public Health (the Department). Organization charts for the Department, the Center and the Program are included in Appendix B. At the time of the review, the Massachusetts Agreement State Program regulated approximately 516 specific licenses authorizing Agreement materials. The review focused on the 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 non-common performance indicators was sent to the Program on January 26, 2006. The Program provided a response to the questionnaire on April 28, 2006. A copy of the questionnaire response can be found on NRC's Agencywide Document Access and Management System (ADAMS) using the Accession Number ML061230678.

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 licensing and inspection actions; (5) field accompaniments of three Program inspectors; and, (6) interviews with staff and management to answer questions or clarify issues. The review team evaluated the information gathered against the IMPEP performance 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 below discusses Massachusetts' actions in response to recommendations made following the previous routine and follow-up IMPEP reviews. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance indicators, and Section 5 summarizes the review team's findings and recommendations. Recommendations made by the review team are comments that relate directly to performance by the Commonwealth. A response is requested from the Commonwealth to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on June 28, 2002, four recommendations were made and transmitted to Dr. Howard K. Koh, Commissioner of the Department on September 19, 2002. The review team's evaluation of the current status of the recommendations is as follows:

1. 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 STP Procedure SA-300. (Section 3.5 of the 2002 IMPEP report)

   Current Status: Although the review team found that there has been some progress made in reporting recent events to the NRC in accordance with STP Procedure SA-300, there were a large number of older events which had not been properly reported as required. Further details are discussed in Section 3.5. This recommendation remains open.

2. 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 SA-201. (Section 4.1.2 of the 2002 IMPEP report)

   Current Status: The review team found that the Commonwealth has 16 overdue regulations that have not been adopted during the on-site review. The Commonwealth used license conditions as alternate legally-binding requirements to address three of the overdue regulations; the Program submitted one of those three license conditions to the NRC for a compatibility review. All three of the license conditions will be replaced by regulations in an upcoming rulemaking package. Further details are discussed in Section 4.1.2. The recommendation remains open.

3. The team recommends that in the interest of national consistency, and where practical, the Program closely follow the format for documenting product evaluations in SS&D registry certificates as detailed in NUREG 1556, Volume 3. (Section 4.2.1 of the 2002 IMPEP report)

   Current Status: The review team found that the registration certificates issued by the program during the review period follow the format of the guidance document. This recommendation is closed.

4. The review team recommends that the Program make corrections to registration certificates MA-1142-D-102-G and MA-0116-102-B. (Section 4.2.1 of the 2002 IMPEP report)

   Current Status: The review team found that the corrections have been made to registration certificate MA-1142-D-102-G. Therefore, this part of the previous recommendation is closed. However, regarding registration certificate MA-0116-D-102-B, the Program has identified additional issues for the vendor, Eurotherm, presently called EGS Gauging Systems, that also needed corrections. The Program sent deficiency letters dated January 9, 2003, and June 26, 2003, to the licensee. At the

time of the current review, the Program has not received a response to the deficiency letters and, consequently, was not able to make the corrections to the registration certificate. Therefore, the second part of this recommendation remains open.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State programs. These indicators include: (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 Program management and staff, reviewed job descriptions and training records, and considered any possible workload backlogs.

The Program, headed by the Program Director, has a total of 18.4 full time equivalents (FTE) assigned to implement the Agreement State program. The Program consists of six units: the Radioactive Materials Unit, the Environmental Unit, the Mammography and Healing Arts Unit, the Low Level Radioactive Waste (LLRW) Unit, the Administration Unit and the Planning/Monitoring Unit. The technical staff in the Radioactive Materials Unit are classified as Environmental Engineers and perform both inspection and licensing functions of radioactive materials. A subset of the technical staff also conduct SS&D evaluations, which is further discussed in Section 4.2.1 of this report. As a result of the Legislature abolishing the LLRW Facility Siting Board (the Board) in February 2002, the Program gained the Board's responsibilities, particularly for conducting an annual survey of LLRW generated by Commonwealth licensees. An additional FTE was gained by the Program to fulfill its new LLRW responsibilities.

The Radioactive Materials Unit (the Unit) is managed by the Radioactive Materials Supervisor and is divided into the basic functions of inspection and licensing. The Unit also has an Inspection Supervisor and a Licensing Supervisor to assist the Radioactive Materials Supervisor in managing the Unit. The review team noted that the Program's policy of requiring staff to be qualified to perform both licensing and inspection functions provides the ability to shift resources to meet program demands.

The review team noted that the Program's funding was obtained through the retained revenue program. The Program's licensees are assessed annual fees based on the licensed activity category and amendment fees. The Program retains revenue up to the total estimated expenses of operating the Program. Excess revenue is deposited in the Commonwealth's general fund.

Six staff members left the Program and two staff members were hired during the review period. At the time of the review, the Program had three vacancies. One vacated each in 2001, 2002 and 2005. The positions vacated in 2001 and 2002 were not filled due to lack of funding for the positions since the Program had been flat funded for about five years since 2000. Beginning July 1, 2005, the Program budget cap was increased and two vacant position could be filled. However, one of the positions had to be rescinded due to unforseen financial obligations to pay for cost of living increases for the rest of the Program staff.

The Program has been in the process of filling the one vacant position since July 2005. The position was offered to several individuals after interviews with potential candidates but they all declined mainly due to the fact that the pay was not competitive to attract qualified individuals who may have other employment opportunities working in the nearby nuclear industry and the high cost of living in the Boston area. The Program management indicated that if the Program budget continues to be capped at the current level in the future, they may not have the funding to support the vacancy position due to potential financial obligations to pay for cost of living increases for the rest of the Program staff.

The review team determined that there was a reduction of approximately 30 percent in FTE for staff members assigned to conduct inspections, license reviews and SS&D reviews since the last IMPEP review (11.75 in 2002 versus 7.4 at the time of the on-site review). This represents a significant reduction of staff members working in those areas.

To overcome the staff shortage, the Program adopted most of the NRC's inspection priorities found in Inspection Manual Chapter (MC) 2800, which allowed the Program to reduce a significant number of inspections yet still maintain an adequate inspection program. The Inspection Supervisor indicated that the Program has benefitted by adopting the inspection priorities MC 2800 and is willing to share their success experience with other Agreement States. The review team noted that the staffing shortages have contributed to the cause of licensing backlog discussed in Section 3.4.

The review team concluded that the Program will continue to face the challenge of staffing shortages due to the fact that in addition to routine licensing, inspection and response to incidents and allegations activities, there are greater demands for Program staff resources to deal with the increased concerns for safety and security of radioactive material. Without increasing funding to support the demands for Program staff resources, the Program is vulnerable to further losses of Program staff positions or may not have sufficient staff resources to meet increasing workload demand which could adversely affect performance. Program management acknowledged the need to promptly fill the current vacancies, as well as address future staffing needs. 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.

