



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

July 18, 2008

Robert J. Walker, Director
Radiation Control Program
Massachusetts Department of Public Health
Schrafft Center, Suite 1M2A
529 Main Street
Charlestown, MA 02129

Dear Mr. Walker:

A periodic meeting with Massachusetts was held on June 19, 2008. The purpose of the meeting was to review and discuss the status of Massachusetts' Agreement State program. The NRC was represented by Kathleen Schneider and me.

I have completed and enclosed a general meeting summary, including any specific actions that will be taken as a result of the meeting.

If you feel that our conclusions do not accurately summarize the meeting discussion, or have any additional remarks about the meeting in general, please contact me at (610) 337-5371, or email to Donna.Janda@nrc.gov to discuss your comments.

Sincerely,
/RA/

Donna M. Janda
Regional State Agreements Officer
Division of Nuclear Materials Safety

Enclosure: as stated

cc w/encl: Salifu Dakubu, MA DPH

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ADAMS Document Accession No. ML082030380

DOCUMENT NAME: G:\Docs\Current\Misc Letter\MA June 2008 Periodic Meeting Summary rev 1.doc

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**AGREEMENT STATE PERIODIC MEETING SUMMARY FOR
MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH (DPH)**

DATE OF MEETING: June 19, 2008

ATTENDEES:

NRC

Kathleen Schneider, Sr. Project Manager, FSME
Donna Janda, RSAO, Region I

Massachusetts DPH

Robert Walker, Radiation Control Program Director
Salifu Dakubu, Materials Supervisor
Robert Gallagher, Inspection Supervisor
Michael Whalen, Events & Database Coordinator
Kenath Traegde, Materials Licensing and SS&D Supervisor

DISCUSSION:

Previous IMPEP Review

In May 2006, the Integrated Materials Performance Evaluation Program (IMPEP) review team found the Massachusetts Agreement State Program's (the Program) performance to be satisfactory for five of the performance indicators reviewed. The review team found Massachusetts' performance to be satisfactory, but needs improvement, for the following two indicators: Technical Quality of Incident and Allegation Activities and Compatibility Requirements. In addition, the review team made 8 recommendations regarding the Program. On August 14, 2006, the Management Review Board (MRB) met to consider the IMPEP review team's proposed findings regarding the Program. The MRB found the Program adequate to protect public health and safety and compatible with the NRC's program. Accordingly, the MRB determined that the next full review of the Program should take place in 4 years and that a periodic meeting should be tentatively scheduled for May 2008.

The status of the Commonwealth's actions to address all open previous IMPEP review findings and/or open recommendations follows:

Recommendation 1: The review team recommends that the Commonwealth pursue adequate funding to support and implement the staffing plan which is needed to meet current program demands as well as the projected increase in workload.

Status:

The Program's funding is obtained through several accounts, including a retained revenue account, which is a fee-based program, and a Bureau of Environmental Health account, which funds approximately 6 staff positions. The Program's licensees are assessed annual fees based on the licensed activity category and amendment fees. The Program retains revenue up to a fixed spending cap determined by the state legislature. Excess revenue is deposited in the Commonwealth's general fund. As of the date of this meeting, the Program was "level" funded and the budget had not been finalized for the upcoming fiscal year beginning July 1, 2008. With

Enclosure

level funding, the Program must pay for increased costs (e.g., staff salary increases, rent increases, etc.) by not filling positions vacated by retirements or attrition. Program management believes that senior management is supportive of increasing the Program's funding to support and implement the staffing plan that is needed to meet current program demands as well as the projected increase in workload. However, Program management believes that, without Legislative Branch support, the Program remains vulnerable to further losses of staff positions or may not have sufficient staff resources to meet increasing workload demand which could adversely affect performance.

This recommendation remains open.

Recommendation 2: The review team recommends that the Commonwealth address each of the licensing cases where increased controls are needed by either issuing license amendments to decrease possession limits or issuing license amendments to include increased controls.

Status:

The Program has worked with licensees to decrease possession limits by issuing license amendments when applicable. The Program issued license amendments to include increased controls for 48 licensees who are subject to the requirements.

It is recommended that this item be reviewed and closed at the next IMPEP review.

Recommendation 3: The review team recommends that the Commonwealth take appropriate and timely follow-up actions commensurate with the potential health and safety significance for all events.

Status:

Since the last IMPEP review, the Program staff was retrained on ensuring that event follow-up actions were commensurate with the potential health and safety significance for all events. The Events Coordinator prints out a list of open actions on a weekly basis to ensure the assigned staff member follows up in a timely manner.

It is recommended that this item be reviewed and closed at the next IMPEP review.

Recommendation 4: The review team recommends that the Commonwealth take necessary steps to ensure that all reportable events are submitted and updated to NRC in accordance with STP Procedure SA-300.

