September 19, 2002

Howard K. Koh, M.D., M.P.H.
Commissioner
Massachusetts Department of Public Health
250 Washington Street, 2nd Floor
Boston, MA 02114

Dear Dr. Koh:

On September 5, 2002, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Massachusetts Agreement State Program. The MRB found the Massachusetts program adequate to protect public health and safety and compatible with the Nuclear Regulatory Commission's program.

Section 5.0, page 17, of the enclosed final report presents the IMPEP team's recommendations for the Commonwealth of Massachusetts. We request your response to the recommendations within 30 days of your receipt of this letter.

Based on the results of the current IMPEP review, the next full review will be in approximately four years.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review and your support of the Radiation Control Program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Carl J. Paperiello
Deputy Executive Director
for Materials, Research and State Programs

Enclosure:
As stated

cc: Robert Walker, Acting Director
Radiation Control Program

Edgar Bailey, CA
OAS Liaison to the MRB

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bcc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

Distribution: See next page DCD (SP01) PDR (YES√)

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF MASSACHUSETTS AGREEMENT STATE PROGRAM

JUNE 24 - 28, 2002

FINAL 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 June 24-28, 2002, by a review team consisting of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Kansas. 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 November 5, 1999, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of January 17, 1998 to June 28, 2002, were discussed with Massachusetts management on June 28, 2002.

A draft of this report was issued to Massachusetts for factual comment on July 29, 2002. The State responded by electronic mail dated August 15, 2002. The Management Review Board (MRB) met on September 5, 2002 to consider the proposed final report. The MRB found the Massachusetts radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The Massachusetts Agreement State program is administered by the Radiation Control Program (the Program) located within the Bureau of Health Quality Management (the Bureau). The Bureau is located within the Department of Public Health (the Department). Organization charts for the Department, the Bureau and the Program are included in Appendix B. At the time of the review, the Massachusetts Agreement State program regulated approximately 529 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 March 15, 2002. The Program provided a response to the questionnaire on June 7, 2002. A copy of the questionnaire response can be found on NRC's Agencywide Document Access and Management System using the Accession Number ML022000261.

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 radiation control program licensing and inspection data base; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of four Program inspectors; and (6) interviews with staff and management to answer questions or clarify issues. The review team evaluated the information that it 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 January 16, 1998, eight recommendations and two suggestions were made and transmitted to Dr. Howard K. Koh, Commissioner of the Department on April 15, 1998. The Management Review Board (MRB) directed that a follow-up review of the Sealed Source and Device Evaluation Program (SS&D) be conducted. The follow-up review was conducted during the period June 19- 21, 2000 and the results were transmitted to Dr. Koh on September 28, 2000. The follow-up review resulted in the closure of two of the eight recommendations and the addition of three new recommendations. The team's review of the current status of the recommendations is as follows:

1. The review team recommends that initial inspections of licensees be performed within six months of the licensee's receipt of licensed material, within six months after commencement of licensed activities, or within one year of license issuance, whichever comes first, consistent with IMC 2800. (Section 3.1 of the 1998 IMPEP report)

   Current Status: The review team found that initial inspections were clearly identified in the Program's database. Since the last review, 108 of the 112 initial inspections were performed within six months after commencement of licensed activities, or within one year of license issuance. This recommendation is closed.

2. The review team recommends that the Commonwealth increase the number of reciprocity inspections to better evaluate the health and safety implications of out-of-state companies working in Massachusetts. (Section 3.1 of the 1998 IMPEP report)

   Current Status: The review team found that in 1998 the Program exceeded the goals of the existing NRC Inspection Manual Chapter (IMC) 1220. The Program reviews all reciprocity requests, determines if the licensee is a candidate to be inspected and attempts to conduct an unannounced inspection of all viable candidates. However, the Program has found that often the reciprocity licensees have already completed their work when the inspector arrives at the job site. The Program was generally able to meet the 20 percent of the candidate reciprocity licensees goal established in the revised IMC 1220 dated June 6, 2002. This recommendation is closed.

3. The review team recommends that program managers conduct annual field accompaniments of each inspector to assess performance. (Section 3.2 of the 1998 IMPEP report)

   Current Status: The review team found that the Program has conducted annual accompaniments of inspectors to assess their performance. Since late 1999, the Inspection Supervisor has been performing and documenting the inspector accompaniments. Prior to that time, the Program Director and Radioactive Materials Supervisor performed the accompaniments. This recommendation is closed.

4. The review team recommended that, due to current program demands and the projected increase in workload, program management closely monitor the filling of the Program vacancies. (Section 3.3 of the 1998 IMPEP report)

   Current Status: The review team found that the Program has increased its staffing level to meet program demands. At the time of the review, the Program had a staffing level of 19.75 full time equivalents (FTE) and three vacancies. As discussed in Section 3.3, program management anticipated filling these vacancies soon. This recommendation is closed.

5. The review team recommended that the Commonwealth manage the training program to ensure that staff receive required training courses to fulfill the Program Qualification requirements for inspectors and license reviewers. (Section 3.3 of the 1998 IMPEP report)

   Current Status: The Program is ensuring that staff receives the required training. The review team examined employees' training records and determined that the Program maintained detailed documentation in the Training Qualification Records. The Program also maintained detailed records of inspections, licensing actions, and SS&D evaluations assigned and completed under the supervision of a Program mentor. This recommendation is closed.

6. The review team recommended that the Program provide written periodic feedback on the disposition of allegations to allegers in accordance with Commonwealth procedures. (Section 3.5 of the 1998 IMPEP report)

   Current Status: The review team found that the Program is providing written feedback to the allegers in accordance with its current procedures. In the 15 allegation files reviewed by the team, all contained a closeout letter to the alleger that summarized the individual's concerns, the Program's actions taken, and their conclusions. This recommendation is closed.

7. The review team recommended that the Program coordinate with NRC staff possible ways to revise SS&D registry certificate MA-0628-D-137-S, to make clear that a generic exemption has not been granted, and that a specific exemption is needed to use the device under special conditions. (Section 2.1 of the 2000 IMPEP report)

   Current Status: The review team found that the Program issued registration certificate MA-1059-D-137-S which superceded MA-0628-D-137-S. The new certificate was revised to clarify that the overpack is required when the device is used at a height more than four feet above a working surface. The new certificate also contains wording that directs regulatory agencies to the specifics of their own regulations in deciding how to license these devices in their jurisdictions. This recommendation is closed

8. The review team recommended that the Program re-evaluate the radiographic source changers in SS&D registry certificate MA-0628-D-127-S dated February 9, 2000,

especially model 650, which does not meet the performance requirements for radiographic operations detailed in 10 CFR 34.20. The SS&D registry certificate should be revised by Program to reflect this reevaluation and those limitations necessary for the use of these devices. The SS&D registry certificate should reflect these modifications in the section on Limitations and/or Other Considerations of Use. A separate registration certificate should be issued for devices which meet the 10 CFR 34.20 requirements. (Section 2.1 of the 2000 IMPEP report)

Current Status: The review team found that the Program revised registration certificate MA-0628-D-127-S by removing model 650. This recommendation is closed.

9. The review team recommended 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 2.1 of the 2000 IMPEP report)

Current Status: The review team found that the Program usually followed the formats specified in NUREG 1556, Volume 3 for documenting SS&D evaluations. However, the team determined that some areas in the SS&D registration certificates are still in need of improvement. This recommendation is closed, however a new recommendation is made in Section 4.2 that identifies the specific areas that still need improvement.

During the 1998 review, two suggestions were made for the Program to consider. The review team determined that the Program considered the suggestions and took appropriate actions.

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 are: (1) Status of Materials Inspection Program; (2) Technical Quality of Inspections; (3) Technical Staffing and Training; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

The review team focused on four factors in reviewing this indicator: inspection frequency, overdue inspections, initial inspection of new licenses, and timely dispatch of inspection findings to licensees. This evaluation is based on the Program's questionnaire responses relative to this indicator, data gathered independently from the Program's licensing and inspection data tracking system, the examination of completed licensing and inspection casework, and interviews with managers and staff.

The team's review of the Program's inspection priorities verified that the inspection frequencies for various types of licenses are at least as frequent, or more frequent than, similar license types listed in the IMC 2800. For example, teletherapy licenses are Priority 2 on the Program's schedule and Priority 3 in IMC 2800. Research and development-other licenses are Priority 3 on the Program's schedule and Priority 5 in IMC 2800.

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 283 licenses, which

included 112 initial inspections. Twenty-five core inspections, including four initial inspections were conducted overdue during the review period. The overdue inspections ranged from a few days to 14 months overdue when conducted.