The Program has a documented training and qualification program that is consistent with the guidance in the NRC/Organization of Agreement States Training Working Group Report and the NRC's MC 1246. Each staff member must document formal training, including basic, specialized, and advanced training, on a Training Qualification record. The Program also has on-the-job training to supplement the course work so that individuals may broaden their work areas. As a part of the Program's in-house and on-the-job training processes, new staff members are assigned increasingly complex licensing duties under the direction of the

Licensing Supervisor and accompany experienced inspectors during increasingly complicated inspections under the direction of the Inspection Supervisor. The review team found that the Program staff is well qualified from an education and experience stand point. All technical staff members have at least Bachelor's degree in the sciences, or equivalent training and experience.

The staff training records demonstrated that the Program is committed to a high degree of training for the staff. Program management indicated that upper-level management has been very supportive of staff training opportunities.

The Commonwealth does not have an oversight board or committee to provide direction to the Agreement State 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 in reviewing this indicator: inspection frequency, overdue inspections of Priority 1, 2, and 3 licensees, initial inspection of new licenses, timely dispatch of inspection findings to licensees, and the performance of reciprocity inspections. The review team's evaluation is based on the Program's questionnaire response relative to this indicator, data gathered from the Program's licensing and inspection database, the examination of completed inspection casework, and interviews with managers and staff.

The review team's evaluation of the Program's inspection priorities verified that the inspection frequencies for all types of licenses, with the exception of two license types, are equal to those listed in MC 2800. Very large, multi-site Medical Institution Broad Scope licenses are inspected annually whereas MC 2800 allows a two year periodicity. Those licensees listed as Priority T (telephone inspections) in MC 2800 are listed as Priority 5 on the Program's schedule.

At the time of the review there were no overdue core inspections, including initial inspections. The review team examined the Program's tracking information for a total of 277 inspections, which included 97 initial inspections. Four core inspections, in addition to four initial inspections, were conducted overdue during the review period. The overdue inspections ranged from a few days to 12 months overdue at the time of inspection.

The timeliness of the issuance of inspection findings was evaluated during the review of inspection casework. The Program has an effective and efficient process which ensures that inspection findings are communicated to licensees in a timely manner. The Program's goal is to complete each inspection report and deliver the notice of violation, as appropriate, to the licensee within 30 days of the inspection's completion date. For 10 routine inspection files examined, all inspection findings were sent to the licensees within 30 days, with the exception of two, which were awaiting final supervisory signature.

During the review period, the Program granted 166 reciprocity certificates, of which, 40 certificates were candidate licensees based upon MC 1220. The review team determined that the Program met and exceeded NRC's criteria of inspecting 20 percent of candidate licensees

operating under reciprocity for the review period. The Program attempts to conduct unannounced reciprocity inspections. However, the Program has found that often the reciprocity licensees have already completed the job when the inspector arrives at the job site.

The review team determined that with respect to Commission Staff Requirements Memorandum (ARM) for COMSTOCK-05-0028, on increased controls, the Program has started to plan for the initial set of inspections of these licensees in accordance with the increased control requirements.

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, and inspection field notes and interviewed inspectors for 11 radioactive materials inspections conducted during the review period. The casework included all of the Program's fully trained materials inspectors, and covered a variety of license types including inspections of various types as follows: manufacturing and distribution broad scope, manufacturing and distribution other, medical institution written directive required, research and development, industrial radiography, medical broad scope, academic broad scope, nuclear pharmacy, medical product distribution, brachytherapy, and limited medical. Appendix C lists the inspection casework reviewed, with case-specific comments, as well as the results of the inspector accompaniments.

The review team noted that the Program currently has seven experienced materials inspectors and one Inspection Supervisor. Based on the casework file reviews, the review team found that routine inspections covered all aspects of the licensee's radiation protection program. The inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that licensee's performance with respect to health and safety was acceptable. The documentation adequately supported violations, recommendations made to the licensee, unresolved safety issues, and discussions held with the licensee during exit interviews. Team inspections were performed when appropriate and for training purposes.

Inspection reports include a written summary of the scope of the licensed activities and categorize violations into severity levels which can be used for escalated enforcement, if necessary. Field notes or inspection reports used to document the inspection reflected a performance-based, risk-informed approach. The Inspection Supervisor conducts and documents supervisory accompaniments of each material inspector once a year.

The Program has adequate numbers and appropriate types of survey meters to support the current inspection program, as well as for responding to incidents and emergency conditions. Each inspector is assigned an instrument kit to be used for inspections and response to incidents. The Program has an outside contractor to calibrate their survey instruments annually. Appropriate, calibrated survey instruments such as Geiger-Mueller (GM) meters, scintillation detectors, ion chambers and micro-R meters were observed by the review team. Contamination wipes and other environmental samples are evaluated at the Program's laboratory located in Jamaica Plains. Instrumentation available at the laboratory includes gas

flow proportional counter, liquid scintillation counter, thermoluminescence dosimeter reader, and high purity germanium detectors with supporting electronics and software.

Three inspectors were accompanied by a review team member during the week of April 3, 2006. The accompaniments included inspections of facilities that were licensed for research and development, medical institution with brachytherapy, and a nuclear cardiology clinic. The facilities inspected are identified in Appendix C. During the accompaniments, each inspector demonstrated appropriate performance-based, and risk informed inspection techniques, adhered to good health physics practices and exhibited knowledge of the regulations. The inspectors were well prepared for the inspection, and thorough in their audits of the licensees' radiation safety programs. Their inspections were adequate to assess radiological health and safety at the licensed facilities.

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.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed the staff for 15 specific licenses. Seventeen separate licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequate facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of the license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, product certifications, supporting documentation, consideration of enforcement history, pre-licensing visits, supervisory review as indicated, and proper signatures. The files were checked for retention of necessary documents and supporting data.

Licensing casework was selected to provide a representative sample of licensing actions that were completed during the review period. The sampling included the following types of licenses: research and development, manufacturing and distribution, medical (mobile and broad scope), fixed gauge, portable gauge, irradiator, nuclear pharmacy, and industrial radiography. Types of licensing actions selected for evaluation included new licenses, amendments to existing licenses, renewals, and terminations. A listing of the licensing casework reviewed can be found in Appendix D.

Overall, the review team found that licensing actions were thorough, complete, consistent, and of acceptable quality with health and safety issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file, and inspectable. The licensee's compliance history was taken into account when reviewing renewal applications and amendments. Except as noted below, the licensing reviewers appropriately used the Program's licensing guides and standard license conditions.

The Program renews licenses every five years. The review team noted that most licensing actions were promptly acted upon, usually within 30 days of receipt. However, the review team noted that the Program has eight renewals that have been pending for more than one year, with a couple dating back to 2002 and 2003. The Licensing Supervisor indicated that it is a staffing

resource issue. The review team did not find any safety-significant impacts on the licensee's programs due to the length of pending renewals.

