



The Commonwealth of Massachusetts  
Executive Office of Health and Human Services  
Department of Public Health  
Bureau of Environmental Health  
Radiation Control Program  
Schrafft Center, Suite 1M2A  
529 Main Street, Charlestown, MA 02129  
(617) 242-3035 (617) 242-3457 - Fax

DEVAL L. PATRICK  
GOVERNOR

TIMOTHY P. MURRAY  
LIEUTENANT GOVERNOR

JUDYANN BIGBY, MD  
SECRETARY

JOHN AUERBACH  
COMMISSIONER

September 9, 2010

Robert J. Lewis, Director  
Office of Federal and State Materials and Environmental Management  
Division of Materials Safety and State Agreements  
Nuclear Regulatory Commission  
Two White Flint North, 8<sup>th</sup> Floor  
10555 Rockville Pike  
Washington, D.C. 20555

Dear Mr. Lewis:

The purpose of this letter is to respond to the draft Integrated Materials Performance Evaluation Program (IMPEP) report dated August 16, 2010, which you forwarded to Suzanne Condon, Associate Commissioner and Director, Bureau of Environmental Health, Massachusetts Department of Public Health (MDPH). This draft report documents the results of the Agreement State review held here at the Radiation Control Program (RCP) on July 12-16, 2010. Ms. Condon has asked me to respond on behalf of MDPH to the draft IMPEP report.

First, we would like to take this opportunity to thank you and the members of the IMPEP Review Team for the thoroughness of this review and the professional manner in which it was carried out. We would also like to especially compliment Ms. Michelle Beardsley, Nuclear Regulatory Commission (NRC), who was the Team Leader for this review. The composition of the Massachusetts Review Team represents a complimentary mix of experience and expertise that resulted in an effective review process and a very positive learning experience for members of our staff.

With regards to our comments, we would like to begin by commenting on the text of the report itself followed by the commenting on the recommendations.

## Section 2.0: Status of Items Identified in Previous Reviews.

Page 4; Recommendation 8. Report states “the second case work certificate (MA-8154-D-803-B) has not been reissued. This recommendation remains open with respect to the reissuance of registration certificate MA-8154-D-803-B with complete text and has been modified accordingly. The review team recommends that the Commonwealth re-issue registration certificate MA-8154-D-803-B with the complete text.” Please see our response to Recommendation 9.

## Section 3.0: Common Performance Indicators

### Section 3.1 Technical Staffing and Training

Page 4, 3<sup>rd</sup> paragraph, first sentence states “a clerical staffer was reassigned outside of the Unit and a technical staffer who performed part-time licensing/inspection duties was transferred to another unit within the Bureau.” The technical staffer who performed licensing/inspection duties was not transferred to another unit within the Bureau, rather he was transferred to the Massachusetts Environmental Laboratory (MERL) which is within the RCP.

Same section, next paragraph, 5<sup>th</sup> sentence states “In addition, the Acting Director expressed concern that the current staff will be tasked with additional duties, such as performing environmental sample analyses for the Pilgrim nuclear power plant groundwater contamination issue, and performing 274i security inspections, among other issues.” We believe the statements made by the Acting Director have been taken out of context in that he was expressing the increasing workload that the remaining Materials Unit staff are faced with following the transfer of one unit member to the MERL and the need to continue to perform Increased Control inspections.

### Section 3.2 Status of Materials Inspection Program

Page 6, 1<sup>st</sup> paragraph (continues from Page 5). We would like to comment that the overdue initial inspections were identified by the staff of the Radioactive Materials Unit and addressed during the review period, resulting in no initial inspections being overdue at the time of the IMPEP review.

### 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 (Section 3.1 of the 2006 IMPEP report).

## RESPONSE

Funding has since been secured and one of the vacant positions has been posted with the closing date for application September 10, 2010. The Radioactive Materials Clerk has been reassigned back to the RCP and has resumed her previous duties.

2. The review team recommends that the Commonwealth monitor and maintain accurate information in its database so it can be used by program management and staff as a reliable planning and tracking tool to ensure that inspections are completed within the required timeframe (Section 3.2).