Status:

The Program retrained the staff about reporting requirements and has a designated Nuclear Materials Events Database (NMED) Coordinator who conducts periodic spot checks to ensure events are being reported and updated as required. Since the last review, the Program had 26 events reported to NMED. A review of NMED identified timely and quality input of incidents.

It is recommended that this item be reviewed and closed at the next IMPEP review.

Recommendation 5: The review team recommends that the Commonwealth adopt regulations necessary for compatibility within the required three year time frame and submit alternate forms of legally binding requirements for NRC review following the guidance in SA-201.

Status:

Since the last review, the Commonwealth submitted 18 final regulations for NRC's review on October 24, 2006. NRC responded on November 30, 2006, and had no comments on the final regulations. The Program's fingerprinting requirements used to address NRC Order EA-07-305 were submitted for review and no comments were identified in the NRC's response dated April 14, 2008. Presently, there are two regulations overdue. One additional final regulation was submitted for review, which had not been previously reviewed by NRC as a draft regulation in accordance with the guidance in SA-201. See the Regulations section below for additional details.

This recommendation remains open.

Recommendation 6: The review team recommends that the Commonwealth make corrections to registration certificate MA-0116-102-B.

Status:

The SS&D Supervisor reported that the licensee had not been cooperative and responded to the Program's request for additional information only after the Program issued the licensee a letter which stated the Commonwealth's intent to issue an Order to ensure the licensee's compliance. The program is currently reviewing the licensee's response.

This recommendation remains open.

Recommendation 7: The review team recommends that the Commonwealth develop and document a set of formal qualification requirements for SS&D reviewers.

Status:

The Program has incorporated formal qualification requirements for SS&D reviewers into their procedures.

It is recommended that this item be reviewed and closed at the next IMPEP review.

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

Status:

The Program plans to issue inactivated registration certificates along with the new SS&D certificates and a cover letter explaining the new procedure. The Program will soon be issuing two registration certificates according to the new procedure.

It is recommended that this item be reviewed and closed at the next IMPEP review.

Organization

The Massachusetts Agreement State Program is administered by the Program, which is located within the Bureau of Environmental Health (the Bureau). The Bureau is located within the Department of Public Health (the Department). There have been no changes to the Program's organization since the previous IMPEP. Mr. Robert Walker remains the Program Director. Mr. Walker reports to an Associate Commissioner who is also the Bureau Director. The Radioactive Materials Unit (the Unit), one of five units in the Program, administers approximately 515 licenses in the radioactive materials program.

Agreement State Program Staffing

A well-trained, stable, and experienced staff is the strength of the Program. The staff is the same as that seen during the last IMPEP review. Mr. Walker stated that funding, which is partially fee based, has been level for several years and is not anticipated to increase in the near future (see discussion on Recommendation 1 above). The Program has three vacant positions, one of which is a new position for a Deputy Director created in anticipation of the Program Director's plan to retire within 16 months. The addition of this position was planned for continuity of management and the Deputy will be expected to act in the Director's position after he retires until a final hiring decision is made by the Bureau Director. Depending on the hiring decision, the Deputy position may then be removed. The Program anticipates filling this new Deputy Director position with a current staff member. The two additional vacant positions cannot be filled due to budget concerns. In addition, the staff member in the Low Level Radioactive Waste position retired and the position was not filled. Those duties were given to another staff member.

The staff is fully engaged due to the current emphasis on increasing the security of radioactive materials and implementation of NRC regulations. With the unfilled positions and budget issues, the Program has to shift resources to address the increased workload due to activities such as implementation of pre-licensing guidance, Increased Controls inspections. The Program has reduced the number of inspections at accelerators and no longer performs inspections of programs which use only non-ionizing radiation sources.

Training

Support for staff training exists in the Program. The Program welcomed the NRC's revised policy on funding training for Agreement States. Program staff has attended NRC and other training courses, including the NRC's Security Systems and Principles Course, for which one staff member is an instructor. Several of the Program staff members participate on various NRC Working Groups and on IMPEP review teams.

Inspections

Massachusetts' inspection frequencies are at least as frequent as NRC's. No inspections are currently overdue with respect to NRC policies. The Program self-identified and corrected a database issue with respect to initial inspection due dates not being correctly assigned.

The Program maintains a sufficient number and variety of calibrated radiological survey instrumentation for use during inspections. Additionally, the Program has a radioanalytical laboratory available for sample analyses.

Licensing

The Program had several pending licensing actions greater than 30 days, some of which were pending for more than one year. The Licensing Supervisor indicated that this was due to licensees not responding in a timely manner to requests for additional information. Most licensing actions are acted upon within 30 days of receipt. All completed licensing actions are reviewed by a second reviewer and the Licensing Supervisor. The Materials Manager reviews all new licenses for administrative format. The Program Director signs all licensing documents.

Regulations

There have been no legislative changes since the last IMPEP review.