The team was informed through staff interviews that the Program was reorganized in October 1999. The Acting Radioactive Materials Supervisor was promoted to the Radioactive Materials Supervisor and one of the inspectors was promoted to the Inspection Supervisor. The Inspection Supervisor became responsible for overseeing inspection related activities within the Program. The review team observed that the majority of overdue inspections occurred prior to the reorganization. Since the reorganization, the Program managed and eliminated the inspection backlog.

In early 2001, the Program recognized that some improvements needed to be made to the tracking system for initial inspections. The Program management implemented a procedure whereby the support staff specifies the inspection due dates of six months from the date of issuance for all new licenses and the Licensing Supervisor provides a monthly listing of all new licenses issued to the Inspection Supervisor.

The timeliness of the issuance of inspection findings was evaluated during the inspection file review. The Program has an effective and efficient process which ensures that inspection findings are communicated to licensees in a timely manner. Within 30 working days of completing the inspection, the Program mails a letter indicating that there were no potential violations identified or a letter detailing the potential violations and requests the licensee's response by a certain date. For 19 routine inspection files examined, all inspection findings were sent to the licensees within 30 days.

During the review period, the Program granted 161 reciprocity permits, of which, 31 permits were core licensees based upon IMC 1220. The Program met and exceeded the reciprocity inspection goals for year 1998 as established in then current IMC 1220. The Program was not able to meet the goals for 1999 and 2001. Program management recognized that improvements needed to be made to their reciprocity inspection program. An inspector was assigned to review all reciprocity requests and notifications, and identify all viable reciprocity inspection candidates. 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. IMC 1220 was revised on June 6, 2002 and new inspection goals of inspecting 20 percent of the candidate core licensees operating under reciprocity each year were set. Based on the revised guidance, the Program met the revised IMC 1220 criteria for the entire review period.

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

3.2 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for 21 radioactive materials inspections conducted during the review period. The casework included all of the Program's fully trained materials inspectors, and covered inspections of various types as follows: manufacturing and distribution broad

scope, manufacturing and distribution other, panoramic pool irradiator, nuclear laundry, medical institution-QMP required, self shielded irradiator, research and development, industrial radiography, medical broad scope, academic broad scope, nuclear pharmacy, medical product distribution, brachytherapy, limited medical, portable gauge and service (source exchange). Appendix C lists the inspection casework files reviewed for completeness and adequacy with case-specific comments.

Based on the casework file reviews, the 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 the cited violations and 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 review team did note that for three inspections with different inspectors, the citations used in the notice of violation transmitted to the licensee did not follow standard enforcement wording. The Inspection Supervisor is aware of this issue and has taken action to more carefully review ongoing correspondence.

Since his appointment in late 1999, the Inspection Supervisor conducts and documents supervisory accompaniments of each material inspector once a year. Prior to that time, inspector accompaniments were conducted by the Program Director or the Radioactive Materials Supervisor. The team noted that the Program currently has nine experienced materials inspectors and one inspector who is currently in training status.

The team accompanied four materials inspectors during the period of April 1 to April 5, 2002. The accompaniments included inspections of facilities that were licensed for research and development, manufacturing and distribution, medical institution with a self shielded irradiator and brachytherapy, and a panoramic pool irradiator. The facilities inspected are identified in Appendix C. During the accompaniments, each inspector demonstrated appropriate performance-based, risk informed inspection techniques and knowledge of the regulations. The inspectors were well prepared for the inspection, and thorough in their audits of the licensees' radiation safety programs. Each inspector conducted confirmatory measurements, and utilized good health physics practices. Their inspections were adequate to assess radiological health and safety at the licensed facilities.

The Program has an adequate number and types of survey meters to support the current inspection program as well as for responding to incidents and emergency conditions. Each inspector is assigned a case of instrumentation for response to incidents. The Program has an outside contractor calibrate their survey instruments annually. Appropriate, calibrated survey instruments such as GM meters, scintillation detectors, ion chambers and micro-R meters were observed. 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. The laboratory participates in accreditation programs conducted by the Environmental Protection Agency (EPA).

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.

3.3 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 responses 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 approximately 529 licenses with a total of 19.75 FTE assigned to implement the materials licensing and inspection program. At the time of the review, the Program had three vacancies. Two of the three positions became vacant in February 2002. These positions have been posted, interviews were conducted in April 2002, and the selections have been made. The Program is currently awaiting authorization to finalize the offers. The third position became vacant during the week of the onsite review. The Program had a total of seven turnovers during the review period. The high turnover rate was due primarily to the competition with local industry for qualified staff. Nevertheless, the Program has been able to fill vacancies in an expedient manner and does not anticipate any change with regard to filling the current vacancies.

The Program consists of three units: Radioactive Materials, Environmental, and Mammography and Healing Arts. The technical staff in the Radioactive Materials Unit are classified as Environmental Engineers and perform both inspection and licensing functions of agreement materials. A subset of the technical staff also conduct sealed source and device evaluations which is further discussed in Section 4.2.2 of this report. The Radioactive Materials Unit is managed by the Radioactive Materials Supervisor and is subdivided into the basic functions of inspection and licensing, each with a supervisor, Licensing Supervisor and Inspection Supervisor. Based on the review, the team determined that the Program's policy of requiring staff to be qualified to perform both licensing and inspection functions provides a strength to the program and an ability to shift resources to meet program demands.

The Program has a documented training and qualification program that is based on NRC's IMC 1246. The team noted that the Program has been able to recruit well qualified technical staff from an educational and experience standpoint. Each staff member must document formal training, including basic, specialized, and advanced training, on a Training Qualification record. Copies of training certificates are maintained in personnel files as evidence of successfully completing the required training course work. In addition, each staff member must document on-the-job training and receive management sign off prior to being authorized to perform assigned tasks independently. The team observed that the Program has exhibited a strong commitment to training and has initiated alternate training courses on its own and in conjunction with other New England states.

The review team noted that the Program has experienced stable funding during the review period due to 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. In fiscal year 2000, the Program was able to increase their budget to meet the demands of operating the program. The Program is currently in the process of seeking approval from the Commonwealth's Executive Office for Administration and Finance to revise fees within the licensed activity categories.

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.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed the staff for 20 specific licenses. Licensing actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were evaluated for overall technical quality including accuracy, appropriateness of the license, its conditions, and tie-down conditions. Casework was evaluated for timeliness; adherence to good health physics practices; reference to appropriate regulations; documentation of safety evaluation reports, product certifications or other supporting documents; consideration of enforcement history on renewals; pre-licensing visits, peer or supervisory review as indicated; and proper signature authority. 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), portable gauge, nuclear pharmacy, veterinary medicine, and industrial radiography. Licensing actions selected for evaluation included five new licenses, four renewals, ten amendments, and one termination. A list of the licenses evaluated with case-specific comments 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 review team noted that the Program used a decay-in-storage license condition that did not include the requirement to hold material for ten half lives prior to disposal. However, this requirement is included in the Commonwealth's regulations and discussed in detail in guidance provided by the Program. During the September 5, 2002 MRB meeting, the review team and the MRB agreed that the less specific license condition does not present a health and safety issue, and that the Program's implementation is acceptable.

The Program renews licenses every five years. The review team noted that licensing actions were promptly acted upon, usually within 30 days of receipt. 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 Radioactive Materials Unit Supervisor reviews and approves all new licenses. He also consults on and approves amendments. The Program Director conducts a secondary management review on selected actions and signs all licensing documents.

The team evaluated financial assurance and decommissioning activities conducted in the Program. The Program had 39 licenses requiring financial assurance which were tracked using a database. The Program developed a spreadsheet to assist in determining the amount of financial assurance required based on the possession limit of radioactive material on the license. The review team found this method to be efficient and effective for managing these licenses, and recommends to the MRB that the Program's use of this spreadsheet be found a good practice. In addition, the 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 is developing a plan to address each site and will report the results to NRC when completed.

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 Response to Incidents and Allegations

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 files, and evaluated the casework and supporting documentation for 11 material incidents. A list of the incident casework examined with case-specific comments is included in Appendix E. The team also reviewed the Program's response to 15 allegations involving radioactive materials, including nine referred by the NRC during the review period.

The 11 incidents selected for review included the following categories: overexposure, loss of

radioactive material, release of radioactive material, misadministration, contamination event, leaking source, equipment failure, procedural failure, and fire. The review team found that the Program's response to incidents was generally complete and comprehensive. 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 onsite investigations when appropriate, and took suitable enforcement and follow-up actions.

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

The primary responsibility for coordination of all incidents and allegations rests with the Event Coordinator and Allegation Coordinator, respectively. The initial response and follow-up to incidents and allegations involving radioactive materials are coordinated with the Licensing Supervisor and Radioactive Material Supervisor. Separate written procedures exist for handling incidents and allegations. The allegation procedure is currently being revised. The Program conducts onsite 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 casework indicates that this approach provides effective and appropriate response actions and does not delay the response time. The procedure and report forms are available to the staff when responding to any incident, accident or emergency involving radioactive materials. All incidents and allegations are assigned individual docket numbers for tracking. The events are also entered in a local events database and assigned a sequential event number. Completed incident docket files are placed in the corresponding licensee file. Completed allegation docket files are placed in a separate folder and maintained in a secure locked drawer.