The review team found that the Program staff routinely use detailed licensing checklists when reviewing licensing actions. All licensing actions are reviewed by a primary license reviewer, who closely monitors the timeliness of licensing actions. All completed licensing actions are then reviewed by a secondary license reviewer and the Licensing Supervisor. The Program Director signs all licensing documents.

The Program issued a revision to their Licensing Procedures in October 24, 2005. This procedure includes guidance for new applications, renewals and amendments. The most significant change was to the section on issuance of reciprocity certificates. The Program also refers to NRC NUREG-1556 series for detailed procedures when needed.

The review team evaluated financial assurance and decommissioning activities conducted in the Program. In addition, the review team found that termination 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.

In 1977, the NRC initiated a review of terminated NRC licenses to determine whether sites had been adequately decontaminated prior to termination and release of the site. As a result of this effort, a number of sites were identified as lacking proper documentation of termination activities, including disposition of materials. Some of these NRC formerly licensed sites were determined to be located in Agreement States and to be the regulatory responsibility of the State. In an effort to reduce the resource impacts on Agreement States, the NRC established a grant program in 2001 for Agreement States to conduct file reviews and initial surveys of the NRC formerly licensed sites. Fourteen sites were determined to be located in Massachusetts. The Commonwealth of Massachusetts submitted a grant proposal to the NRC and was awarded a grant of $36,890.70 to review the 14 sites within the Commonwealth on June 5, 2002. The Commonwealth completed the grant project, closed all the 14 site files, and submitted a final report to the NRC in a letter dated November 19, 2002.

The final report includes the Commonwealth’s assessments and findings for each site file reviewed. Based on review of the final report, the review team determined that the Commonwealth conducted a through review of these NRC formerly licensed sites. The basis to close each site file is well documented and supported by radiological status of the site including survey results obtained during site visits of these formerly licensed sites.

The review team examined the licensees that the Program had determined met the criteria for the increased controls, as per COMSTOCK-05-0028. Each applicable licensee was issued a license amendment requiring increased controls, with exceptions discussed below, and will continue to issue increased controls to any additional future licensees meeting the threshold criteria.

The review team determined that the Program had correctly identified the licensees that require increased controls based on this criteria except for about 20 licensees that were overlooked due to a misinterpretation of COMSTOCK-05-0028. Specifically, certain reciprocity licensees and some licensees that may temporally possess sources exceeding quantity of concern, for example, during the source exchange period, were not issued license amendments to include

increased controls. The review team discussed this oversight with Program management and staff, and the Program agreed to take action to address this finding. 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.

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.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Program's actions in responding to incidents, the review team examined the Program's 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 and supporting documentation for 11 material incidents. A listing of the incident casework examined, with case-specific comments, can be found in Appendix E. The review team also evaluated the Program's response to 13 allegations involving radioactive material received during the review period, including three referred to the Commonwealth by the NRC.

The review team discussed the Program's event and allegation procedures, tracking system, file documentation, NMED, and notification of incidents to the NRC Headquarters Operations Center with Program management and staff. The Program's event procedures include reporting requirements consistent with the Office of State and Tribal Programs (STP) Procedure SA-300, "Reporting Material Events."

The primary responsibility for coordination of all incidents and allegations rests with the Event Coordinator. The initial response and follow-up to incidents and allegations involving radioactive materials are coordinated with the Licensing Supervisor and Radioactive Materials Supervisor. A combined written procedure exists for handling all incidents and allegations. If an inspection is warranted, the Inspection Supervisor 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 all incidents and allegations reported and the planned response. Review of the casework indicated that this approach provides effective and appropriate response actions and generally does not delay the response time.

The procedure and report forms are available to the staff when responding to any event, accident or emergency involving radioactive materials. All events, as well as allegations, are assigned individual docket numbers for tracking. The events are also entered into a local events database and assigned a sequential event number. Completed events and allegation docket files are placed in the corresponding licensee's file.

The 11 incident files selected for review included the following categories: overexposure, loss of radioactive material, medical, transportation, leaking source and fire. The review team found that the Program's response to events was generally complete and comprehensive except for the two events discussed below. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. The Program

dispatched inspectors for on-site investigations when appropriate and took suitable enforcement and follow-up actions.

The review team found two events received by the Program in 2003 where they were not acted on in a timely manner. One event involved a high dose-rate remote afterloader malfunction and the other one involved a leaking sealed source. In both cases, the Program received the event report, opened a case, but did not take any action to follow up or resolve the issue. The review team discussed these two events with the Program. Program management indicated that they plan to take follow-up action to close these two action items. Although the review team concluded that these are two isolated cases and do not represent an overall performance issue with respect to the Program's handling of events, the review team believes that these cases could have been identified and acted on if the Program effectively utilized its existing database, which allows management to periodically track the Program's action items. Specifically, the Program staff periodically generates reports containing the status of all the essential action items, including event opening and closing dates. The review team does not believe that the Program has effectively used these reports to monitor the status of progress of each event and close out the event in a timely manner. The review team further noted that a significant number of events remained open. 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.

The 2002 IMPEP review team identified that the Program was not reporting significant or routine events in a timely manner as requested in STP Procedure SA-300. Prior to the on-site review, the review team queried the NMED system and identified 33 NRC reportable events over the review period. During the on-site review, the Program provided a list of 52 events reported to NMED since June 2002. The review team noted that among the 52 events, some are not NRC reportable events.

The review team evaluated the timeliness of the 33 NRC reportable events and noted that approximately 35 percent of the these events were not reported in a timely manner as requested in STP Procedure SA-300. The review team noted that routine and follow-up event information was not reported to NMED on a monthly basis as requested in STP Procedure SA-300. The review team discussed the issue of reporting events and providing follow-up event information with Program management and staff responsible for NMED data entry. Program management indicated that the poor performance in reporting and updating events was due to the changeover in staff responsible for the Events Coordinator position and the extra time and effort needed in learning the NMED software to enter information into the database. Although the review team found that there has been some progress made in reporting recent events to the NRC in accordance with STP Procedure SA-300, there were a significant number of older events which had not been properly reported as required. Thus, as discussed in Section 2 above, the recommendation from the 2002 IMPEP report remains open.

During the review period, the Program received 13 allegations including three referred to the Commonwealth by the NRC. The review team evaluated all allegations received by the Program. The review team noted that the Program promptly responded with appropriate investigations, follow-up, and closeout actions. All allegation files contained written closeout correspondence to the alleger summarizing the Program's actions regarding the concerns raised. The review team also determined that the Program can protect an alleger's identity. There were no performance issues identified from the review of the files or the documentation.

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

IMPEP identifies four non-common performance indicators to be used in reviewing 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. The Massachusetts Agreement State program does not cover uranium recovery operations, so only the first three non-common performance indicators were applicable to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

Massachusetts became an Agreement State on March 21, 1997. The authority under which the Program administers the Agreement is in Massachusetts General Law 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 last review.