The Program submitted two proposed regulations and one final regulation to the NRC on May 14, 2008, which are presently under review and NRC staff expect to complete the review by July 14, 2008.

The following regulations are overdue:

- “Compatibility with IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments,” 10 CFR 71 amendments (69 FR 3698), that became effective on October 1, 2004. This proposed regulation was submitted by the Program to NRC on May 14, 2008, and NRC’s review was issued on July 1, 2008 with comments identified on this regulation.
- “Medical Use of Byproduct Material - Recognition of Specialty Boards,” 10 CFR 35 amendments (70 FR 16336; 71 FR 1926) that became effective April 29, 2005. The Program staff believes that this regulation has been adopted, but was not sent to the NRC for review. NRC staff discussed the submittal process for regulation reviews and the Program staff planned to submit the package following the periodic review. A proposed regulation package was submitted with insufficient information on June 20, 2008, and was not accepted for review.

The following final regulation adopted by the Commonwealth was submitted to NRC on May 14, 2008, and is under review:

- “Financial Assurance for Materials Licensees,” 10 CFR 30, 40, and 70 amendments (68 FR 57327), that became effective on December 3, 2003. NRC’s review was issued on July 1, 2008 with comments identified on this regulation.

NRC staff identified the following regulation changes and adoptions that will be needed in the future:

- “Security Requirements for Portable Gauges Containing Byproduct Material,” 10 CFR 30 amendments (70 FR 2001) that became effective July 11, 2005. This regulation was submitted by the Program to NRC on May 14, 2008, and NRC’s review was issued on July 1, 2008 with no comments on this regulation.
- “National Source Tracking System,” 10 CFR Part 20 amendment (71 FR 65865, 72 FR 59162) that is due for State adoption by January 31, 2009.
- “Minor Amendments – 10 CFR Parts 20, 30, 32, 35, 40 and 70,” 10 CFR amendments (71 FR 15005) that are due for State adoption by March 27, 2009.
- “Medical Use of Byproduct Material – Minor Corrections and Clarifications,” 10 CFR Parts 32 and 35 amendments (72 FR 45147, 72 FR 54207) that are due for State adoption by October 29, 2010.
- “Requirements for Expanded Definition of Byproduct Material,” 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendments (72 FR 55864) that are due for State adoption by November 30, 2010.
- “Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements,” 10 CFR Parts 30, 31, 32 and 150 amendments (72 FR 58473) that are due for State adoption by December 17, 2010.
- “Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent,” 10 CFR Parts 19 and 20 amendments (72 FR 68043) that are due for State adoption by February 15, 2011.

Security

The current security climate and potential future security measures were discussed in detail, including discussions on fingerprinting requirements and security of self-shielded irradiators. The Program is aware of relevant security issues. The Program tracks radioactive sources to quantities much lower than NRC requires. The Commonwealth entered into 274i Agreements with NRC to inspect materials licensee compliance with NRC-ordered security measures and with RAMQC.

Incidents/Allegations

Program staff communicates reportable incidents to the NRC Operations Center and Region I. The Event Coordinator is responsible for ensuring all incidents and allegations are handled properly. Staff members are responsible for entering incident information into the Nuclear Materials Events Database (NMED), as incidents occur. Since the last IMPEP review in May 2006, twenty-six (26) events were reported to NMED. A review of NMED identified timely and quality input of incidents.

The Program indicated that two events had potential for national implications. One event (EN43461, NMED Event No. 070401) involved the shipment to a MA licensee of deuterium water contaminated with 2.7 curies of H-3. The second event (EN43767, NMED Event No. 070683) involved the improper disposal of several generally-licensed static eliminators containing Am-241.

There were no allegations referred to the Program since the last IMPEP. Approximately seven allegations per year are received by the Program.

Sealed Sources and Devices

The Commonwealth has an active SS&D program which has issued 61 licensing actions since the last IMPEP.

Emerging Technologies

The Program has identified PET MRI and electronic brachytherapy as areas involving emerging technologies which will need to be addressed in their Program.

Feedback on the NRC's Program

Items discussed included current NRC initiatives for the National Source Tracking System, Web-Based Licensing, fingerprinting, GAO initiatives (e.g., orders versus rulemaking), pre-licensing checklists, and upcoming regulations to be adopted. The Program staff indicated that one strength of their Program is meeting NRC requests for information in a timely manner.

CONCLUSIONS:

The Massachusetts Radiation Control Program continues to be a strong, stable Agreement State program. The Program staff is experienced and well trained. Budget issues continue to be of concern regarding adequate funding of the Program and freezing of vacant positions. With the increased focus on the safety and security of radioactive material, adequate program resources have become much more critical. Any further reduction in staff may be detrimental to the Commonwealth's Radiation Control Program.

NRC staff recommends that the next IMPEP review should be conducted as scheduled in FY 2010 (tentatively May 2010).