During the on-site review, the Program provided a list of 56 incidents reported to NMED since January 1998. The Program also provided a printout of their events database from January 31, 1998 to the present. The team's review of the NMED database found 76 Agreement State status events listed for the review period. Based on the data in NMED, 42 of these events required reporting to the NRC, 12 events did not require reporting to NRC and it could not be established if the remaining 22 events should have been reported.

In order to evaluate the Commonwealth's performance with regard to event reporting, the review team developed its own table of incidents using information from the three sets of data (the events in NMED, the events that the Program indicated were reported to the NRC and the events in the Program's local database). The team identified a total of 170 events, including 154 events involving Agreement State material, 12 events involving NARM, and four events involving radioactive material where the origin could not be determined from the information provided. The team identified one event that required reporting to the NRC that was not reported. The team also identified nine events that were apparently reported by the Commonwealth to NMED, but were not identified during the team's search of the NMED database. Two of these events required reporting, the other seven did not. It could not be established why these events were not included in NMED. The review team discussed with the Program the need to submit the information for events that required reporting to the NRC that were not reported, including the one event identified by the team and the two additional events not found in NMED that were required to be reported.

The team also determined that 35 of the reportable events were not reported to the NRC in the appropriate period of time specified in STP Procedure SA-300. These events were reported a few weeks to two years overdue. Eleven of the event reports were determined to be incomplete by the review team. 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 difficulty using the NMED program to enter information into the database. 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.

During the review period, the Program received 31 allegations including nine referred to the Commonwealth by the NRC. The review team reviewed 15 allegations including the allegations referred by NRC. The team noted that the Program promptly responded with appropriate investigations, follow-up, and closeout actions. All files contained written closeout correspondence to the alleger summarizing the Program's actions regarding the concerns raised. The 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, Response to Incidents and Allegations, be found satisfactory with recommendations for improvement.

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State Programs: (1) Legislation and Program Elements Required for Compatibility; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. Massachusetts' Agreement does not authorize regulation of uranium recovery activities, so only the first three non-common performance indicators were applicable to this review.

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 Legislation

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. It was noted that the current legislation and regulations had previously been found adequate in 1997 during the review of the Commonwealth's request for an Agreement and no new legislation has been passed since then.

4.1.2 Program Elements Required for Compatibility

The Commonwealth regulations for control of radiation are located in 105 CMR 120 of the Massachusetts Regulations for Control of Radiation 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 responses to the questionnaire, 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. Interviews were also conducted with the Program's staff.

During the onsite review the team found that the following three regulations have not been adopted and are overdue. They have not been incorporated as license conditions or other legally binding requirements:

- "Low Level Waste Manifest, Information and Reporting," 10 CFR Parts 20, 61 amendments (60 FR 15649, 60 FR 25983) that became effective March 1, 1998. The Agreement States were expected to promulgate their regulations no later than March 1, 1998 so that NRC and the Agreement States would require this national system to be effective at the same time.

  This rule was originally published on March 27, 1995 to be effective March 2, 1998. Massachusetts became an Agreement State on March 27, 1997, however NRC did not notify the Commonwealth that this rule was not part of their regulations during negotiations for the Agreement. This was not identified during the 1998 IMPEP review. However, due to the fact that material cannot be transferred out-of-state without a uniform manifest, the regulation is being implemented. Although the essential elements of the regulations are being implemented, the Commonwealth is required to adopt the rule to meet the Commission's policy on adequacy and compatibility.

- "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, 1998.

- "Transfer for Disposal and Manifests: Minor Technical Conforming Amendment," 10 CFR Part 20 amendments (63 FR 50127) that became effective November 20, 1998.

The Program intends to address these regulations in the upcoming regulations promulgation period scheduled to be completed in 2003.

In addition, the team noted that the Commonwealth used other forms of generic legally binding requirements to address the following three rules.

- "Recognition of Agreement State Licensees in Areas Under Exclusive Federal Jurisdiction Within an Agreement State," 10 CFR Part 150 amendment (62 FR 1662) that became effective on February 27, 1997.

  The team observed that license conditions were being used to satisfy this requirement. The license condition has been found compatible by the NRC.

- "Deliberate Misconduct by Unlicensed Persons," 10 CFR Parts 30, 40, 61, 70 and 150 amendments (63 FR 1890, 63 FR 13773) that became effective on February 12, 1998.

  The team determined that the Commonwealth has provisions to address this rule under Chapter 111, Section 50, statute 120.016 (I) of Massachusetts' Law. The

Commonwealth provided additional information on this rule on September 5, 2002. NRC will evaluate the material to determine if the rule is compatible.

- "Radiological Criteria for License Termination," Parts 20, 30, 40 and 70 (62 FR 39057) that became effective on August 20, 1997.

  In their request for an Agreement in March 1997, the Commonwealth provided criteria for unrestricted releases. No provisions were included for restricted releases or public participation. The team noted that the Commonwealth was more restrictive than NRC by not allowing for restricted releases. The Commonwealth has a statute that addresses public participation for sites involving hazardous materials through the Massachusetts' Department of Environmental Protection. This statute appears to address NRC's requirement for public notification and participation for licenses requiring a decommissioning plan, however, additional information will be requested by NRC to determine if the Commonwealth's rules are compatible.

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.

The Program will need to address the following regulations in upcoming rulemakings or by adopting alternate legally binding requirements:

- "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, 2000.

- "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 10 CFR Part 39 amendments (65 FR 20337) that became effective on May 17, 2000.

- "New Dosimetry Technology," 10 CFR Parts 34, 36 and 39 amendments (65 FR 63750) that became effective on January 8, 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, 2001.

- "Revision of the Skin Dose Limit," 10 CFR Part 20 (67 FR 16298) that became effective April 5, 2002.

- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32 and 35 amendments that became effective on April 24, 2002.

Based on the IMPEP evaluation criteria, the review team recommends that Massachusetts' performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, be found satisfactory.

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 Quality of the Product Evaluation; (2) Technical Staffing and Training; 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's response to the IMPEP questionnaire on this indicator. A review of selected new, amendment, transferred, and inactivation SS&D evaluations and supporting documents covering the review period was conducted. The team observed the Program's use of guidance documents and procedures, and interviewed the staff, and the Licensing Supervisor involved in SS&D evaluations.

The Program completed 123 SS&D actions and 4 evaluations of incidents or failures involving Massachusetts products since June 2000. More than 200 certificates were transferred from the State of Illinois when Massachusetts became an Agreement State due to a business' relocation of certain operations. The Program has approximately 100 of these certificates that will require an assessment for inactivation, or amendment, for continued use in the SS&D registry.

4.2.1 Technical Quality of the Product Evaluation Program

Thirteen SS&D case files were selected by the team for review including work performed by all reviewers. The cross-section sampling included all of the Commonwealth's major SS&D manufacturers and distributors, including the following types: beta gauge; calibrator; brachytherapy source and afterloader; liquid scintillation counter; neutron sources; beta and gamma point sources; and line sources. The SS&D actions selected for evaluation included four new certificates, three amendments, four transfers, and two inactivations. The SS&D certificates evaluated by the review team are listed with case specific comments in Appendix F.

The team reviewed SS&D actions, deficiency correspondence, and checklists for SS&D cases within the review period. 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 generally followed the recommended guidance from the NRC SS&D training workshops and NUREG-1556, Volume 3, issued in July 1998. All applicable and pertinent regulations, industrial 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. 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 team found that the SS&D files were maintained in an orderly manner and correspondence was filed chronologically.

The review team noted that the Program's SS&D evaluations have improved since the 2000

follow-up IMPEP review. The Program revised their standard operating procedure for SS&D evaluations to institute a policy for approving registration certificates in addition to the two reviews conducted by the technical staff. The Licensing Supervisor and Radioactive Materials Supervisor review and approve all new registration certificates. The Licensing Supervisor reviews and approves all amended registration certificates. These reviews are not technical in nature, but are to ensure that registration certificates are technically sound, legible, and understandable. A majority of the current team's comments in Appendix F concern numerous non-safety related variances from the format for documenting SS&D evaluations as described in NUREG-1556, Volume 3. The review team concluded that many of these variances should have been identified in the second review. Although the team determined that a secondary review was performed in each case, the scope of the secondary review was not always apparent. The team discussed with the staff and Licensing Supervisor the benefits of detailing the secondary review with an additional checklist, or using a second set of initial blocks on the primary reviewers checklist. In addition, the secondary review should ensure that the certificate follows the format in NUREG-1556, Volume 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.