## RESPONSE

The review team identified that during the period of time captured by the review team a total of 23 high priority inspections were conducted overdue by more than 25 percent of the inspection frequency prescribed by IMC 2800. The review team also identified 23 initial inspections that were conducted overdue. Overall, the review team calculated that the Program performed 19 percent of its Priority 1, 2, 3, and initial inspections overdue during the review period. This issue concerning completion of inspections within the prescribed frequency was identified by the Materials Unit staff and addressed during the review period, resulting in the statement by the review team that “no high priority inspections were overdue at the time of the review” and “no initial inspections were overdue at the time of the review.” To further address this recommendation the RCP has implemented policies and procedures to monitor and maintain our inspection program consistent with the inspection frequencies established by the Agency and compatible with those of IMC 2800. Examples include the posting of an Environmental Engineer III to fill one of the existing vacancies, establishing a process whereby the status of all inspections are reviewed on a weekly basis, ensuring that inspections are assigned at least 3 months before the due date, and changes within the database designed to verify correct data (such as next inspection due date) is entered.

Importantly, as discussed during the exit meeting Associate Commissioner Condon has re-assigned a senior manager from the Bureau to the RCP to assist with and facilitate these efforts. Her name is Beverly Anderson.

3. The review team recommends that the Commonwealth routinely perform accompaniments of each inspector, at least annually, to ensure quality and consistency in the inspection program (Section 3.3).

## RESPONSE

The RCP has established a database tool to schedule and track inspector accompaniments to ensure quality and consistency in the inspection program.

4. The review team recommends that the Commonwealth verify that licensees conducting operations under reciprocity have the proper security conditions on the license, as applicable (Section 3.4).

RESPONSE

The Supervisor of Materials Licensing and the Reciprocity Reviewer will check for Increased Controls conditions in the subject reciprocity applicant's license prior to conducting operations in Massachusetts. If the subject reciprocity licensee does not have such conditions listed on the license and clearly has maximum quantities listed on their license that are above IC limits, the reviewer will contact the licensee and the NRC Region 1 or the Agreement State Office to determine why there is no IC condition listed on the license. If the matter cannot be resolved, the applicant will not be allowed to conduct activities in Massachusetts.

We have already implemented this change to our review process for reciprocity applicants.

5. The review team recommends that the Commonwealth take necessary steps to ensure that all reportable events are submitted and updated to NRC in accordance with STP Procedure SA-300. (Section 3.5 of the 2002 IMPEP report)

RESPONSE

The staff will be reminded to initially report all reportable events in a timely fashion, and updated to NRC in accordance with STP Procedure SA-300. The Event Coordinator and the Materials Unit Supervisor will routinely monitor all open events to ensure timely reporting.

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

RESPONSE

The statement in paragraph four of Section 4.1.2 should have said that at the time of this review the four amendments had been promulgated and a hard copy was given to the IMPEP team with a promise to submit an electronic copy when available from the Secretary of State. The package that was submitted to NRC for review on April 9, 2010 contained both proposed and final regulations. The proposed sections are in red or crossed-out and final regulations as published are in black. Thus, the amendments in RATS ID 2006-1 ("Medical Use of Byproduct Material – Recognition of Specialty Boards") were published in 2006 and have been on the Program's web-page. The Program submitted them to NRC in 2006 but not in "Roadmap" format (a format that the Program was not familiar with).

All Materials Licenses issued by the Program have always had a condition which states "The licensee shall only transport radioactive material or deliver radioactive material to a carrier for

transport in accordance with the provisions of 49 CFR parts 170 through 189, 10 CFR Part 71, and 105 CMR 120.770 "Transportation of Radioactive Material." This is a legally binding condition and has been in use, with approval by NRC, from 1997 when the Commonwealth became an Agreement State. However, the Commonwealth has adopted regulations 105 CMR 120.770 for compatibility with 10 CFR Part 71, these regulations were revised and sent to NRC as proposed for review in July 2008. The revisions to 105 CMR 120.770 have been published as of 4/30/2010.

At each draft of regulations, effort is made to accommodate up and coming amendments.

