



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION I  
2100 RENAISSANCE BLVD., SUITE 100  
KING OF PRUSSIA, PA 19406-2713

December 21, 2017

Eva Nair, Program Manager  
Radiological Health Program  
Air & Radiation Management Administration  
Maryland Department of the Environment  
1800 Washington Boulevard, Suite 750  
Baltimore, Maryland 21230

Dear Ms. Nair:

A periodic meeting with your staff was held on November 2, 2017. The purpose of this meeting was to review and discuss the status of the Maryland Agreement State Program. The U.S. Nuclear Regulatory Commission (NRC) was represented by James Trapp, Director, Division of Nuclear Materials Safety (DNMS), U.S. NRC Region I, Farrah Gaskins, Health Physicist, DNMS, U.S. NRC Region I, and me.

I have completed and enclosed a general meeting summary, including any specific actions resulting from the discussions. A Management Review Board (MRB) meeting to discuss the outcome of the periodic meeting will be scheduled for a future date. Once the date is known, call-in information for the MRB will be provided in a separate transmission.

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) 337-5214 or via e-mail at [Monica.Ford@nrc.gov](mailto:Monica.Ford@nrc.gov) to discuss your concerns.

Sincerely,

*/RA/*

Monica Lynn Ford  
Regional State Agreements Officer  
Division of Nuclear Materials Safety  
U.S. NRC Region I

Enclosure:  
Periodic Meeting Summary for Maryland

cc w/encl.: Alan Jacobson, Manager  
Radioactive Materials Division

December 21, 2017

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Radiological Health Program  
Air & Radiation Management Administration  
Maryland Department of the Environment  
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**SUNSI Review Complete: MLF (Reviewer's Initials)**

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AGREEMENT STATE PERIODIC MEETING SUMMARY FOR  
MARYLAND DEPARTMENT OF THE ENVIRONMENT  
RADIOLOGICAL HEALTH PROGRAM

DATE OF MEETING: November 2, 2017

<b>U.S. Nuclear Regulatory Commission (NRC) Attendees</b>	<b>Maryland Radiological Health Program Attendees</b>
James Trapp, Director, Division of Nuclear Materials Safety, Region I	Eva Nair, Program Manager, Radiological Health Program
Monica Ford, State Agreements Officer, Region I	Alan Jacobson, Program Manager, Radioactive Materials Division
Farrah Gaskins, Acting State Agreements Officer, Region I	Charles Cox, Supervisor, Licensing Section
	Alan Goldey, Supervisor, Inspection Section
	Angelo Bianca, Deputy Director, Air and Radiation Administration (exit only)
	Horacio Tablada, Deputy Secretary, Maryland Department of the Environment (exit only)

**DISCUSSION:**

An Integrated Materials Performance Evaluation Program (IMPEP) review of the Maryland Agreement State Program (the Program) was conducted on November 2-6, 2015. On January 21, 2016, the Management Review Board (MRB) found the State's performance satisfactory for all seven indicators reviewed. Two recommendations were made regarding Maryland's training and qualification program and implementation of a quality assurance program for licensing actions. Additionally, it was determined that the four recommendations from the 2011 IMPEP review should be closed. The Program was found adequate to protect public health and safety, and compatible with the NRC's program. The MRB directed that the next IMPEP review be held in approximately four years and that a periodic meeting be held in two years. This report is a summary of that periodic meeting.

**TOPICS COVERED DURING THE MEETING INCLUDED:**

**Feedback on the NRC's Program**

The Program noted that there is good communication with the NRC and that they have a good working relationship with Region I. The Program also noted that they have received good support from the NRC Headquarters staff while working to implement Web-Based Licensing (WBL). The Program stated that support from the NRC for training was crucial to the future of the National Materials Program and appreciates the training courses and opportunities provided by the NRC.

**Organization**

The Program is administered by the Radioactive Materials Licensing & Compliance Division, which is located within the Radiological Health Program. The Radiological Health Program is

Enclosure

located in the Air and Radiation Administration. There have been no changes to the Program's organization since the 2015 IMPEP review.

#### Program Budget/Funding

The Program is fully funded by fees which are placed into a dedicated account. The Program has the regulatory authority to increase fees every year, if needed, and can carry over fees from one year to the next.