The team observed that registration certificate MA-1142-D-102-G did not address an important redundant safety feature, or provide adequate information on why it was not needed. The team noted that this device is manufactured in a foreign country and distributed domestically by a company in Massachusetts. The manufacturer is wholly owned by the domestic distributor. The QA/QC procedures for the manufacturer and distributor are on file, but the certificate did not reference how the two QA/QC procedures were related. The foreign manufacturer provided its QA/QC procedures in the application, however, the application did not contain QA/QC procedures for the domestic distributor. The team also noted that registration certificate MA-0116-102-B contained inconsistent radiological training requirements. The team recommends that the Program make corrections to registration certificates MA-1142-D-102-G and MA-0116-102-B.

The Program updated and re-issued its standard operating procedure for processing registration applications on June 16, 2000. The review team reviewed the procedure and identified some areas that needed additional instructions for the SS&D reviewer. The team noted that the External Radiation Level section did not include survey meter information such as type, window thickness, sensitivity, calibration date, etc., and conditions under which the survey meter was used. In addition, the QA/QC section did not include a discussion about requiring distributors located in the Commonwealth to have QA/QC procedures for products that are manufactured by a foreign manufacturer and distributed domestically. The team discussed with the Licensing Supervisor the value of modifying the procedure to include these features. The Licensing Supervisor informed the team that QA/QC procedures were addressed in the Program's Regulatory Guide 6.9 field guide which was adapted from NRC's Regulatory Guide 6.9. The Licensing Supervisor agreed that modifying the procedure to add these features was appropriate.

4.2.2 Technical Staffing and Training

The Program reported that five staff, including the Licensing Supervisor, currently have authority to sign SS&D evaluations, in addition to their responsibilities for materials licensing

casework and inspections. Since the 2000 follow-up IMPEP review, the Program has trained and qualified three additional SS&D reviewers. One of the staff reviewers who was previously authorized to sign SS&D evaluations was promoted to a management position within the review period. The team examined the training and experience folders for the three staff that were trained and qualified since June 2000. All three have engineering backgrounds by education and attended the NRC SS&D workshop. One of the newly qualified staff members had many years of experience in SS&D evaluation in private industry. In addition to documentation of training, the staff had detailed documentation of SS&D casework assignments, dates, and the name of the Program mentor. As noted in Section 3.3, the Program, as a matter of policy, cross trains its staff to perform materials licensing, inspection and SS&D review. Staff were not permitted to work independently until the Licensing Supervisor was satisfied that the individual had demonstrated adequate competency and recommended to work independently through memorandum to the Radioactive Materials Supervisor.

4.2.3 Evaluation of Defects and Incidents Regarding Sealed Sources and Devices

During the review period, the Commonwealth reported four incidents involving equipment failure or malfunction. The team examined all four incidents. Two of the incidents were completed and two were currently under review by the Program and pending resolution. A list of incident casework examined with case-specific comments is included in Appendix E.

The 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 one allegation related to the SS&D Evaluation Program. The team noted that the Program promptly responded with an appropriate investigation, follow-up, and closeout action. The file contained written closeout correspondence to the alleger summarizing the Program's actions regarding the concerns raised. There were no performance issues identified from the review of the file or the documentation. The team found that the Program investigation was well documented and reasonable.

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

4.3 Low-Level Radioactive Waste (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 the following indicators: Status of Materials Inspection Program, Technical Quality of Inspections, Technical Staffing and Training, Technical Quality of Licensing Actions, Legislation and Program Elements Required for Compatibility and SS&D Evaluation Program. The team found Massachusetts performance to be satisfactory with recommendations for improvement for the indicator, Response to Incidents and Allegations. Accordingly, the review team recommended and the MRB concurred in finding the Massachusetts Agreement State program to be adequate 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 next full review should be in approximately four years.

Below are the recommendations, as mentioned earlier in the report, for evaluation and implementation, as appropriate, by the Commonwealth. The good practice approved by the MRB is also given.

RECOMMENDATIONS:

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)

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)

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)

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

GOOD PRACTICE:

1. The Program developed a spreadsheet to assist in determining the amount of financial assurance required based on the possession limit of radioactive material on the license. The review team found this method to be efficient and effective for managing these licenses, and recommends to the MRB that the Program's use of this spreadsheet be found a good practice (Section 3.4).

LIST OF APPENDICES AND ATTACHMENTS

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Vivian Campbell, Region IV	Team Leader Technical Staffing and Training
Duncan White, Region I	Technical Quality of Inspections Inspection Accompaniments Response to Incidents and Allegations
Osiris Siurano, STP	Status of Materials Inspection Program Legislation and Program Elements Required for Compatibility
James Harris, Kansas	Technical Quality of Licensing Actions
Seung Lee, NMSS/IMNS	Sealed Source and Device Evaluation Program

APPENDIX B

COMMONWEALTH OF MASSACHUSETTS

EXECUTIVE OFFICES AND DEPARTMENTS

AND

RADIATION CONTROL PROGRAM

ORGANIZATION CHARTS

ML022000286, ML022000296, ML022000303

APPENDIX C

INSPECTION 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: AEA Technology QSA, Inc. License No.: 12-8361
Location: Burlington, MA Inspection Type: Routine, Unannounced
License Type: Manufacturing and Distribution Broad Scope Priority: 1
Inspection Date: 7/17-18/01 Inspectors: AC, JS

File No.: 2
Licensee: Biomeasure, Inc. License No.: 20-5391
Location: Milford, MA Inspection Type: Routine, Unannounced
License Type: Research and Development Priority: 3
Inspection Date: 4/5/02 Inspector: SL

Comment:
a) Citation wording in notice of violation did not follow standard enforcement language.

File No.: 3
Licensee: CIS-US, Inc. License No.: 60-0053
Location: Bedford, MA Inspection Type: Routine, Unannounced
License Type: Manufacturing and Distribution Priority: 2
Inspection Date: 4/4/02 Inspector: JD

File No.: 4
Licensee: Steris-Isomedix Services License No.: 28-7911
Location: Northborough, MA Inspection Type: Routine, Unannounced
License Type: Panoramic Pool Irradiator Priority: 1
Inspection Date: 4/1/02 Inspector: AC

File No.: 5
Licensee: Interstate Nuclear Services License No.: 03-5291
Location: Springfield, MA Inspection Type: Special, Unannounced
License Type: Nuclear Laundry Priority: 2
Inspection Date: 3/10/99 Inspectors: RG, RF

File No.: 6
Licensee: North Shore Medical Center License No.: 44-0161
Location: Salem, MA Inspection Type: Routine, Unannounced
License Type: Medical Institution-QMP required, Brachytherapy and Self Shielded Irradiator Priority: 3
Inspection Date: 4/2/02 Inspector: TC

File No.: 7
Licensee: Venegas Industrial Testing Labs License No.: 56-0184
Location: Nashua, NH Inspection Type: Routine, Announced
License Type: Industrial Radiography Priority: 1
Inspection Date: 1/28/00 Inspector: RW

File No.: 8
Licensee: Delta Airlines License No.: 56-0270
Location: Boston, MA Inspection Type: Routine, Announced
License Type: Industrial Radiography Priority: 1
Inspection Date: 3/20/01 Inspector: KM

File No.: 9
Licensee: New England Medical Center License No.: 60-0160
Location: Boston, MA Inspection Type: Routine, Announced
License Type: Medical Institution Broad, Gamma Knife, HDR Priority: 1
Inspection Date: 9/18-19/00 Inspectors: GS, AC

File No.: 10
Licensee: Tufts University School of Medicine License Nos.: 00-0450 & 60-0159
Location: Boston, MA Inspection Type: Routine, Unannounced
License Type: Academic Broad Scope Priority: 1
Inspection Date: 10/28-29/99 Inspector: MW

File No.: 11
Licensee: Medi-Physics dba Nycomed Amersham License No.: 58-0001
Location: Woburn, MA Inspection Type: Routine, Unannounced
License Type: Nuclear Pharmacy Priority: 1
Inspection Date: 2/21/01 Inspectors: MW, JD

File No.: 12
Licensee: Gammamed USA License No.: 56-0267
Location: North Andover, MA Inspection Type: Routine, Announced
License Type: Medical Products Distribution Priority: 3
Inspection Date: 12/17/99 Inspector: KT

File No.: 13
Licensee: Boston Biomedical Research Institute License No.: 13-7482
Location: Boston, MA Inspection Type: Routine, Unannounced
License Type: Research and Development Priority: 3
Inspection Date: 2/2-3/99 Inspector: MS

Comment:
a) Citation wording in notice of violation did not follow standard enforcement language.