4.1.2 Program Elements Required for Compatibility

The Commonwealth regulations for the Program are located in Title105 of the Code of Massachusetts Regulations Section 120, and apply to ionizing and non-ionizing radiation, whether emitted from radionuclides or devices. Massachusetts requires a license for possession and use of radioactive materials, including naturally occurring and accelerator-produced radionuclides.

The review team evaluated the Program's response to the questionnaire relative to this indicator, interviewed Program management and staff, reviewed the status of regulations required to be adopted by the Commonwealth under the Commission's adequacy and compatibility policy and verified the adoption of regulations with data obtained from STP's State Regulation Status Data Sheet.

The review team examined the Program's rulemaking process and found that, depending on the number of regulations being processed, the amount of time to promulgate regulations from the date regulations are drafted until the effective date of the regulations can take up to approximately 18 months. Regulations are drafted by Program staff, reviewed by Program management, and are then sent to the NRC for a compatibility review. Any comments received by the NRC are evaluated, and the regulations are revised as necessary. The regulations, revised to address NRC comments, are then reviewed by the Program's legal counsel. The time required for the legal counsel review ranges from one week to one year, depending on the size of the rulemaking package. 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 Department of Public Health Council (Council) for public publication approval. The regulations are published in two newspapers and in the Commonwealth Register for a minimum of 30 days for public review and comment. 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 management and are submitted to the Council for promulgation. Once the Council approves the regulations for promulgation, the Secretary of the Commonwealth establishes an effective date, which is usually 30 days after the date of approval. A copy of the final promulgated regulations are then sent to the NRC for review as final regulations.

The review team determined that 16 regulations have not been adopted within the 3-year time frame. The review team noted that three of the 16 overdue regulations were identified as overdue during the 2002 IMPEP review. During the 2002 IMPEP review, the Program indicated an intent to promulgate the three overdue regulations in 2003. Program staff indicated during this on-site review that the reasons the three overdue regulations were not promulgated in 2003 were: (1) the process to promulgate the regulations took longer than originally anticipated, (2) the Program staff preferred to promulgate a larger regulation package instead of three regulations, and (3) the Program staff preferred to promulgate a regulation package with significant changes, such as changes to 10 CFR Part 35, that had an upcoming implementation date.

The following 13 regulations including the three overdue regulations identified during the 2002 IMPEP review have not been adopted and are overdue:

- "Timeliness in Decommissioning Material Facilities," 10 CFR Parts 30, 40, 70 amendments (59 FR 36026) that became effective August 15, 1997.

- "Low Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20, 61 amendments (60 FR 15649, 60 FR 25983) that became effective March 1, 1998.

- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19, 20 amendments (60 FR 36038) that became effective August 14, 1998.

- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, 70 amendments (60 FR 38235) that became effective November 24, 1998.

- "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, 70 amendments (62 FR 39057) that became effective August 20, 2000.

- "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations," 10 CFR Part 34 amendment (63 FR 37059) that became effective July 9, 2001.

- "Minor Corrections, Clarifying Changes and a Minor Policy Change," 10 CFR Parts 20, 35, 36 amendments (63 FR 39347, 63 FR 45393) that became effective October 26, 2001.

- "Transfer for Disposal and Manifests: Minor Technical Conforming Amendment," 10

CFR Part 20 amendments (63 FR 50127) that became effective November 20, 2001.

- "Respiratory Protection and Controls to Restrict Internal Exposure," 10 CFR Part 20 amendments (64 FR 54543, 64 FR 55524) that became effective on February 2, 2003.

- "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 10 CFR Part 39 amendments (65 FR 20337) that became effective on May 17, 2003.

- "New Dosimetry Technology," 10 CFR Parts 34, 36 and 39 amendments (65 FR 63750) that became effective on January 8, 2004.

- "Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 16298) that became effective April 5, 2005.

- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32 and 35 (67 FR 20249) amendments that became effective on April 24, 2005.

In addition, the review team noted that the Commonwealth used other forms of generic legally binding requirements to address the following three regulations and one Order:

- "Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State," 10 CFR Part 150 amendment (62 FR 1662) that became effective February 27, 2000.

- "Deliberate Misconduct by Unlicensed Persons," 10 CFR Parts 30, 40, 61, 70, 71, 150 amendments (63 FR 1890, 63 FR 13773) that became effective on February 12, 2001.

- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30, 31 and 32 amendments (65 FR 79162) that became effective February 16, 2004.

- "Increased Controls for Risk-Significant Radioactive Sources," NRC Order EA-05-090, that became effective December 1, 2005.

All 16 overdue regulations have been submitted to the NRC, as proposed regulations, for review and comment. NRC has reviewed the proposed regulations, and submitted comments on 5 of the 16 regulations. The Program expects to promulgate the 16 overdue regulations in June 2006 and submit the final regulations to the NRC in July 2006. The review team noted that of the license conditions being used in place of regulations or NRC Orders only the license condition used to address NRC order EA-05-090 has been submitted to the NRC for a compatibility review.

As discussed in Section 2.0, the recommendation from the 2002 IMPEP review, 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 SA-201, remains open.

The Program will need to address the following regulations in upcoming rulemakings or by

adopting alternate legally binding requirements:

- "Financial Assurance for Materials Licensees," 10 CFR Parts 30, 40, 70 amendments (68 FR 57327) that will become effective December 3, 2006.

- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697) that will become effective October 1, 2007.

- "Medical Use of Byproduct Material - Recognition of Specialty Boards, " 10 CFR Part 35 amendment (70 FR 16336, 71 FR 1926) that will become effective April 29, 2008.

- "Security Requirements for Portable Gauges Containing Byproduct Material," 10 CFR Part 30 amendment (70 FR 2001) that will become effective July 11, 2008.

Based on the IMPEP evaluation criteria, the review team recommends that Massachusetts' performance with respect to the indicator, Compatibility Requirements, be found satisfactory, but needs improvement.

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

In conducting this review, three sub-indicators were used to evaluate the Program's performance regarding their SS&D Evaluation Program. These sub-indicators include: (1) Technical Staffing and Training; (2) Technical Quality of the Product Evaluation; and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

In assessing the SS&D Evaluation Program, the review team examined information provided by the Program in response to the IMPEP questionnaire relative to this indicator. A review of selected new, amended, transferred, and inactivated SS&D evaluations and supporting documents covering the review period was conducted. The review team noted the staff's use of guidance documents and procedures, interviewed the staff and the supervisor involved in SS&D evaluations, and verified the use of regulations, license conditions, and inspections to enforce commitments made in the applications.

The Program completed 149 SS&D actions and six evaluations of events or failures involving Massachusetts products since June 2002.

