



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I**  
2100 RENAISSANCE BOULEVARD, SUITE 100  
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

October 1, 2013

Roland G. Fletcher, Manager  
Radiological Health Program  
Air & Radiation Management Administration  
Maryland Department of the Environment  
1800 Washington Boulevard, Suite 750  
Baltimore, MD 21230-1718

Dear Mr. Fletcher:

A periodic meeting was held with you and your staff on August 28, 2013. 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 Daniel Collins, Duncan White, Sophie Holiday and me.

I have completed and enclosed a general meeting summary, including any specific actions that will be taken as a result of this 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 [Donna.Janda@nrc.gov](mailto:Donna.Janda@nrc.gov) to discuss your comments.

Sincerely,

***/RA M. L. Ford for/***

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

Enclosure: As stated

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Distribution:

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AGREEMENT STATE PERIODIC MEETING SUMMARY FOR MARYLAND  
DEPARTMENT OF THE ENVIRONMENT (MDE)

DATE OF MEETING: August 28, 2013

<b>NRC Attendees</b>	<b>Maryland Radiological Health Program (RHP)</b>
Donna Janda, RSAO, Region I	Roland, Fletcher, Manager, Radiological Health Program
Daniel Collins, Deputy Director, Division of Nuclear Materials Safety, Region I	Raymond Manley, Chief, Radioactive Materials Licensing & Compliance Division
Duncan White, Branch Chief, Agreement State Program Branch, FSME	Barbara, Park, Supervisor, Radioactive Materials Licensing Section
Sophie Holiday, Health Physicist, FSME	Alan Jacobson, Supervisor, Radioactive Materials Inspection Section

**DISCUSSION:**

During the 2011 Integrated Materials Performance Evaluation Program (IMPEP) review of the Maryland Agreement State Program (the Program), the review team found the State's performance satisfactory for six performance indicators: Technical Staffing and Training, Status of Materials Inspection Program, Technical Quality of Inspections, Technical Quality of Incidents and Allegations, Compatibility Requirements, and Sealed Source and Device Evaluation Program. The review team found the State's performance satisfactory, but needs improvement, for the performance indicator, Technical Quality of Licensing Actions. Four recommendations regarding Program performance were made by the IMPEP review team. On November 3, 2011, the Management Review Board (MRB) met to consider the proposed final IMPEP report on the Maryland Agreement State Program. The MRB found the Program adequate to protect public health and safety and compatible with NRC's program. The MRB directed that the next full IMPEP review take place in approximately four years.

The following is a status summary of the four recommendations that were identified in the 2011 Maryland final IMPEP report:

1. The review team recommended that the State take measures to ensure that sufficient information pertaining to the inspection review of items of non-compliance as well as the effectiveness of licensee corrective actions is adequately documented in inspection records.

Status: The Division Chief stated that inspectors have been trained and reminded to ensure that documentation of the effectiveness of licensee corrective actions is included in inspection records. Each inspection report is reviewed by the inspection supervisor to ensure the documentation is in the report. In addition, the Program is now documenting inspection reports in a manner similar to the reports in NRC Manual Chapter 2800, "Materials Inspection Program." Also, during the license

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renewal process, the license reviewer determines, from a review of the most recent inspection report, if the licensee's response to a Notice of Violation is adequate. The reviewer then takes action based on the adequacy of the licensee's response.

2. The review team recommended that the State perform a self-assessment of selected licensing actions issued during the review period, and on a routine basis in the future, to ensure that the Program's review of licensing actions are adequately documented and that licensing actions are thorough and consistent with the regulations and appropriate licensing guidance.

Status: According to the Division Chief, the Program has performed several activities to address this recommendation. Since September 2012, a total of 25 licensing actions were reviewed by the Program's licensing team during staff meetings. Overall, the reviewers confirmed that licensing practices were thorough and consistent with regulations and licensing guidance. In addition, after a review of financial assurance actions, the Program implemented changes to the review process for decommissioning funding plans and followed up with applicable licensees.

After the 2011 IMPEP review, the Program conducted an initial review of their licenses and determined, at that time, that no emergency plans were required. However, in subsequent follow up activities, the Program determined that the licensing process could be further strengthened for those licensees that have the inclusive possession condition of "any radioactive material between atomic numbers 3 and 83." The Program is having these licensees submit written documentation confirming their exemption from the requirement for an emergency plan as defined under COMAR 26.12.01.01 C.23(b).