File No.: 14
Licensee: Clark University License No.: 02-2454
Location: Worcester, MA Inspection Type: Routine, Unannounced
License Type: Academic Type C Broad Scope Priority: 5
Inspection Date: 3/4/99 Inspector: RF

Comment:
a) Citation wording in notice of violation did not follow standard enforcement language.

File No.: 15
Licensee: Northeastern University License No.: 06-4327
Location: Boston, MA Inspection Type: Routine, Unannounced
License Type: Academic Broad Scope Priority: 2
Inspection Date: 2/13/02 Inspector: MI

File No.: 16
Licensee: Mount Auburn Hospital License No.: 44-0017
Location: Cambridge, MA Inspection Type: Routine, Unannounced
License Type: Medical Institution-QMP required, Brachytherapy Priority: 3
Inspection Date: 2/4/99 Inspector: MB, GS

File No.: 17
Licensee: Anna Jaques Hospital License No.: 44-0038
Location: Newburyport, MA Inspection Type: Routine, Unannounced
License Type: Medical Institution-QMP required Priority: 3
Inspection Date: 12/12/00 Inspector: TB

File No.: 18
Licensee: Longview Inspection NRC License No.: 42-27593-01
Location: Wellesley, MA Inspection Type: Reciprocity
License Type: Industrial Radiography Priority: NA
Inspection Date: 6/15/99 Inspector: RF

File No.: 19
Licensee: Massachusetts General Hospital License No.: 60-0055
Location: Boston, MA Inspection Type: Special, Announced
License Type: Medical Institution Broad Priority: 1
Inspection Date: 5/23/00 Inspectors: JD, GS

File No.: 20
Licensee: John Turner Consulting NH License No.: 423R
Location: Clemsford, MA Inspection Type: Reciprocity
License Type: Portable Gauge Priority: NA
Inspection Date: 9/19/01 Inspector: AC

File No.: 21
Licensee: J.L. Shepherd and Associates
CA License No.: 1777-19
Location: Lexington, MA
Inspection Type: Reciprocity
License Type: Service (source exchange)
Priority: NA
Inspection Date: 2/8/00
Inspector: KM

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: Steris-Isomedix Services
License No.: 28-7911
Location: Northborough, MA
Inspection Type: Unannounced, Routine
Type: Panoramic Pool Irradiator
Priority: 1
Inspection Date: 4/1/02
Inspector: AC

Accompaniment No.: 2
Licensee: North Shore Medical Center
License No.: 44-0161
Location: Salem, MA
Inspection Type: Unannounced, Routine
Type: Medical Institution-QMP required and Brachytherapy and Self Shielded Irradiator
Priority: 3
Inspection Date: 4/2/02
Inspector: TC

Accompaniment No.: 3
Licensee: CIS-US, Inc.
License No.: 60-0053
Location: Bedford, MA
Inspection Type: Unannounced, Routine
Type: Manufacturing and Distribution
Priority: 2
Inspection Date: 4/4/02
Inspector: JD

Accompaniment No.: 4
Licensee: Biomeasure, Inc.
License No.: 20-5391
Location: Milford, MA
Inspection Type: Unannounced, Routine
Type: Research and Development
Priority: 3
Inspection Date: 4/5/02
Inspector: SL

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: Radiocat — License No.:44-0328
Location: Springfield, MA — Amendment No.: 0
License Type: Veterinary Medicine — Type of Action: New
Date Issued: 11/13/00 — License Reviewer: GS

Comment:
a) Decay-in-storage condition does not state the requirement to hold waste for decay-in-storage for a minimum of 10 half-lives.

File No.: 2
Licensee: The Cat Hospital — License No.:48-0316
Location: Auburn, MA — Amendment No.: 1
License Type: Veterinary Medicine — Type of Action: Amendment
Date Issued: 2/22/01 — License Reviewer: GS

Comment:
a) Decay-in-storage condition does not state the requirement to hold waste for decay-in-storage for a minimum of 10 half-lives.

File No.: 3
Licensee: Starmet — License No.: SM-0179
Location: Concord, MA — Amendment No.: 18
License Type: Manufacturer — Type of Action: Renewal
Date Issued: Pending — License Reviewer: SL

File No.: 4
Licensee: Arthur D. Little — License No.: 30-1122
Location: Cambridge, MA — Amendment No.: 1
License Type: Calibration Service — Type of Action: Termination
Date Issued: 12/3/99 — License Reviewer: JD

File No.: 5
Licensee: TW Environmental Services — License No.: 49-0198
Location: Boston, MA — Amendment No.: 0
License Type: XRF Gauge — Type of Action: New
Date Issued: 9/5/97 — License Reviewer: MS

File No.: 6
Licensee: Syncor International License No.: 42-0146
Location: Woodland Hills, CA Amendment No.: 13
License Type: Nuclear Pharmacy Type of Action: Renewal
Date Issued: Pending License Reviewer: MW

Comment:
a) Decay-in-storage condition does not state the requirement to hold waste for decay-in-storage for a minimum of 10 half-lives.

File No.: 7
Licensee: .Minuteman Environmental Services License No.: 49-0069
Location: Medway, MA Amendment No.: 1
License Type: XRF Gauge Type of Action: Renewal
Date Issued: 9/17/01 License Reviewer: AC

File No.: 8
Licensee: Marine Biological Lab License No.: 00-5952
Location: Woods Hole, MA Amendment No.: 35
License Type: Research and Development Type of Action: Amendment
Date Issued: 6/6/00 License Reviewer: GS

Comments:
a) Conditions 14 and 20 are redundant.
b) Decay-in-storage condition does not state the requirement to hold waste for decay-in-storage for a minimum of 10 half-lives.

File No.: 9
Licensee: Kane, Jack License No.: 49-0306
Location: Sharon, MA Amendment No.: 0
License Type: XRF Gauge Type of Action: New
Date Issued: 6/8/00 License Reviewer: AC

File No.: 10
Licensee: Bruker Daltonics License No.: 38-0257
Location: Billerica, MA Amendment No.: 1
License Type: Manufacturer/Distributor Type of Action: Amendment
Date Issued: 4/5/00 License Reviewer: AC

File No.: 11
Licensee: Northeast Generation Services License No.: 48-0348
Location: West Springfield, MA Amendment No.: 0
License Type: Research and Development Type of Action: New
Date Issued: 5/24/01 License Reviewer: AC

File No.: 12
Licensee: Polaroid Corporation License No.: 02-8483
Location: Waltham, MA Amendment No.: 1
License Type: Industrial Type of Action: Amendment
Date Issued: 4/29/98 License Reviewer: SL

File No.: 13
Licensee: Conam Inspection License No.: 16-5591
Location: Auburn, MA Amendment No.: 9
License Type: Industrial Radiography Type of Action: Amendment
Date Issued: 2/13/02 License Reviewer: JD

File No.: 14
Licensee: Charles River Labs License No.: 60-0168
Location: Wilmington, MA Amendment No.: 5
License Type: Broad Scope, Research and Development Type of Action: Amendment
Date Issued: 4/24/02 License Reviewer: TC

Comment:
a) Decay-in-storage condition does not state the requirement to hold waste for decay-in-storage for a minimum of 10 half-lives.

File No.: 15
Licensee: Raytheon License No.: 01-1026
Location: Sudbury, MA Amendment No.: 4
License Type: Research and Development Type of Action: Amendment
Date Issued: 4/6/99 License Reviewer: KT

File No.: 16
Licensee: Brigham & Women's Hospital License No.: 44-0004
Location: Boston, MA Amendment No.: 11
License Type: Broad Scope, Medical Type of Action: Amendment
Date Issued: 4/12/02 License Reviewer: GS

Comment:
a) Decay-in-storage condition does not state the requirement to hold waste for decay-in-storage for a minimum of 10 half-lives.

File No.: 17
Licensee: Bristol Myers-Squibb License No.:60-0088
Location: North Billerica, MA Amendment No.: 7
License Type: Broad Scope, Research and Development Type of Action: Amendment
Date Issued: 12/21/01 License Reviewer: JS

Comment:
a) Decay-in-storage condition does not state the requirement to hold waste for decay-in-storage for a minimum of 10 half-lives.

File No.: 18
Licensee: AEA Technology License No.:12-8361
Location: Burlington, MA Amendment No.: 28
License Type: Broad Scope, Research and Development Type of Action: Amendment
Date Issued: 4/10/02 License Reviewer: AC

Comment:
a) Decay-in-storage condition does not state the requirement to hold waste for decay-in-storage for a minimum of 10 half-lives.