4.2.1 Technical Staffing and Training

The Program reported that currently two staff members and the Licensing Supervisor have authority to sign SS&D evaluations, in addition to their responsibilities for materials licensing casework and inspections. The review team examined the training and experience folders for the two staff members. All had engineering backgrounds by education and attended the NRC SS&D workshop. In addition to the courses attended for training, the training records had detailed documentation of SS&D casework assignments, dates, and the name of the Program mentor. Staff members were not permitted to work independently until the Licensing Supervisor was satisfied that the individual had demonstrated adequate competency and recommended working independently through a memorandum to the Radioactive Materials Supervisor. The review team found that the Program's SS&D staff completed the casework within an average of

six to eight weeks and that there is no backlog of SS&D cases. The review team determined that the current staffing level is adequate for conducting SS&D safety evaluations.

The review team also reviewed the Program's qualification criteria for SS&D reviewers. The document, used by the Program and made available to the review team, is entitled "Qualification Criteria in the Radioactive Materials Regulatory Program Area," dated December 10, 1997, specified only that the SS&D reviewers must attend the SS&D Review Workshop and that any additional training will be determined by the individual's supervisor. According to the provisions of MD 5.6, Part III(G)(1)(a)(ii), the applicable IMPEP criterion specifies that the "[q]ualification criteria for reviewers are established, implemented, and documented" for a training program to be satisfactory. The review team found that the qualification requirements, left to the supervisor's determination without further written guidance, are not consistent with the provisions of the guidance. The review team recommends that the Commonwealth develop and document a set of formal qualification requirements for SS&D reviewers.

4.2.2 Technical Quality of the Product Evaluation Program

Seventeen SS&D case files were selected by the review team for review including work performed by all reviewers. The cross-section sampling included a variety of the Program's SS&D manufacturers and distributors, with a range of products including the following types: radiography exposure device, brachytherapy source, brachytherapy afterloader, liquid scintillation counter, high energy beta source, x-ray fluorescence analyzer, gas chromatograph, ordnance detection system, high energy photon source, ion mobility spectrometer, static eliminator, and formation tester. The SS&D actions were also selected to represent a variety of actions which included five new certificates, seven amendments, four inactivations, and reactivation. A listing of the SS&D certificates evaluated by the review team, with case specific comments, can be found in Appendix F.

The review team evaluated the conduct of the SS&D safety evaluations, deficiency correspondence, and checklists for the SS&D cases within the review period. The SS&D certificates were reviewed for accuracy, appropriateness of authorizations, tie-down statements, and overall technical quality. Casework was evaluated for timeliness, adherence to good radiation safety practices, acceptable engineering practices, references to appropriate regulations, documentation of safety evaluation reports, manufacturing Quality Assurance/Quality Control (QA/QC), supporting documents, peer or supervisory review as indicated, and proper signature authority. The files were checked for retention of necessary documents and other supporting data.

Analysis of the casework and interviews with the staff confirmed that the Program followed the recommended guidance from the NRC SS&D training workshops and NUREG-1556, Volume 3, Rev. 1. All applicable and pertinent regulations, industry standards, and applicable references were available and used appropriately in performing the SS&D reviews. Appropriate review checklists were used to assure that all relevant materials were submitted and reviewed. The checklists were retained in the case files. The registration certificates summarized the product evaluation and provided license reviewers with adequate information on areas requiring additional attention to license the possession, use, and distribution of the products. The review team's comments in Appendix F did not identify any safety issues, and the comments are presented to show non-safety related variances from documentation traditional in SS&D evaluations as described in NUREG-1556, Volume 3.

The review team found that the SS&D files were maintained in an orderly manner and correspondence was filed chronologically. The review team noted that the records filing system is organized in a comprehensive manner to maintain all previous actions regarding the SS&D registration certificates. Specifically, all actions ranging from initial approval through sequential amendments, changes, and corrections to the latest action are maintained and stored in one file. In the file, the individual actions are clearly separated from each other and fully documented. As a result, the records filing system provides, for each SS&D registration, a most readily accessible historical overview of all the current as well as the previous actions. The review team recommends that the Commonwealth's filing system for SS&D casework files be identified as a good practice.

The review team also noted that the Program performed, during the review period, a number of other SS&D related actions that were beyond the scope of traditional SS&D safety evaluations. Specifically, the Program completed a number of equipment related actions, such as:

- Conducted a full safety evaluation of a device for the State of New Hampshire where no qualified reviewers were available (Registration Certificate NH-1184-D-101-S).

- Reviewed an event, and followed up with a quality assurance inspection, involving a source disconnect in an AEA Model 660 radiography camera, reported by the State of Florida. As a result, the vendor issued a service bulletin and modified the maintenance procedure.

- Identified, and followed up with a quality assurance inspection, connection issues involving radiography sources that were distributed by the vendor, Industrial Nuclear, Inc., in noncompliance with the SS&D specifications. As a result, the vendor modified the fabrication procedures, and the QA program.

- Initiated an investigation, upon notification from the U.S. Nuclear Regulatory Commission and the Canadian Nuclear Safety Commission, to determine the root cause of potential excessive S-tube wear involving AEA Model 660B radiography cameras. The investigation was still open at the time of the review.

The review team noted that the Program conducted the SS&D evaluations on the basis of the standard operating procedure, dated June 16, 2000. In addition, the Program used a checklist for each case to assure that all aspects of the safety evaluation had been satisfactorily completed. Both reviewers initialed and dated the check list. The review team noted that the Licensing Supervisor also reviewed, initialed, and dated the checklist, thus, providing an additional quality assurance check for the safety evaluation process. The review team recommends that the Commonwealth's use of initialed and dated check lists be identified as a good practice.

In reviewing the case files, the review team noted that the Program issued a number of inactivated registration certificates that did not contain the full text, but only a reference to another registration certificate (e.g., MA-1059-S-905-S, MA-1059-S-919-S). The review team noted that NRC also received a notification about this practice from another Agreement State stating that they noticed that all technical content was deleted in inactivated sheets and that they would prefer the method of leaving all the original information in the inactivated sheet and just adding the statement about 'no longer distributed or serviced.' The Program's staff

explained to the review team that such short-form inactivated registrations referred only to active ones which did contain the full text. By using a short format, the information is not readily available to the users, and the referenced certificate, containing the full text, might be later deleted from the National Sealed Source and Device Registry when the vendor discontinues distribution of the product. It is the historical practice of the SS&D community nationwide that the full text is retained in inactivated registrations. Furthermore, the applicable guidance in NUREG-1556, Vol. 3, Rev. 1, Section 13.4, specifies that the inactivated certificate should contain information sufficient to be used as the basis for continued licensing of the product. 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 Program 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.

The review team discussed this issue with the Program and the Program management indicated that they will issue future inactive certificates with full text, the previously issued certificates will be revised, and the SS&D safety evaluation procedure will be expanded to address the inactivation process.