7. The review team recommends that the Commonwealth reissue the certificate MA-0555-S-102-S to contain a table indicating radiation levels under maximum loading conditions. (Section 4.2.2).

#### RESPONSE

This certificate is a registration for a californium-252 neutron source. It is typical that quantities of such neutron sources are identified in terms of grams as well as curies or Bequerels. It is also typical that the dose rates for both the gamma and neutron components be listed in dose rate per unit mass, such as millirem per hour per microgram (mrem/hr- $\mu$ g). This provides the reviewer with a convenient and simple conversion for any neutron source mass.

The dose rate table in MA-0555-S-102-S is listed in this traditional manner for neutron sources. The maximum source activity and mass of Cf-252 are provided on the certificate, so it is just a matter of applying the conversion to both the gamma and neutron dose rate per unit mass to arrive at the maximum total dose rate. These values are calculated, which is also typical since neutron dose rates are difficult to measure.

However, it is agreed that this table could be misinterpreted for maximally loaded conditions if the license reviewer does not follow all of the text in the description. Therefore, another table will be added to MA-0555-S-102-S with maximum dose rates under maximally loaded conditions calculated.

8. The review team recommends that the Commonwealth make corrections to registration certificate MA-0166-D-102-B. (Section 4.2.2 of subsequent reports; incorrectly identified as MA-0116-102-B in the 2002 and 2006 reports).

#### RESPONSE

Certificate Number MA-0116-D-102-B is the correct designation for the certificate containing Model HUB-77A.

The new certificate containing the Model HUB-77A, MA-1287-D-103-B, was completed on July 23, 2010, and sent to the NRC for posting in the National Registry of Sealed Sources and Devices. A new certificate number was issued since the SSD vendor code changed in the interim for this licensee.

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

#### RESPONSE

As a first comment, Certificate Number MA-8154-D-803-B was issued on February 09, 2005, which is before this IMPEP review period.

Inactive Certificate Number MA-8154-D-803-B was issued on February 9, 2005 to correct a duplicate registration issue in the National Registry of Sealed Source and Devices. On June 24, 1993, Registration Number NR-0143-D-102-B was amended by the NRC to combine model series Lab-X 1000 and Lab-X 2000 into one certificate. At the same time Registration Number NR-0143-D-103-B, which originally listed only the Lab-X 1000 series, was not inactivated, superseded, or deleted from the Registry. In order to correct that circumstance we issued a formal inactivation for NR-0143-D-103-B (MA-8154-D-803-B) which contained the duplicate Lab-X 1000 series.

Since the information for the Lab-X1000 series was already listed in MA-8154-D-802-B with its own succession of amendments and conditions, we could not violate those actions by inactivating the Lab-X1000 series again via a separate and independent pathway. The only logical choice was to reference MA-8154-D-802-B on the inactive certificate MA-8154-D-803-B.

The “short form” agreement was initiated during a phase in the early 2000’s when QSA Global, Inc. was removing models from multiple sheets to incorporate into other active sheets. This rendered some certificates void of models, so the short form was created to reference the new location of the subject models on the abbreviated certificate being inactivated. An image of the original certificate was to be electronically attached to the abbreviated certificate since it was destined to be deleted from the Registry.

Instead of converting MA-8154-D-803-B into full text, we recommend that an image of NR-0143-D-103-B be electronically attached to MA-8154-D-803-B in the Registry. That will preserve the pedigree of the certificate. It will also not supersede the inactivation process already exercised in the creation of MA-8154-D-802-B which inactivated both the Lab-X1000 and Lab-X2000 series.

Other than the clear advantage of using the short form in this unique case, we will not use it under the original agreed circumstances again. If we initiate the removal and placement of models on other certificates that renders the original certificate void of models, we will inactivate the certificate with the information preserved. We will also provide the reference to the certificates where the models have been relocated.

It should be noted that no inactivations were performed using the short form since before the last IMPEP in June of 2006.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert A. Gallagher". The signature is written in a cursive style with a prominent initial "R" and a long horizontal stroke at the end.

Robert Gallagher, Acting Director