File No.: 19
Licensee: Valley Safety Services License No.:44-0056
Location: Belchertown, MA Amendment No.: 2
License Type: Analytical Lab Type of Action: Renewal
Date Issued: 1/31/01 License Reviewer: AC

File No.: 20
Licensee: New England PET Imaging System License No.: 44-0373
Location: North Andover, MA Amendment No.: 0
License Type: Mobile Medical Type of Action: New
Date Issued: 1/10/02 License Reviewer: BW

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1
Licensee: Anna Jacques Hospital — Licensee No.: 44-0038
Site of Incident: Newburyport, MA — Incident Log No.: 09-1076
Date of Incident: 9/24/98 — Type of Incident: Misadministration
Investigation Date: 10/22/98 — Type of Investigation: On-site

Summary of Incident and Final Disposition: The wrong patient was given 22 millicuries of Tc-99m MDP for bone scan. The Program performed a special inspection and determined that a technologist failed to verify the patient's identity with two forms of identification. The inspection also verified licensee's corrective actions.

File No.: 2
Licensee: NEN Life Sciences — Licensee No.: 00-3200
Site of Incident: Boston, MA — Incident Log No.: 12-2191
Date of Incident: 12/4/00 — Type of Incident: Overexposure
Investigation Date: 12/6/00 — Type of Investigation: On-site

Summary of Incident and Final Disposition: During transfer of 3.5 curies of Y-90 in a 3-milliliter solution within a bioassay hood, the vial and cap separated and the vial fell to the floor of the hood, splashing the operator. The employee's initial actions resulted in the spread of contamination in the room. Best estimate of shallow dose equivalent to the individual's chin was 263 rad. On-site inspections focused on the overexposure, training, emergency procedures and Y-90 operational issues. Subsequent follow-up inspection focused on licensee's corrective actions and monitoring changes to Y-90 operations into Spring of 2001.

File No.: 3
Licensee: Lahey Clinic — Licensee No.: 44-0015
Site of Incident: Burlington, MA — Incident Log No.: 12-1643
Date of Incident: 12/16/99 — Type of Incident: Contamination Event
Investigation Date: 12/23/99 — Type of Investigation: Phone and On-site

Summary of Incident and Final Disposition: During the intravenous injection of an I-131 therapy dose of 90 millicuries, the butterfly value became disconnected and all but 1.5 millicuries spilled on the floor. The patient's therapy dose was completed a few days later. The Program reviewed the licensee's corrective actions documented in their 12/23/99 letter. A closeout letter was issued to the licensee on 1/12/00 and verification of corrective actions occurred at the next inspection.

Comment:
a) Event reported late to NMED on 4/2/01 (NMED No. 010311).

File No.: 4
Licensee: Ion Track Instruments — Licensee No.: 15-5253
Site of Incident: Wilmington, MA — Incident Log No.: 05-2633
Date of Incident: 5/17/01 — Type of Incident: Leaking Source and Equipment Problem
Investigation Date: 5/23 - 7/1/01 — Type of Investigation: Phone

Summary of Incident and Final Disposition: Upon receipt a leak test of a set of Ni-63 source assemblies (NER-004) revealed contamination received from vendor (Isotope Products). The vendor caused the contamination by pinching the ends of the foil when placing it into the source cup, causing the ends to chaff. The Program reviewed NMED for similar events and followed the licensee's actions with vendor. The vendor changed foil size to ensure that they could be placed in the source cup without pinching ends.

Comments:
a) Event reported late to NMED on 7/10/01 (NMED No.010658)
b) NMED has not been updated to document closure of the event.

File No.: 5
Licensee: Brigham and Women's Hospital — Licensee No.: 44-0004
Site of Incident: Boston, MA — Incident Log No.: 08-2036
Date of Incident: 8/17/00 — Type of Incident: Equipment Failure
Investigation Date: 8/18/00 - 1/30/01 — Type of Investigation: Phone and On-site

Summary of Incident and Final Disposition: The licensee initially reported a possible misadministration involving intra vascular brachytherapy (IVB) procedure with a Novoste Beta Cath unit. The seed train did not deploy into the treatment area and the licensee immediately retracted it. The Program determined that a misadministration did not occur and followed the manufacturer's evaluation of the incident. The manufacturer determined that cellulose (paper) introduced in the system caused the blockage in the transfer system. This contamination was mostly likely introduced at the licensee's facility.

Comments:
a) Event reported late to NMED on 6/12/01 (NMED No. 010537)
b) NMED has not been updated to document closure of the event.

File No.: 6
Licensee: Starmet NMI Licensee No.: SU-1453
Site of Incident: Concord, MA Incident Log No.: 09-2088
Date of Incident: 9/26/00 Type of Incident: Fire
Investigation Date: 9/27/00 Type of Investigation: On-site

Summary of Incident and Final Disposition: A fire of depleted uranium (DU) chips which started spontaneously in a barrel was discovered by a security guard. The guard contacted the licensee's emergency response team (ERT). The barrel was stored in an area with 13 other barrels with DU chips. The licensee used a forklift to move the flaming drum to a deluge box away from the other drums to allow it to cool and extinguish. The licensee took air samples of the area and building exhaust and completed bioassays of the guard and ERT. The Program initiated a special inspection the day after the event. The licensee and the Commonwealth determined that there was no release of DU from the building and that the guard had a small uptake of DU.

Comment:
a) NMED has not been updated to document closure of the event. (NMED #010534)

File No.: 7
Licensee: University of Massachusetts Memorial Medical Center Licensee No.: 02-4523
Site of Incident: Worcester, MA Incident Log No.: 01-3155
Date of Incident: 1/29/02 Type of Incident: Misadministration and Procedural Failure
Investigation Date: 1/30/02 Type of Investigation: Phone

Summary of Incident and Final Disposition: During an IVB procedure with 1.56 GBq of Sr-90, the sources did not traverse to the treatment site and were hung up for approximately 40 seconds. The licensee determined that the dose to the patient's arm was approximately 1.43 rad shallow dose equivalent. The licensee modified their IVB procedures to include not over tightening the hemostatic valve.

Comment:
a) Event not reported to NMED.

File No.: 8
Licensee: Briggs Engineering and Testing Licensee No.: 66-0042 (reciprocity)
Site of Incident: Boston, MA Incident Log Nos.: 05-0906 & 02-0813
Date of Incident: 5/21/98 Type of Incident: Equipment Failure
Investigation Date: 6/1/98 Type of Investigation: On-site

Summary of Incident and Final Disposition: A 63 Curie Ir-192 source became stuck during radiographic operations in a trench at Logan International Airport. The source was ultimately retracted into the exposure device by the Radiation Safety Officer. The highest dose during recovery was approximately 500 millirem. The manufacturer serviced the equipment just prior to the Logan Airport job and evaluated the equipment after the incident. The manufacturer could not identify any equipment problems. A special inspection by the Program included re-enactment of the operation at Logan. The licensee's corrective actions were verified at subsequent inspection.

Comments:
a) Event reported late to NMED on 6/3/98 (NMED No. 980611)
b) NMED has not been updated to document closure of the event.

File No.: 9
Licensee: Lowell University Licensee No.: 60-0049
Site of Incident: Lowell, MA Incident Log No.: 10-2932
Date of Incident: 10/4/01 Type of Incident: Loss Radioactive Material
Investigation Date: 10/15/01 Type of Investigation: Phone

Summary of Incident and Final Disposition: The licensee reported the loss of a 2 nanocurie Pu-239 source. The source was last seen on May 2001. The licensee checked possible locations where the source could have been used and was unable to locate it.

Comment:
a) The Program has not closed out in the event file.

File No.: 10
Licensee: St. Vincent's Hospital Licensee No.: 12-8691
Site of Incident: Worcester, MA Incident Log No.: 11-1116
Date of Incident: 11/3/98 Type of Incident: Release of Radioactive Material
Investigation Date: 11/4-17/98 Type of Investigation: Phone

Summary of Incident and Final Disposition: A patient was given a 193 millicurie I-131 therapy dose and left the hospital without authorization of licensee. The Program evaluated the licensee's attempts to locate patient and probable dose scenarios to a member of the public (the highest scenario yielded a dose of 440 millirems). The incident file indicates that patient was never located but was believed to be isolated from others.

Comments:
a) Event reported late to NMED on 6/12/01 (NMED No. 010537)
b) NMED has not been updated to document closure of the event.

File No.: 11

Licensee: AEA Technology QSA
Licensee No.: 12-8361
Site of Incident: Burlington, MA
Incident Log No.: 06-1923
Date of Incident: 6/19/00
Type of Incident: Overexposure and Procedural Failure
Investigation Date: 6/20-23/00
Type of Investigation: Site

Summary of Incident and Final Disposition: Two unauthorized individuals removed the overpack and the primary shielding plug from an incoming shipment of 1650 curies of Co-60 in the licensee's locking dock area (a restricted area). A radiation safety technician entered the area, immediately stopped further disassembly of the package, and replaced the primary shielding plug. Due to the high exposure rates off the package in its partially disassembled condition (a vertical beam of 0.6 roentgens per second at 0.3 meters), the licensee was concerned that the two individuals may have been overexposed. Subsequent re-enactments and information from the individuals' dosimeters resulted in assigned doses of 42 and 50 millirems. The Program conducted a special inspection of the incident and closely followed the licensee's investigation. The Program determined that the root cause of the event was loss of management control in communicating the proper processing of the package. A notice of violation was issued to the licensee.