4.2.3 Evaluation of Defects and Incidents Regarding SS&D

The review team examined all incidents during the review period for relevance to SS&D issues. Six incidents involved equipment failure or malfunction. The review team found that the Program fully reviewed three of the six incidents, took appropriate follow-up actions, and documented completion in the records. One incident is under timely review. Two of the six incidents, both from 2003, were not closed out and are still open which are discussed in Section 3.5. The Program's handling of SS&D related incidents is similar to that for other incidents discussed in Section 3.5. Therefore, the conclusions presented in Section 3.5 apply.
The review team conducted a search of the NMED system to determine whether other incidents might have taken place that were not registered by the Program staff. No additional incidents related to malfunctioning devices or products were identified.

During the review period, the Program received no allegations related to the SS&D evaluation program.

Based on the IMPEP evaluation criteria, the review team recommends that the Program's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement" to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although the Massachusetts Agreement State program has LLRW disposal authority, NRC has not required States to have a program for licensing a LLRW 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, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in Massachusetts. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found Massachusetts' performance to be satisfactory for five of the performance indicators reviewed. The review team found Massachusetts performance to be satisfactory, but needs improvement for the following two indicators: Technical Quality of Incident and Allegation Activities and Compatibility Requirements. Accordingly, the review team recommends that the Massachusetts Agreement State Program be found adequate to protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommends that the next full IMPEP review should be conducted in approximately four years.

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

RECOMMENDATIONS:

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)

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)

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)

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 STP Procedure SA-300. (Open recommendation from 2002 IMPEP review) (Section 3.5)

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 SA-201. (Open recommendation from the 2002 IMPEP review) (Section 4.1.2)

6. The team recommends that the Program make corrections to registration certificate MA-0116-102-B. (Open recommendation, second part only, from the 2002 IMPEP review) (Section 2.0, Recommendation 4)

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

8. The review team recommends that the Commonwealth issue inactivated SS&D 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)

GOOD PRACTICE:

1. The Program maintains a records filing system which provides, for each SS&D registration, a most readily accessible historical overview of all the current as well as the previous actions. Specifically, all actions ranging from initial approval through consequential amendments, changes, and corrections to the latest action are maintained and stored in one file. In the file, the individual actions are clearly separated from each other and fully documented. (Section 4.2.2)

2. In performing the SS&D safety evaluations, the Program uses a checklist for each case to assure that all aspects of the safety evaluation had been satisfactorily completed. Both reviewers initial and date the check list, and in addition, the SS&D supervisor also reviews, initials, and dates the checklist, thus, providing an additional quality assurance check for the safety evaluation process. (Section 4.2.2)

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Kevin Hsueh, STP	Team Leader Technical Staffing and Training
Shawn Seeley, Maine	Technical Quality of Inspections Technical Quality of Incident and Allegation Activities Inspection Accompaniments
Sheri Minnick, RI	Technical Quality of Licensing Actions
Shawn Smith, STP	Status of Materials Inspection Program Compatibility Requirements
John Jankovich, NMSS	Sealed Source and Device Evaluation Program

APPENDIX B

COMMONWEALTH OF MASSACHUSETTS

EXECUTIVE OFFICES AND DEPARTMENTS

AND

RADIATION CONTROL PROGRAM

ORGANIZATION CHARTS

ML061710265

APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1
Licensee: North Shore Medical Center — License No.: 44-0161
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Dates: 1/10-11/06 — Inspector: AC

File No.: 2
Licensee: New England Medical Specialists — License No.: 67-0324
Inspection Type: Routine, Unannounced — Priority: 5
Inspection Date: 4/6/06 — Inspector: BP

Comment:
Incomplete report, supervisory review not within 30 days.

File No.: 3
Licensee: Brsitol-Myers Squibb — License No.: 60-0088
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 2/3/06 — Inspector: AC

File No.: 4
Licensee: Bristol-Myers Squibb — License No.: 60-0088
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Dates: 9/24-25/03 — Inspectors: MW, JS

File No.: 5
Licensee: Neurophysics — License No.: 55-0523
Inspection Type: Initial, Announced — Priority: 5
Inspection Date: 4/6/06 — Inspector: MI

File No.: 6
Licensee: Caritas Norwood Hospital — License No.: 44-0008
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 1/31/06, 2/3/06, 2/16/06 — Inspector: BP

File No.: 7
Licensee: ABC Testing — License No.: 19-7781
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Date: 12/7/04 — Inspector: JD

Comment:
Wrong date referenced in correspondence to licensee. Should be 2/7/05 and not 2/7/04 as listed.

File No.: 8
Licensee: Baker Testing Services License No.: 19-0672
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 1/13/06 Inspector: MI

File No.: 9
Licensee: TEI Analytical License No.: N/A
Inspection Type: Reciprocity Priority: 1
Inspection Date: 7/15/05 Inspector: MI

File No.: 10
Licensee: Varian License No.: 66-0111
Inspection Type: Reciprocity Priority: 5
Inspection Date: 3/9/06 Inspector: TC

File No.: 11
Licensee: Selectix Pharmaceuticals License No.: 55-0466
Inspection Type: Initial, Announced Priority: 3
Inspection Date: 2/23/05 Inspector: TC

File No.: 12
Licensee: Lowell General Hospital License No.: 44-0060
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 4/5/06 Inspector: BG

Comment:
Supervisory review not within 30 days

INSPECTOR ACCOMPANIMENTS

In addition, the following inspection accompaniments were performed as part of the IMPEP review.

Accompaniment No.: 1
Licensee: Lowell General Hospital License No.: 44-0060
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 4/5/06 Inspector: BG

Comment:
inspectors meter failed prior to inspection. Observed licensee surveys.

Accompaniment No.: 2
Licensee: Neurophysics License No.: 55-0523
Inspection Type: Initial, Unannounced Priority: 5
Inspection Date: 4/6/06 Inspector: MI

Accompaniment No.: 3
Licensee: New England Medical Specialists
License No.: 67-0324
Inspection Type: Routine, Unannounced
Priority: 5
Inspection Date: 4/6/06
Inspector: BP

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1
Licensee: ABC Testing, Inc. License No.: 19-7781
Type of Action: Amendment Amendment No.: 7
Date Issued: 11/18/05 License Reviewers: JS, KT

File No.: 2
Licensee: Advance Testing Company, Inc. License No.: 48-0236
Type of Action: Renewal Amendment No.: 5
Date Issued: 10/23/03 License Reviewers: SL, BP

File No.: 3
Licensee: Beth Israel Deaconess Medical Center License No.: 44-0403
Type of Action: New Amendment No.: N/A
Date Issued: 8/2/02 License Reviewers: GS, KT

File No.: 4
Licensee: Beth Israel Deaconess Medical Center License No.: 44-0403
Type of Action: Amendment Amendment No.: 2
Date Issued: 11/21/05 License Reviewers: AC, MI