#### Technical Staffing and Training (2015 IMPEP: Satisfactory)

The Program allocates eight technical staff, which includes the licensing and inspection supervisors and one contractual position, and one Division Manager to the radioactive materials program. This adds up to 9.0 full time equivalents (FTE) for the Program.

Since the 2015 IMPEP review the Program has had several staff changes. The Program Manager for the Radiological Health Program retired in March 2017. A new Program Manager was named later that same month. Additionally, the Program Manager for the Division of Radioactive Materials retired in October 2016. The Program filled this position temporarily by promoting the Inspection Section Supervisor and in May 2017, this temporary promotion became permanent. To fill the vacated Inspection Supervisor position, the Program temporarily promoted one of its lead inspection staff. This temporary promotion will become permanent in December 2017. The Program will then have a vacancy at the technical staff level in inspection. In addition, a technical staff inspector left the program after the last IMPEP review. The Program filled this position with the contractual employee from the licensing section. This created a contractual vacancy in the licensing section. These two vacancies existed at the time of the periodic meeting. An exception had been requested to hire a contractual employee for the licensing section. The Program also noted it plans to request an exception to fill the vacancy in the inspection section.

There are two inspection staff going through qualification. The Program stated that both inspectors should be fully qualified inspectors by the end of the year. The Program continues to track refresher training and staff are meeting the requirement of 24 hours of refresher training every two years. There was one recommendation made for this indicator during the 2015 IMPEP review.

**Recommendation:** The review team recommends that Maryland develop, update, and implement a training and qualification program that meets the essential elements of the NRC's Inspection Manual Chapter (IMC) 1248 to ensure that new staff are properly trained to license and inspect all Maryland radioactive material license types.

**Status:** The Program developed and, on February 23, 2016, subsequently implemented a training and qualification program that meets the essential elements of the NRC's IMC 1248. The Program has added self-study and a qualification card to track progress of the Licensing staff during the qualification process. The Program has also implemented the use of on-the-job training in the licensing qualification process. The Program noted that it takes at least two years for an inspector or a license reviewer to be qualified on all types of radioactive material.

### Status of Materials Inspection Program (2015 IMPEP: Satisfactory)

The Program reported that it has conducted 141 Priority 1, 2, and 3 inspections since the 2015 IMPEP review. Five of those inspections were completed overdue. The inspections ranged from four days to eight months beyond the +/- 25% window allowed by the inspection frequency. The Program has completed 29 initial inspections since the 2015 IMPEP review, none of which were completed overdue. Additionally the Program stated that no inspections, including initial inspections, were currently overdue. The Program conducted 7 reciprocity inspections out of 23 candidate licensees in calendar year 2015 (30%), 5 reciprocity inspections out of 25 candidate licensees in calendar year 2016 (20%), and at the time of the meeting, 3 reciprocity inspections out of 21 candidate licensees in calendar year 2017 (14%). The Program stated that they planned to conduct six additional reciprocity inspections before the end of calendar year 2017.

### Technical Quality of Inspections (2015 IMPEP: Satisfactory)

The Program has a general inspection procedure equivalent to the NRC's Manual Chapter 2800 and uses the NRC's Inspection Procedures for specific modalities. The Program uses a form similar to the NRC's form 591 "Safety and Compliance Inspection Report," called an "E-1", to issue clear inspection reports in the field. The inspection supervisor reviews all inspections reports to ensure completeness. Letters to licensees which communicate notice of violations are signed out by the division manager. The Program stated that they are meeting their goal of issuing inspection documentation within 30 days of the inspection.

The Program management accompanies all of its inspectors at least once each year. Additionally, the Division Manager also performs inspections and is accompanied by the Inspection Supervisor.

### Technical Quality of Licensing Actions (2015 IMPEP: Satisfactory)

The Program has approximately 550 specific licensees. The Program performs approximately 100 licensing actions per calendar quarter. At the time of the periodic meeting, the Program stated that there were no actions in-house greater than one year. All licensing actions receive a secondary review by the licensing supervisor to ensure technical quality. The staff has open discussions on licensing actions during bi-weekly staff meetings. License reviewers use the NRC's NUREG 1556 series as guidance when completing actions. The Program noted that they are discussing changing the renewal frequency for specific licenses from every 7 years to every 10 years.