File Number: 12
Licensee: Baker Testing Services
Licensee No.: 19-0672
Site of Incident: Rockland, MA
Docket No.: 05-1884
Date of Incident: 5/16/00
Type of Incident: Cable Failure
Investigation Date:
Type of Investigation:

Summary of Incident and Final Disposition: A radiography licensee reported that a male ball connector attached to the control cable broke off while connecting to the female connector of a Model 660A source assembly. Subsequent analysis by the manufacturer, AEA Technology, QSA, was inconclusive since the 550 connector ball was not returned. However, it was speculated that the working life of 5 years was most likely exceeded. (NMED #010277)

File Number: 13
Licensee: New England Medical Center
Licensee No.: 60-0160
Site of Incident:
Docket No.: 08-2820
Date of Incident:8/17/01
Type of Incident: Device Failure
Investigation Date:
Type of Investigation:

Summary of Incident and Final Disposition: This was a misadministration involving the IVB on a patient administered from the pelvic region. Difficulties were encountered in delivering the sources to the specified treatment area. In addition, the sources failed to return to the shield following the final treatment. The event was reported to the manufacturer and several corrective action initiatives were addressed.

File Number: 14
Licensee: AEA Technology QSA
Licensee No.: 12-8361
Site of Incident: Burlington, MA
Docket No.: 09-1495
Date of Incident: 9/3/99
Type of Incident: Drop Test Failure
Investigation Date:
Type of Investigation:

Summary of Incident and Final Disposition: Testing of the Models 770 and 771 cobalt source changers for compliance with ANSI N432 resulted in the failure of both devices following the 30 foot drop test. This was reported to the NRC on 9/3/99, with a copy concurrently sent to the Commonwealth. AEA has redesigned the Models 770 and 771 and has submitted an amendment to SS&D Certificate Number NR-0628-D-111-S for the Model 770, which is currently under review. The Commonwealth is currently reviewing the manufacturer's amendment request and will prepare an amendment to NR-0628-D-108-S for the Model 771. (NMED #990607)

File Number: 15
Licensee: AEA Technology QSA
Licensee No.: 12-8361
Site of Incident: Burlington, MA
Docket No.: 01-3144
Date of Incident: 1/17/02
Type of Incident: Device Shield Hot-Spots
Investigation Date:
Type of Investigation:

Summary of Incident and Final Disposition: The manufacturer has self-identified shield "hot-spots" on the top surface of some Model 880 radiography cameras where surface dose rates exceed transportation limits of 200 mR/hr. Actions are being taken via an "auto-radiographing" technique to assess the cameras already in the field. The manufacturer has identified poor quality control of the supplying vendor as the source of the problem. The Commonwealth is currently reviewing the changes in the quality control of the shield manufacture.

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

File No.: 1
Registry No.: MA-0116-D-102-B SS&D Type: Beta Gauge
Manufacturer: Eurotherm Gauging Systems, Inc. Model No.: HUB-77A
Date Issued: 10/3/00

Comments:

a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3, as follows:
   1) The first page of the certificate should read “CUSTOM DEVICE,” not “CUSTOM USE.”
   2) The ISOTOPE and MAXIMUM ACTIVITY should be on the same line
   3) The section head should read “LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE,” not “LIMITATIONS AND/OR CONSIDERATIONS OF USE.”
   4) REFERENCES section should have the letter senders’ names.
   5) “DEVICE TYPE” should not be in Attachments
b) The checklist was not signed or dated by the primary or secondary reviewer.
c) The calibration information for the external radiation survey meter was not available in EXTERNAL RADIATION LEVELS Section. Validation of readings is customarily verified in the safety evaluation process by noting instrument calibrations in accordance with 10 CFR 20.1501(b) or equivalent Agreement States regulations.
d) The “LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE” section did not contain a limitation statement that preventive and corrective maintenance should be performed by the specifically licensed personnel.
e) The application stated that persons having limited training in radiological protection can safely operate the device. However, the certificate stated that the device can be safely operated by persons not having training in radiological protection. No substantial information was available to reach this conclusion.

File No.: 2
Registry No.: MA-1059-D-114-S SS&D Type: Calibrator
Manufacturer: AEA Technology PLC Model 773, 77314
Date Issued: 11/7/01

Comments:

a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3, as follows:
   1) This certificate is for device so the header should read “SAFETY EVALUATION OF DEVICE,” not “SAFETY EVALUATION OF SEALED SOURCE.”
   2) International System of Units and special units were not used consistently.
   3) The section head should read “LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE,” not “LIMITATIONS AND/OR CONSIDERATION OF USE.”
   4) DEVICE TYPE should not be in Attachments.

File No.: 2 (continued)
b) The checklist was not signed or dated by the primary or secondary reviewer.
c) The label attachment method was not specified in the LABELING Section.
d) The amendment request letter dated July 26, 2001, was not specified in REFERENCES Section.
e) The superseded registration certificate NR-628-D-114-S has not yet been converted to inactive status.

File No.: 3
Registry No.: MA-1059-S-276-S SS&D Type: Beta Source
Manufacturer: AEA Technology PLC Model No.: KAC.D1, KAC.D2, KAC.D3, KAC.D4, KAC.D5
Date Issued: 9/22/00

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3, as follows:
    1) The certificate is for a sealed source, and should read “SEALED SOURCE TYPE,” not “DEVICE TYPE.”
    2) This is a new certificate so it does not need “(AMENDED IN ITS ENTIRETY)” in the header.
    3) The certificate should read “CUSTOM SOURCE,” not “CUSTOM DEVICE.”
    4) International System of Units and special units were not used consistently.
    5) ISO standard was used, however, ANSI was cited in LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE and SAFETY ANALYSIS SUMMARY sections.
    6) REFERENCES section should have the letter senders’ names.
b) The checklist was not signed or dated by the primary or secondary reviewer.
c) No statistical data was given to claim that the capsule can withstand an internal pressure of 50 atm with 90% confidence limit.
d) No calibration date was given for the external dose measurements. Validation of readings is customarily verified in the safety evaluation process by noting instrument calibrations in accordance with 10 CFR 20.1501(b) or equivalent Agreement States regulations.
e) The superseded registration certificate IL-136-S-240-S has not yet been converted to inactive status.

File No.: 4
Registry No.: MA-1059-D-356-S SS&D Type: Brachytherapy Afterloader
Manufacturer: Sirtex Medical Limited Model No.: SIR-Spheres
Date Issued: 3/27/02

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3, as follows:
    1) The certificate is for a device and should read “SEALED SOURCE TYPE,” not “DEVICE TYPE” in the header.

File No. 4 (continued)

2) The certificate should read “MANUFACTURERS,” not “MANUFACTURER,” because there are two manufacturers.
3) The sealed source model designation was not given in the first page.
4) The certificate should read “CUSTOM SOURCE,” not “CUSTOM DEVICE.”
5) The REFERENCES section should have the letter senders’ names

b) The checklist was not signed or dated by the primary or secondary reviewer.
c) The instructions for handling and storing and the label information for the storage containment were not given in the LABELING Section. For medical devices and sources, the provisions of 10 CFR 32.74 or equivalent Agreement States regulations specify additional requirements regarding handling and storing.
d) The radiation profile measurement did not provide the survey meter information including calibration in EXTERNAL RADIATION LEVEL Section. Validation of readings is customarily verified in the safety evaluation process by noting instrument calibrations in accordance with 10 CFR 20.1501(b) or equivalent Agreement States regulations.

File No.: 5
Registry No.: MA-1059-S-358-S SS&D Type: Neutron Source
Manufacturer: AEA Technology QSA Inc. Model No.: AMN.V997, AMN.V340
Date Issued: 3/11/02

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3, as follows:
1) The Certificate is for sealed source so it should read “SEALED SOURCE TYPE,” not “SOURCE TYPE.”
2) The Certificate should read “MANUFACTURERS,” not “MANUFACTURER,” because there are two manufacturers.
3) The Certificate should read “CUSTOM SOURCE,” not “CUSTOM DEVICE.”
4) International System of Units and special units were not used consistently.
5) The Certificate should read “LIMITATIONS AND/OR OTHER CONDITIONS OF USE,” not “LIMITATIONS AND CONDITIONS OF USE.”
6) This is a new certificate so it does not need “continue to” words in SAFETY ANALYSIS SUMMARY

b) The checklist was not signed or dated by the primary or secondary reviewer.
c) For X1, the diameter was 7.85 millimeters in DESCRIPTION, however, it was 7.844 millimeters in ATTACHMENT.
d) The calibration information for the survey meter was not given. Validation of readings is customarily verified in the safety evaluation process by noting instrument calibrations in accordance with 10 CFR 20.1501(b) or equivalent Agreement States regulations.
e) The superseded registration certificate NR-136-S-136-S has not yet been converted to an inactive status.