File No.: 5
Licensee: Baystate Health System, Inc. License No.: 60-0095
Type of Action: Renewal Amendment No.: 18
Date Issued: 7/5/05 License Reviewers: AC, MI

File No.: 6
Licensee: Clinomics Laboratories License No.: 55-0307
Type of Action: Amendment Amendment No.: 4
Date Issued: 4/4/05 License Reviewers: AC, KT

File No.: 7
Licensee: Cyclis Pharmaceuticals, Inc. License No.: 55-0409
Type of Action: Termination Amendment No.: 2
Date Issued: 10/9/03 License Reviewer: AC

File No.: 8
Licensee: Children's Hospital, Boston License No.: 60-0137
Type of Action: Amendment Amendment No.: 12
Date Issued: 3/30/06 License Reviewers: MI, KT

File No.: 9
Licensee: Beth Israel Deaconess Medical Center
Type of Action: Amendment
Date Issued: 11/18/05
License No.: 60-0432
Amendment No.: 5
License Reviewers: JS, KT

File No.: 10
Licensee: Eastern Isotopes
Type of Action: New
Date Issued: 4/12/04
License No.: 42-0473
Amendment No.: N/A
License Reviewer: AC

File No.: 11
Licensee: Dositec, Inc.
Type of Action: Amendment
Date Issued: 11/21/05
License No.: 21-3261
Amendment No.: 9
License Reviewers: JS, KT

File No.: 12
Licensee: Ratheon Company
Type of Action: Renewal
Date Issued: 6/23/05
License No.: 01-1027
Amendment No.: 3
License Reviewers: JD, AC

File No.: 13
Licensee: Raytheon Company
Type of Action: Amendment
Date Issued: 12/2/05
License No.: 01-1027
Amendment No.: 4
License Reviewers: JS, KT

File No.: 14
Licensee: Solutia, Inc.
Type of Action: Renewal
Date Issued: 6/6/05
License No.: 00-5146
Amendment No.: 4
License Reviewers: MI, AC

File No.: 15
Licensee: Unitech Services Group
Type of Action: Void
Date Issued: 3/29/05
License No.: 03-5291
Amendment No.: N/A
License Reviewers: AC, MW

File No.: 16
Licensee: QSA Global, Inc.
Type of Action: Financial Assurance
Date Issued: 2/16/06
License No.: 12-8361
Amendment No.: N/A
License Reviewers: AC, KT

File No.: 17
Licensee: Tiax LLC
Type of Action: Amendment
Date Issued: 7/24/02
License No.: 30-1121
Amendment No.: 3
License Reviewers: KT, BW

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1
Licensee: AEA Technology — Licensee No.: 12-8361
Date of Incident: 2/14/03 — Incident Log No.: 02-3979
Investigation Date: assigned 2/19/03 — Type of Incident: Leaking source
Type of Investigation: On-site/phone

Comment:
This is a reportable event and was not reported to the NRC.

File No.: 2
Licensee: NITON — Licensee No.: 55-0238
Date of Incident: 10/14/04 — Incident Log No.: 10-5189
Investigation Date: N/A — Type of Incident: Leaking source
Type of Investigation: N/A

Comment:
This is a reportable event and was not reported to the NRC.

File No.: 3
Licensee: Perkin Elmer — Licensee No.: 00-3205
Date of Incident: 1/30/06 — Incident Log No.: 04-6276
Investigation Date: 3/10/06 — Type of Incident: Transportation
Type of Investigation: On-site/phone

Comment:
This is a reportable event and was not reported to the NRC.

File No.: 4
Licensee: Brigham & Women's Hospital — Licensee No.: 44-0004
Date of Incident: 6/23/03 — Incident Log No.: 06-4245
Investigation Date: N/A — Type of Incident: Medical
Type of Investigation: N/A

Comments:
a) This is a 24-hour reportable event and was not reported to the NRC in a timely manner.
b) Event was not entered into NMED.

File No.: 5
Licensee: North Shore Medical Center — Licensee No.: 44-0161
Date of Incident: 9/25/01 — Incident Log No.:12-5245
Investigation Dates: 10/26/04, 11/18/04, 11/22/04 — Type of Incident: Overexposure
Type of Investigation: On-site/phone

File No.: 6
Licensee: Sverdrup Civil, Inc.
Licensee No.: 48-0233
Date of Incident: 8/7/02
Incident Log No.:09-3644
Investigation Date: 9/9/02
Type of Incident: Unplanned fire
Type of Investigation: On-site/phone

Comment:
This is a reportable event and was not reported to the NRC.

File No.: 7
Licensee: Cardinal Health, LLC
Licensee No.: 41-0366
Date of Incident: 6/3/04
Incident Log No.: 01-6064
Investigation Date: 6/7/04
Type of Incident: Overexposure
Type of Investigation: On-site/phone

Comments:
a) This is a reportable event and was not reported to the NRC.
b) Reassigned to another reviewer on 8/26/05.

File No.: 8
Licensee: Lahey Clinic Foundation
Licensee No.: 44-0015
Date of Incident: 9/1/04
Incident Log No.: 09-5115
Investigation Date: 9/2/04
Type of Incident: Loss of material
Type of Investigation: On-site/phone

Comment:
Event not closed.

File No.: 9
Licensee: Level 1, Inc.
Licensee No.: N/A
Date of Incident: 1/29/03
Incident Log No.: 01-3958
Investigation Date: 1/29/03
Type of Incident: Loss of material
Type of Investigation: Phone

Comments:
a) This is a reportable event and was not reported to the NRC.
b) Event was not entered into NMED.

File No.: 10
Licensee: Niton Corporation
Licensee No.: 55-0238
Date of Incident: 12/3/03
Incident Log No.:10-5189
Investigation Date: 10/19/04
Incident: Leaking source
Type of Investigation: On-site/phone

Comments:
a) This is a reportable event and was not reported to the NRC.
b) Event was not entered into NMED.
c) Originally assigned 10/19/04, reassigned 1/14/05.

File No.: 11
Licensee: Perkin Elmer
Licensee No.: 00-3200
Date of Incident: 6/4/02
Incident Log No.: 06-3433
Investigation Date: 6/4/02
Type of Incident: Transportation
Type of Investigation: Phone

Comments:
a) This is a reportable event and was not reported to the NRC.
b) Event was not entered into NMED.

