



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

February 24, 2010

Roland G. Fletcher, Manager
Radiological Health Program
Air & Radiation Management Administration
Maryland Department of the Environment
1800 Washington Blvd, Suite 750
Baltimore, MD 21230-1724

Dear Mr. Fletcher:

A periodic meeting with your Office was held on November 4, 2009. The purpose of the meeting was to review and discuss the status of the Maryland Department of the Environment's Agreement State program. The NRC was represented by Michelle Beardsley 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

AGREEMENT STATE PERIODIC MEETING SUMMARY FOR
MARYLAND DEPARTMENT OF THE ENVIRONMENT
AIR & RADIATION MANAGEMENT ADMINISTRATION
RADIOLOGICAL HEALTH PROGRAM

DATE OF MEETING: November 4, 2009

NRC Attendees	Maryland Radiological Health Program Attendees
Donna Janda, Region I RSAO	Roland Fletcher, Manager, Radiological Health Program
Michelle Beardsley, FSME	Raymond Manley, Chief, RAM Licensing & Compliance Division
	Alan Jacobson, Supervisor, RAM Inspection Section
	Barbara Park, Supervisor, RAM Licensing Section

DISCUSSION:

In August 2007, the Integrated Materials Performance Evaluation Program (IMPEP) review team found the Maryland Department of the Environment (MDE) Agreement State Program's (the Program) performance to be satisfactory for all performance indicators. No recommendations were made by the review team regarding the Program. On November 14, 2007, 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. Based on the results of the IMPEP review, the review team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately four years and that a periodic meeting be held in approximately two years from the date of the IMPEP.

This summary describes that periodic meeting.

Topics covered during the meeting included:

Program Strengths

A well-trained, stable, and experienced staff is a major strength of the Program. An additional strength was implementation of increased security requirements including Increased Controls inspections, fingerprinting, and the National Source Tracking System. The Program receives good management and administrative support. In addition, the Program staff routinely reviews IMPEP reports from other States to identify items for possible future use by the Maryland program. Since the most recent IMPEP, MDE implemented a department-wide enforcement program which allows for the collection of civil penalties. The Program staff believes this new policy will encourage licensees to be more accountable regarding program performance.

Program Weaknesses

The Program identified a potential weakness in their handling of bankruptcies involving materials licensees. The Program managers and licensing section developed a flowchart which provides direction on handling bankruptcies.

In addition, the Program staff identified a potential weakness in communicating issues involving a State of Maryland materials licensee to the NRC and other Agreement States. The Program Manager indicated that the State intends to share more detailed information on root cause analysis and generic implications when reporting future events involving this particular licensee. In addition the Program is working on entering event information for all Maryland materials licensees into NMED in a timelier manner.

Feedback on the NRC's Program

The Program staff commented that the overall relationship with the NRC is good. In particular, the Program noted that the NRC funding of training is appreciated.

The Program staff also discussed the challenges faced by NRC and Agreement States with implementation of the National Source Tracking System and future implementation of Web-Based Licensing.

The Program noted that dealing with the Tc-99m shortage and resulting exemption was a resource drain on the licensing staff due to the large number of licensing amendment requests to address.

Agreement State Program Staffing and Training

Since the August 2007 IMPEP, the Program hired two technical staff members, one each in the inspection and licensing areas, who are undergoing qualification training. The Program is now fully staffed with nine full-time staff members, including managers and one contractor. This staffing level does not include administrative support staff. The Program has one license reviewer in a contractor position which currently cannot be converted to a permanent State position due to budget constraints. The MDE recently performed a staffing analysis to determine adequacy of the Program's staffing level and determined that approximately 11 full-time equivalent (FTE) technical staff and five FTE program support staff are needed to effectively manage the radioactive materials program. This analysis has been submitted to senior MDE management for review.

Support for staff training exists in the Program. The Program staff welcomed the NRC's revised policy on funding training for Agreement States. Program staff members attend NRC and other training courses and seek alternate resources for training such as in-house and on-the-job training.

Organization

The Program is administered by the Radioactive Materials Licensing and Compliance Division, which consists of the Inspection Section and Licensing Section. The Division is headed by a full-time Division Chief. Each Section has three full-time technical staff and a Section Head.

Program Budget/Funding

The State has experienced a significant budget shortfall and implemented staff furloughs over the last two years. The Program Manager stated that the radioactive materials program, which is fee-based with occasional State funding, is adequately funded at this time. License fees have not been increased since 2004. A new fee package proposing a 70-75% fee increase is under management review.

Inspection/Licensing Programs

The Program has approximately 625 radioactive materials licenses. The Program's inspection frequencies are at least as frequent as NRC's. The Program has completed all 60 Priority 5 inspections which were overdue at the time of the August 2007 IMPEP. No inspections were overdue at the time of this meeting. The Program maintains a database to monitor inspection scheduling and tracking. Management is aware of the importance of inspection program schedules. The Program has completed the first round of Increased Controls (IC) inspections and continues to conduct IC inspections in conjunction with the routine safety inspection.

The Program maintains a database for tracking licensing actions and did not have a licensing backlog at the time of this meeting. The Program staff developed a procedure to handle license abandonments. The Program issues Notices of Violations to licensees who abandon their licenses. The Program staff noted that they have difficulty at times locating some of these licensees. The Program has been conducting pre-licensing site visits since 1996. The staff will not issue a license if the information gathered during the pre-licensing visit does not match the information provided in the license application.