File No.: 6
Registry No.: MA-1142-D-102-G SS&D Type: Liquid Scintillation Counter
Manufacturer: Wallac Oy Model No.: 1220
Date Issued: 3/21/02

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3, as follows:
   1) The section head should read “LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE,” not “LIMITATIONS AND OTHER CONSIDERATIONS OF USE.”
   2) “DEVICE TYPE” should not be in Attachments.
   3) International System of Units and special units were not used consistently.
b) The checklist was not signed or dated by the primary or secondary reviewer.
c) Important features were not given in the DESCRIPTION Section. However, appropriate features were addressed during the review.
d) The Drawing No. 10360835 was cited in the DESCRIPTION Section; however, Drawing No. 10360835-A was provided in the application.
e) The label attachment method, size, and location were not given in the LABELING Section.
f) The Drawing No. 10360835 in Attachment # 2 was cited in the DIAGRAM Section, however, the Attachment # 3 showed it as 1036354.
g) The survey meter information including calibration date was not given in EXTERNAL RADIATION LEVELS Section.
h) The manufacturer is wholly owned by the domestic distributor. The QA/QC procedures for the manufacturer and distributor are on file, but the certificate did not reference how the two QA/QC procedures were related.

File No.: 7
Registry No.: MA-1059-S-198-S SS&D Type: Neutron Source
Manufacturer: AEA Technology, QSA Inc. Model No.: AMN.CYn
Date Issued: 9/25/01

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3, as follows:
   1) Certificate should read “SEALED SOURCE TYPE,” not “SOURCE TYPE” in the first page.
   2) Use maximum, not nominal ± 10%, format for MAXIMUM ACTIVITY.
   3) International System of Units and special units were not used consistently.
   4) The section head should read “LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE,” not “LIMITATIONS AND OTHER CONSIDERATIONS OF USE.”
   5) On page 6 of 7, the section header and content is out of order.
b) The checklist was not signed or dated by the primary or secondary reviewer.

c) The survey meter information including calibration was not given in EXTERNAL RADIATION LEVELS Section. Validation of readings is customarily verified in the safety evaluation process by noting instrument calibrations in accordance with 10 CFR 20.1501(b) or equivalent Agreement States regulations.

File No.: 8
Registry No.: MA-1059-S-240-S SS&D Type: Neutron Applications
Manufacturer: AEA Technologies, QSA, Inc. Model No.: AMN.PEn
Date Issued: 10/30/01

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3, as follows:
   1) The certificate should read “SEALED SOURCE TYPE,” not “SOURCE TYPE.”
   2) International System of Units and special units were not used consistently.
   3) The section head should read “LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE,” not “LIMITATIONS AND OTHER CONSIDERATIONS OF USE.”
   4) This is new certificate so it does not need “continue to” words in the SAFETY ANALYSIS SUMMARY section.
b) The checklist was not signed or dated by the primary or secondary reviewer.
c) The isotope of reference source for AMN.PE2 and the calibration information for the survey meter were not given in EXTERNAL RADIATION LEVELS Section. Validation of readings is customarily verified in the safety evaluation process by noting instrument calibrations in accordance with 10 CFR 20.1501(b) or equivalent Agreement States regulations.
d) The containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in the certificate was missing in SAFETY ANALYSIS SUMMARY Section.
e) The reference dated February 26, 2002, was not cited, and the letter dated June 29, 2001, was cited twice in the REFERENCES Section.
f) The superseded registration certificate IL-136-S-240-S has not yet been converted to inactive status.

File No.: 9
Registry No.: MA-1059-D-802-S SS&D Type: Gamma Source
Manufacturer: AEA Technologies, QSA, Inc. Model No.: BDC.L
Date Issued: 10/30/01

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3, as follows:
   1) The certificate should read “SEALED SOURCE TYPE,” not “SOURCE TYPE.”
   2) The PROTOTYPE TESTING section was incomplete.
   3) International System of Units and special units were not used consistently.
   4) The title should read “LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE,” not “LIMITATIONS AND/OR CONSIDERATIONS OF USE.”
b) The checklist was not signed or dated by the primary or secondary reviewer.

c) The limitation statement “The source shall only be distributed to persons specifically licensed by the NRC or an Agreement State” was missing in “LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE.
d) The references dated March 28, 1984, and August 30, 1984, were not available.

File No.: 10
Registry No.: MA-1078-S-102-S SS&D Type: Brachytherapy Source
Manufacturer: Implant Sciences Corporation Model No.: 3500
Date Issued: 3/5/02

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3, as follows:
    1) The certificate should read “MANUFACTURER/DISTRIBUTOR,” not “MANUFACTURER/DISTRIBUTOR” in the Page 1 of 1.
    2) Megabequerel was missing in the MAXIMUM ACTIVITY.
    3) International System of Units and special units were not used consistently.
    4) The section head should read “LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE,” not “LIMITATIONS AND/OR CONSIDERATIONS OF USE.”
    5) REFERENCES section should have the letter senders’ names.
b) The checklist was not signed or dated by the primary or secondary reviewer.
c) The instructions for handling and storing and the label for the storage container were not cited in the LABELING Section. For medical devices and sources, the provisions of 10 CFR 32.74 or equivalent Agreement States regulations specify additional requirements regarding handling and storing.
d) The reference dated January 22, 2002, was not available.
e) The cover letter dated February 18, 2002, stated that Model 3500 replaced Model 3000 (MA-1078-S-101-S). However, Model 3000 was not converted to inactive status.

File No.: 11
Registry No.: MA-1078-S-101-S SS&D Type: Brachytherapy Source
Manufacturer: Implant Sciences Corporation Model No.: 3000
Date Issued: 9/8/00

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3, as follows:
    1) International System of Units and special units were not used consistently.
    2) The section head should read “LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE,” not “LIMITATIONS AND CONSIDERATIONS OF USE.”
    3) REFERENCES section should have the letter senders’ names.
b) The checklist was not signed or dated by the primary or secondary reviewer.

c) The instructions for handling and storing and the label for the storage container were not cited in the LABELING Section. For medical devices and sources, the provisions of 10 CFR 32.74 or equivalent Agreement States regulations specify additional requirements regarding handling and storing.
d) The letter dated June 6, 1999, was not available, however, the letter dated June 16, 1999, was available in the background file.

File No.: 12
Registry No.: MA-1059-S-336-S SS&D Type: Gamma and beta line sources
Manufacturer: AEA Technology QSA Inc. Model No.: AMC.LA1 and SIC.LA1
Date Issued: 3/27/01

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3, as follows:
   1) The certificate should read “SEALED SOURCE TYPE,” not “SOURCE TYPE.”
   2) The certificate should read “MANUFACTURERS,” not “MANUFACTURER” because there are two manufacturers.
   3) The certificate should read “CUSTOM SOURCE,” not “CUSTOM DEVICE.”
   4) International System of Units and special units were not used consistently.
   5) The section header should read “LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE,” not “LIMITATIONS AND/OR CONSIDERATION OF USE.”
   6) “SEALED SOURCE TYPE” should not be in Attachment.
b) The checklist was not signed or dated by the primary or secondary reviewer
c) The transport Holder Number was X0845 in DESCRIPTION, however, it was X8045 in ATTACHMENT.
d) The labeling attachment method and the size of label were not available in LABELING Section.
e) The handling instructions (ref HI001 or HI013) were not available in LABELING Section. For medical devices and sources, the provisions of 10 CFR 32.74 or equivalent Agreement States regulations specify additional requirements regarding handling and storing.

File No.: 13
Registry No.: MA-8114-D-801-G SS&D Type: Beta gauge
Manufacturer: Thermo Environmental Instruments, Inc. Model No.: 650
Date Issued: 8/24/00

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3, as follows:
   1) This is new certificate so it does not need “(AMENDED IN ITS ENTIRETY)” in the header.
   2) International System of Units and special units were not used consistently.
   3) “DEVICE TYPE” should not be in Attachment.
b) Checklist was checked only by the primary reviewer. Neither signature nor date was given by the primary and the secondary reviewers.

c) The amendment request letter dated January 5, 2000, was not cited in REFERENCES section.
d) The Attachments showed the registration certificate number as MA-8016-D-801-G, not MA-8114-D-801-G.

ATTACHMENT

August 15, 2002 Letter from Robert J. Walker
Massachusetts' Response to Draft IMPEP Report
ML022340538