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

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

File No.: 1
Registry No.: MA-1059-D-334-S
Manufacturer: AEA Technology QSA, Inc.
Date Issued: 2/12/04
SS&D Type: (A) Industrial Radiography
Model No.: 880 Series
Type of Action: Amendment
SS&D Reviewers: JED, JS

File No.: 2
Registry No.: MA-1059-D-334-S
Manufacturer: AEA Technology QSA, Inc.
Date Issued: 11/09/05
SS&D Type: (A) Industrial Radiography
Model No.: 880 Series
Type of Action: Amendment
SS&D Reviewers: JED, JS

File No.: 3
Registry No.: MA-1059-D-334-S
Manufacturer: AEA Technology QSA, Inc.
Date Issued: 7/13/04
SS&D Type: (A) Industrial Radiography
Model No.: 880 Series
Type of Action: Amendment
SS&D Reviewers: JED, JS

File No.: 4
Registry No.: MA-1216-S-101-S
Manufacturer: RadioMed Corp.
Date Issued: 7/28/04
SS&D Type: (AA) Manual Brachytherapy
Model No.: Series 35, Series 80
Type of Action: New
SS&D Reviewers: JS, JED

Comment:
FDA's Form 510(k) was not in the file.

File No.: 5
Registry No.: MA-1142-D-102-G
Manufacturer: PerkinElmer Life Sciences, Inc.
Date Issued: 2/23/04
SS&D Type: (Y) Calibrators
Model No.: Series 1200
Type of Action: Amendment
SS&D Reviewers: JED, JS

Comment:
a) Meticulous records in file (phone logs, e-mails) to follow-up with the licensee.

File No.: 6
Registry No.: MA-1059-S-905-S SS&D Type: (E) Beta Gauges
Manufacturer: AEA Technology QSA, Inc. Model No.: SIF.D2
Date Issued: 8/31/04 Type of Action: Inactivation
SS&D Reviewers: JS, JED

Comments:
a) Inactivation questions (as specified in NUREG-1556, Vol. 3, Rev. 1, Section 13.4) were not in the file.
b) The inactivated registration certificate did not contain the full text, but only reference to another registration, i.e., MA-1059-S-137-S.

File No.: 7
Registry No.: MA-8173-D-802-G SS&D Type: (Y) Calibrators
Manufacturer: Perkin Elmer Life Sciences, Inc. Model No.: Series 1200
Date Issued: 4/24/06 Type of Action: Inactivation
SS&D Reviewers: JED, JS

File No.: 8
Registry No.: MA-8154-D-803-B SS&D Type: (U) X-ray Fluorescence
Manufacturer: Oxford Instruments of America, Inc. Model No.: Lab-X 1000 Series
Date Issued: 2/05/05 Type of Action: Inactivation
SS&D Reviewers: JED, JS

Comment:
The inactivated registration certificate did not contain the full text, but only reference to another registration, i.e., MA-8154-D-802-B.

File No.: 9
Registry No.: MA-8154-D-802-B SS&D Type: (U) X-ray Fluorescence
Manufacturer: Oxford Instruments of America, Inc. Model No.: Lab-X 1000 and 2000 Series
Date Issued: 9/27/04 Type of Action: Inactivation
SS&D Reviewers: JED/JS

File No.: 10
Registry No.: MA-1234-D-101-G SS&D Type: (N) Ion Generators, Chromatography
Manufacturer: ThermoEnvironmental Instruments, Inc. Model No.: EGIS Defender
Date Issued: 6/02/05 and 8/02/05 (correction) Type of Action: New
SS&D Reviewers: JS, JED

Comment:
The registration certificate was issued on the basis of a draft (instead of a final) operations manual; thus, the vendor may change the manual after the issuance of the certificate. The Program requested (in a telephone call on 05/16/06) a final version from the vendor.

File No.: 11
Registry No.: MA-1234-D-101-G SS&D Type: (N) Ion Generators, Chromatography
Manufacturer: ThermoEnvironmental Instruments, Inc. Model No.: EGIS Defender
Date Issued: 8/02/05 Type of Action: Amendment
SS&D Reviewers: JS, JED

File No.: 12
Registry No.: MA-1229-D-101-S SS&D Type: (AF) Other Medical Uses
Manufacturer: Sirtex Wilmington LLC Model No.: SIR-Spheres
Date Issued: 5/6/05 Type of Action: New
SS&D Reviewers: JED, JS

Comments:
a) The distribution/fabrication of the device was transferred from one vendor to another, and a statement in the Safety Analysis Summary references the registration of the previous vendor (MA-1059-D-365-S). However, the documents in the file do not contain information that would back up the cross-reference.
b) The records did not show that the reviewers verified that the new vendor accepted all commitments made by the previous vendor, as specified by the guidance in NUREG-1556, Vol.3, Rev. 1, Section 13.6, Item 6.
c) The label as approved does not show Sirtex's address in the U.S. and the previously used labels do not show a U.S. address, as specified by the guidance in NUREG-1556, Vol. 3, Rev. 1, Section 5.5.

File No.: 13
Registry No.: MA-1218-D-103-S SS&D Type: (H) General Neutron Source Applications
Manufacturer: Ancore Corp. Model No.: UXO-EDS-1
Date Issued: 4/21/05 Type of Action: New
SS&D Reviewers: JED, JS

Comment:
This is a custom registration for a user located in Massachusetts.

File No.: 14
Registry No.: MA-1059-S-250-S SS&D Type: (D) Gamma Gauging Source
Manufacturer: AEA Technology, Inc. Model No.: CKC.P1, CKC.P6
Date Issued: 10/22/02 Type of Action: Reactivation
SS&D Reviewers: JS, JED

Comments:
a) This is a reactivation of MA-1059-S-818-S.
b) The Model CKC.P6 was not in MA-1059-S-818-S, it was transferred from MA-1059-344-S.

File No.: 15
Registry No.: MA-0399-D-104-G SS&D Type: (N) Ion Generators, Chromatography
Manufacturer: GE Ion Track Model No.: 6 various models
Date Issued: 6/7/04 Type of Action: Amendment
SS&D Reviewers: JS, JED

File No.: 16
Registry No.: NH-1184-D-104-S SS&D Type: (O) Ion Generators, Static Eliminator
Manufacturer: BAE Systems Model No.: Laser System
Date Issued: 6/7/04 Type of Action: New
SS&D Reviewers: TMK, DPO

Comments:
a) The Program performed the SS&D review for the State of New Hampshire.
b) The Program issued a transmittal letter, dated 02/26/03, to New Hampshire with two attachments: (1) draft SS&D registration certificate, and (2) deficiency questions for New Hampshire to ask from the licensee. Attachment 2 was not in the file, it was located during the review on the C:/ drive of one of the staff. Attachment 2 was placed into the file.
c) The checklist left the following sections blank: Prototype Testing/Historical Use, Radiation Profiles, Quality Assurance, Installation, Safety Instructions, Accompanying Documentation.
d) The checklist was not signed and dated.

File No.: 17
Registry No.: MA-0399-D-104-G SS&D Type: (N) Ion Generators, Chromatography
Manufacturer: GE Ion Track Model No.: 6 various models
Date Issued: 5/5/03 Type of Action: Amendment
SS&D Reviewers: JS, JED