Regulations

Since the August 2007 IMPEP, the State submitted ten final regulation packages and two legally binding requirements to NRC for a compatibility review to address the following amendments:

- "New Dosimetry Technology," 10 CFR Parts 34, 36, and 39 amendment (65 FR 63750), that was due for Agreement State implementation on January 8, 2004.
- "Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 16298), that was due for Agreement State implementation on April 5, 2005.
- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendment (67 FR 20249), that was due for Agreement State implementation on October 24, 2005.
- "Financial Assurance for Materials Licensees," 10 CFR Parts 30, 40, and 70 amendment (68 FR 57327), that was due for Agreement State implementation on December 3, 2006.
- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697), that was due for Agreement State implementation on October 1, 2007.

- “Security Requirements for Portable Gauges Containing Byproduct Material,” 10 CFR Part 30 amendment (70 FR 2001), that was due for Agreement State implementation on July 11, 2008.
- “Medical Use of Byproduct Material – Recognition of Specialty Boards,” 10 CFR Part 35 amendment (70 FR 16336 and 71 FR 1926), that was due for Agreement State implementation on April 29, 2005.
- “Minor Amendments,” 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendment (71 FR 15005), that was due for Agreement State implementation on March 27, 2009.
- “National Source Tracking System – Serialization Requirements,” 10 CFR Part 32 with reference to Part 20 Appendix E amendment (71 FR 65685), that was due for Agreement State implementation on February 6, 2007.
- “National Source Tracking System,” 10 CFR Part 20 amendment (71 FR 65685, 72 FR 59162), that was due for Agreement State implementation on January 31, 2009.
- “Medical Use of Byproduct Material – Minor Corrections and Clarifications,” 10 CFR Parts 32 and 35 amendment (72 FR 45147 and 72 FR 54207), that is due for Agreement State adoption by October 29, 2010.
- “Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material,” NRC Order EA-07-305 (72 FR 70901), that was due for Agreement State implementation by June 5, 2008.

The State will need to address the following NRC amendments in the future:

- “Requirements for Expanded Definition of Byproduct Material,” 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendment (72 FR 55864), that is due for Agreement State adoption by November 30, 2010.
- “Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements,” 10 CFR Parts 30, 31, 32, and 150 amendment (72 FR 58473), that is due for Agreement State adoption by December 17, 2010.
- “Occupational Dose Records, Labeling, Containers, and Total Effective Dose Equivalent,” 10 CFR Parts 19 and 20 amendment (72 FR 68043), that is due for Agreement State adoption by February 15, 2011.
- “Medical Use of Byproduct Material – Authorized User Clarification,” 10 CFR Part 35 (74 FR 33901), that is due for Agreement State adoption by September 28, 2012.

Event Reporting

The Program has reported 12 events to the NRC since the 2007 IMPEP review. Follow up and closure information for all events reported by the Program are included in the State's NMED entries.

Response to Incidents and Allegations

The Program continues to be sensitive to notifications of incidents and allegations. Incidents are quickly reviewed for the potential effect on public health and safety. Staff is dispatched to perform onsite investigations when necessary. No allegations were referred from NRC to the Program since the 2007 IMPEP review.

Significant Events and Generic Implications

The Program reported several significant events since the 2007 IMPEP review. One event involved a manufacturer with 14 incidents involving high dose rate remote (HDR) afterloader units at various locations across the nation. The State performed independent root cause analyses on the incidents to identify any generic implications. Another significant event involved an individual receiving an extremity overexposure during a teletherapy source exchange at a hospital in Brazil. The State provided valuable support to NRC on coordination of information exchange with Brazil and the International Atomic Energy Agency.

Sealed Source and Device Evaluation Program

Since the August 2007 IMPEP, the Program has issued one new SS&D certificate to an HDR manufacturer and one amendment.

Current State Initiatives

The Program staff discussed several initiatives, including State representation on the Southern States Energy Board; increasing knowledge of the National Source Tracking System; participation on NRC/OAS/CRCPD conference calls; and continued actions to address issues related to disposal of sources from a licensed manufacturing facility.

Emerging Technologies

Topics discussed included positron emission mammography and the use of portable gauges which do not contain radioactive material.

Large, Complicated, or Unusual Authorizations for Use of Radioactive Material

The Program staff has received inquiries from licensees regarding use of depleted uranium/yellowcake.

State's Mechanisms to Evaluate Performance

The State has created a tracking system to follow all escalated enforcement actions from beginning to end. In addition, all training, licensing, and inspection information is tracked on Program databases. Program managers review monthly reports on inspections, violations, and pre-licensing visits. Supervisors perform inspection accompaniments of all materials inspectors. The Program licensing staff meets once to twice per month to review the status of licensing actions. Evaluation plans for new personnel are reviewed every six months and updated as needed.

Current NRC Initiatives

NRC staff discussed ongoing initiatives with the Program staff. These included pre-licensing guidance, fingerprinting orders, national source tracking, web-based licensing, generally-licensed devices, working group prioritization activities, blending of low level radioactive waste, Part 37 rulemaking, safety culture, FSME management changes, and enhancements to the FSME website.

SUMMARY:

The Maryland radioactive materials program continues to be a strong, stable Agreement State program. The Program staff is experienced and well trained. The Program staff has experienced several mandatory furlough days in the past year due to State budget issues. With the increased focus on the safety and security of radioactive material, adequate program resources have become much more critical and the State is closely monitoring the need to increase staffing when necessary. In addition, the Program has drafted a new fee package which is currently under management review.

NRC staff recommends that the next IMPEP review should be conducted as scheduled in FY 2011 (tentatively August 2011).