Since the 2011 IMPEP review, the Program developed procedures and letters to address emergency plans for applicable licensees. In addition, the Program has changed the amendment review process for licensees who request to terminate their license. The Division Chief stated that the Program staff has carefully reviewed the efficacy and completeness of their licensing checklist and how license reviewers apply the checklist. The staff believes that discussions of the process were very helpful in ensuring consistency in the licensing process.

The Program has implemented an ongoing review of licensing actions. During each calendar quarter, all license reviewers and the Licensing Supervisor are each assigned a licensing action for quality review that was completed within the previous six months.

3. The review team recommended that the State: (1) take measures to ensure that financial assurance requirements are reviewed as part of significant licensing actions and during licensing renewals; (2) evaluate the need for financial assurance related to the radionuclide production (cyclotron) licensees; and (3) perform a review of the adequacy and validity of financial assurance mechanisms already on file with the Program.

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Status: The Division Chief stated that this issue was identified by the Program prior to the 2011 IMPEP review. Since the review, the Program reviewed all financial assurance instruments and conducted training for all staff. The Program loaded the financial assurance instruments into a database to maintain an ongoing record. The Program staff reviewed the licensing procedures to determine where the process could be strengthened in relation to financial assurance matters. The Program is in the process of developing a new procedure for addressing decommissioning funding plans and has now incorporated by reference most of NRC's regulations in their proposed regulations. In addition, the Program is working with the State of Maryland Attorney General's Office to have a Financial Advisor assist with the financial assurance review process in the future.

The Division Chief stated that the Program has addressed the comment in the IMPEP report regarding the financial assurance considerations associated with cyclotron activities at a broad scope licensee. The licensee now has financial assurance for their cyclotron activities. The Program also revised the license condition that was being used for financial assurance commitments to adequately reflect all factors associated with financial assurance obligations. Licenses with the new license condition were reissued to affected licensees.

4. The review team recommended that, for the 25 obsolete SS&D registrations identified in Appendix G, the Program take actions to submit the status of those registrations for inclusion in the national Sealed Source and Device Registry, to include transfer of each registration to inactive status as recommended in Section 13.4 of NUREG 1556, Volume 3, Revision 1, "Applications for Sealed Source and Device Evaluation and Registration," and to take measures to ensure that future registrations that become obsolete are inactivated in a timely manner.

Status: In addition to the 25 obsolete SS&D registrations identified during the 2011 IMPEP review, the Program identified an additional 8 obsolete SS&D registrations that needed to be addressed. Since the 2011 IMPEP review, the Program has inactivated all 33 sheets. In addition, the Program reviewed the licensing procedure and developed an inactivation checklist to capture all necessary information which would be needed to complete the inactivation process.

#### OTHER TOPICS COVERED DURING THE MEETING INCLUDED:

##### Program Strengths

The Program has an experienced and well-trained licensing and inspection staff which maintains operational efficiency in times of staff shortages. In addition, the Division Chief noted that a strength of the Program is having a Regulations Committee which meets at least once per month and has a dedicated staff member to ensure that the Program is current with their regulations.

##### Program Weaknesses

The Program identified the following challenges currently being faced by managers and staff: finding a mechanical engineer for SS&D reviews; getting work done when short staffed (using

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supervisors and licensing staff perform inspections in order to avoid overdue inspections); and knowledge management concerns with many supervisors approaching retirement.

#### Agreement State Program Staffing and Training

The Program staff currently consists of six full-time and two part-time technical staff members and three managers. Since the 2011 IMPEP review, the Program lost one inspector and hired one inspector and one license reviewer. Both new staff members are currently in the qualification process. There are currently no vacancies in the Program.

#### Organization

The Maryland Agreement State Program is administered by the Radiological Health Program under the Air and Radiation Management Administration of the Maryland Department of the Environment. There have been no reorganizations since the 2011 IMPEP review.

#### Program Budget/Funding

The Program is fully funded by licensing fees which are placed into a dedicated account. The Division Chief stated that approximately five years ago the Maryland legislature passed a rule that provided the legislature access to the dedicated fund. Funding for equipment purchases is provided through a U.S. Department of Energy Southern States Energy Grant.

#### Inspection and Licensing Programs

The Program's inspection frequencies are at least as frequent as NRC's. Since the 2011 IMPEP review, the Program began using a new database for all inspection data. The Program reported that 3 out of 120 routine inspections were completed overdue since the 2011 IMPEP review. No Priority 1, 2, or 3 inspections are currently overdue. Due to previous staffing shortages, the Program has a backlog of Priority 5 inspections. Now that the Program is fully staffed, the backlog is being addressed. In the past year, the Division Chief performed 9 inspections during times of staffing shortages. The Program is conducting security inspections at two-year frequencies with the exception of industrial radiography, which is performed at one-year intervals.