During the 2015 IMPEP review, the review team noted that 163 of Maryland's licenses included a condition that licensed material may be used at temporary job sites throughout the State of Maryland without specifying that, for work at a federal facility, the jurisdictional status of the temporary job site must be determined by the licensee. The team determined that the license condition needed clarification. At the time of the IMPEP review, the Program committed to modifying the condition during the next amendment or renewal of the affected licenses. This item was discussed during the periodic meeting and the Program stated that all 163 licenses had been updated to correctly delineate jurisdiction. There was one recommendation made for this indicator during the 2015 IMPEP review.

**Recommendation:** The review team recommends that Maryland develop and implement a quality assurance program to ensure that licenses are reviewed for completeness and accuracy prior to issuance by the State. The quality assurance program may include, for example,

checklists, peer checks, independent reviews, periodic training, and/or other error prevention techniques.

**Status:** Maryland has developed and has begun implementing a quality assurance program for licensing actions. The Program noted that they completed a root cause analysis to understand previous deficiencies. The Program developed and implemented a checklist for common proofreading errors and templates for different types of licenses, and plans to reinstate peer checks for new licensing actions and renewals. The Program is working on developing a written procedure to incorporate these items.

#### Technical Quality of Incidents and Allegation Activities (2015 IMPEP: Satisfactory)

The Program reported 28 reportable and non-reportable events to the NRC since the 2015 IMPEP review. It was noted during the periodic meeting that the Program needs to ensure that once their investigations of reportable events are finished that it closes the item in the NRC's Nuclear Materials Events Database (NMED). Currently, the Division Manager is responsible for closing and completing events in NMED. The Program requested to be added to the list of states to receive NMED training in fiscal year 2018 so that more staff can share in the responsibility of completing and closing events in NMED. After the periodic meeting, this request was provided to the Office of Nuclear Material Safety and Safeguards who added Maryland to the list of states requesting to receive NMED training.

The Program received three allegations since the 2015 IMPEP review. One of the allegations was referred to the Program by the NRC. The Program noted that all allegations have been dispositioned and closed.

#### Compatibility Requirements (2015 IMPEP: Satisfactory)

Since the 2015 IMPEP review, there have been no changes to legislation that have impacted Maryland's program. The Program stated that it takes approximately nine months to adopt regulations once the process is started. At the time of the periodic meeting, the Program had no regulations overdue for adoption.

#### Sealed Source and Device (SS&D) Evaluation Program (2014 IMPEP: Satisfactory)

The Program has two qualified SS&D reviewers. There are three companies in the State that have active registrations. The Program has received three actions, one new registration and two inactivations, since the 2015 IMPEP review.

#### Current State Initiatives

The Program is currently working on implementing WBL. The date of full implementation has not yet been determined. Maryland has also developed checklists for specifically licensed X-ray fluorescence (XRF) analyzer renewals.

#### Emerging Technologies

The state issued an SS&D certificate of registration in January 2016 to Xcision for their "GammaPod." The GammaPod is a new a technology that will allow breast cancer patients to receive stereotactic radiotherapy by overcoming clinical and technical challenges that existed previously.

### Large, Complicated or Unusual Authorizations

Maryland discussed two such items. The first involves one of the Program's broad scope licensees who requested to use small quantities of enriched uranium for testing. The second is a licensee who is undergoing decommissioning and working with the Program to remove material from its possession. Since 2014, the licensee has been able to dispose of over 2000 radioactive sources amounting over 100,000 Curies of radioactive material.

### State's Mechanisms to Evaluate Performance

The Program performs formal self-assessments and audits.

### NRC Current Initiatives

NRC staff presented information on several initiatives ongoing at the NRC. These included:

- Issuance of the revised Inspection Manual Chapter 2800
- Ongoing revision to Management Directive 5.6 and the request for comments
- Clarification on financial assurance requirements for Germanium-68/ Gallium-68 generators and Agreement State Compatibility
- Clarification of changes to 10 CFR Part 71
- Changing licensing renewals from 10 to 15 years
- Implementation of the revised Risk Significant Radioactive Materials checklist and guidance

### CONCLUSIONS:

The Maryland Agreement State Program continues to be an effective, well maintained program. There were two vacancies at the time of the periodic meeting. The Program continues to address the two recommendations made during the 2015 IMPEP review. The Program is effectively managing its licensing and inspection activities and responds to incidents and allegations appropriately.

NRC staff recommends that the next IMPEP review be conducted as scheduled in November 2019.