The Program currently has approximately 535 specific licenses. Maryland licensees are subject to a seven-year license renewal term. The Program will be promulgating regulations to require licensees to submit renewal applications seven months prior to the license expiration date. The Program has to meet certain metrics for their licensing actions, including a requirement for greater than 90 percent of the license amendments must be completed within 45 days of submission and license renewals must be completed within seven months of submission.

#### Regulations and Legislative Changes

There have not been any legislative changes or proposals that have affected the Program since the 2011 IMPEP review. The State has promulgated three supplements incorporating three amendments since the 2011 IMPEP review. The Program anticipates submitting three additional supplements, which will incorporate five amendments for promulgation by the end of calendar year 2014. The Program currently has no overdue regulations.

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The RHP Regulations Committee has placed the new 10 CFR Part 37 regulations on their agenda as an important upcoming item to be addressed. The Program managers noted that addressing new regulations is challenging at times and having the Regulations Committee and adopting some regulations by reference is very helpful.

#### Event Reporting

The Program has reported five radioactive materials events to the NRC since the 2011 IMPEP review. The Division Chief stated that three additional events were submitted to the NRC Nuclear Material Events Database (NMED) this week, including one event involving a leak in a pump in the main pool of a panoramic irradiator. This event did not require reporting to the NRC Operations Center. The Program continues to close out events in NMED as appropriate.

#### Response to Incidents and Allegations

The Program continues to be sensitive to notifications of incidents and allegations. Incidents are quickly reviewed for their effect on public health and safety. Staff is dispatched to perform onsite investigations when necessary. The Program is aware of the need to maintain an effective response to incidents and allegations. Since the 2011 IMPEP review, six allegations which were initially received by the NRC were transferred to the Program for follow up action.

#### Sealed Source and Device (SS&D) Evaluation Program

The Program currently has five active SS&D registration sheets, including one new sheet under review for a new medical device (GammaPod). The Program currently does not have a contract for an engineer to conduct the engineering review for this new device and is working with NRC to have the engineering portion of the device review completed by NRC.

At the time of this meeting, the State was still licensing the distribution of high dose rate remote afterloader devices for a manufacturer who had moved their operations to Georgia in 2012. The State of Maryland could not terminate the license until such time as the State of Georgia issued a new license to this manufacturer for distribution of these devices. Since the periodic meeting, the State of Georgia issued the new distribution license and the State of Maryland could move forward with terminating the distribution license held by Maryland.

#### Current State Initiatives

The Program managers noted that the MDE is in the process of changing their requirements for license renewal submissions. Once enacted, licensees will be required to submit renewal applications seven months prior to the license expiration date.

Each year the Air and Radiation Management Administration submits a list of priorities to the Governor. One of the priorities submitted this year was regarding a State of Maryland radioactive materials licensee who has been under court order for several years for numerous violations of Maryland regulations. The Program noted that there has been some progress with this licensee regarding waste shipments and security measures.

The Program staff provides support to the Preventive Radiological Nuclear Detection Program activities and participates in nuclear power plant exercises. The Program is currently changing

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certain general licenses to specific licenses. In addition, the Program is interested in using web-based licensing.

#### Emerging Technologies

The Program noted the following emerging technologies: the use of smartphones being implemented as a tool for materials inspectors; licensing of the new GammaPod medical treatment device; and moving toward a paperless system (reciprocity, inspection database).

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

The Program managers noted that they are currently licensing a new medical device which will be used for the treatment of breast cancer. The Program is reviewing service provider and manufacturing/distribution licenses for this device. In addition, the Program and NRC are reviewing the SS&D registration sheet for this new device.

#### State's Mechanisms to Evaluate Performance

The Program provides major inspection and licensing data on a monthly basis and enforcement data on a quarterly basis to MDEStat, which is a tool used by MDE for an annual report which is posted as a public record on the MDE website. The State of Maryland audits the Program every three years. Supervisors perform reviews of inspection reports and licensing actions. The inspection supervisor conducts supervisory accompaniments of inspectors on an annual basis. The Program inspection and licensing staffs hold one to two staff meetings per month.

#### CONCLUSIONS:

The State of Maryland Radiological Health Program has an experienced and well-trained staff which continues to address the recommendations that were made during the 2011 IMPEP review. The Program is experiencing some backlog in Priority 5 inspections but now that it is fully staffed, the Program is working off the backlog. NRC staff recommends that the next IMPEP review should be conducted as scheduled in FY 2015 (tentatively August 2015).