



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

February 18, 2016

Benjamin H. Grumbles, Secretary  
Maryland Department of the Environment  
1800 Washington Boulevard  
Baltimore, MD 21230

Dear Mr. Grumbles:

On January 21, 2016, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Maryland Agreement State Program. The MRB found the Maryland program adequate to protect public health and safety, and compatible with the U.S. Nuclear Regulatory Commission's program.

Section 5.0, page 16, of the enclosed final report contains a summary of the IMPEP team's findings. Based on the results of the current IMPEP review, the next full review of the Maryland Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled for November 2017.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

*/RA/*

Glenn M. Tracy,  
Deputy Executive Director for Materials, Waste,  
Research, State, Tribal, Compliance, Administration,  
and Human Capital Programs  
Office of the Executive Director for Operations

Enclosure:  
Maryland IMPEP Final Report

cc: See next page

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Department of Environment

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**ML16028A314**

**via email\***

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Letter to B. Grumbles from G. Tracy dated February 18, 2016

SUBJECT: Maryland FY2016 FINAL IMPEP REPORT

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM  
REVIEW OF THE MARYLAND AGREEMENT STATE PROGRAM

NOVEMBER 2-6, 2015

**FINAL REPORT**

Enclosure

## EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Maryland Agreement State Program. The review was conducted during the period of November 2-6, 2015, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Tennessee.

Based on the results of this review, Maryland's performance was found satisfactory for all seven performance indicators reviewed.

The review team made two recommendations (see Section 5.0) and determined that the four recommendations from the 2011 IMPEP review, regarding inspection review of licensee non-compliance and corrective actions, performing self-assessments of previous licensing actions, reviewing licensee financial assurance requirements and mechanisms, and inactivation of obsolete sealed source and device registrations are completed in a timely manner, should be closed (see Section 2.0).

Accordingly, the review team recommended, and the Management Review Board (MRB) agreed, that the Maryland Agreement State Program is adequate to protect public health and safety and is compatible with the NRC's program. The review team recommended, and the MRB agreed, that the next IMPEP review take place in approximately 4 years with a periodic meeting mid-cycle.

## 1.0 INTRODUCTION

This report presents the results of the IMPEP review of the Maryland Agreement State Program. The review was conducted during the period of November 2-6, 2015, by a review team composed of technical staff members from the NRC and the State of Tennessee. Review team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6 (MD 5.6), "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of August 13, 2011, to November 6, 2015, were discussed with Maryland's managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to Maryland on April 23, 2015. Maryland provided its response to the questionnaire on October 15, 2015. A copy of the questionnaire response can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) (Accession Number ML15341A223).

A draft of this report was issued to Maryland on December 7, 2015, for factual comment. Maryland responded to the findings and conclusions of the review by letter dated January 8, 2016. A copy of Maryland's response can be found in ADAMS (Accession Number ML16012A168), and the review team's resolution of comments using ML16014A108. The MRB met on January 21, 2016, to consider the proposed final report. The MRB found the Maryland Agreement State Program adequate to protect public health and safety, and compatible with the NRC's program.

The Maryland Agreement State Program is administered by the Radioactive Materials Licensing and Compliance Division (the Division) of the Radiological Health Program (the Program). The Radiological Health Program is located within the Air and Radiation Management Administration (the Administration) of the Department of the Environment (the Department). Organizational charts for Maryland can be found in ADAMS (Accession Number ML15299A193).

At the time of the review, the Maryland Agreement State Program regulated 539 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Maryland.

The review team evaluated the information gathered against the established criteria for each common and the applicable non-common performance indicator and made a preliminary assessment of the Maryland Agreement State Program's performance.

## 2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on August 12, 2011. The final report is available in ADAMS (Accession Number ML113180028). The results of the previous review and the status of the 2011 recommendations are as follows:

Technical Staffing and Training: Satisfactory  
Recommendation: None

Status of Materials Inspection Program: Satisfactory  
Recommendation: None

Technical Quality of Inspections: Satisfactory

Recommendation: The review team recommends 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 (Section 3.3 of the 2011 IMPEP report).

Status: The review team identified four inspection casework files which contained documentation related to items of non-compliance, including the notice of violation issued by the Program; the licensee's response to the notice of violation, including the licensee's corrective actions to address the violation(s); the Program's acknowledgement of the licensee's response; and the documentation in the Program's inspection report closing out the violation. Based on a review of these files, the review team determined that Maryland is adequately documenting the inspection review of items of non-compliance and the effectiveness of licensee corrective actions. The review team recommended, and the MRB agreed, that this recommendation be closed.

Technical Quality of Licensing Actions: Satisfactory but Needs Improvement

Recommendation: The review team recommends that Maryland 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 (Section 3.4 of the 2011 IMPEP report).

Status: Maryland reviewed 37 licensing actions and found 25 of 37 licensing actions to be acceptable. Twelve licensing actions were found deficient and needed a deficiency letter, an amendment, a corrected copy of the license, or a re-evaluation of a renewal action. Of the 12 deficient licensing actions 4 were completed by a former license reviewer and 8 were completed by one of the current license reviewers. Maryland has corrected all 12 of the deficient licensing actions. The current licensing supervisor started with Maryland in March 2015 and has performed a root cause evaluation of these deficient licensing actions from the self-assessments. The supervisor identified the improper use of checklists and the carryover of errors from one licensing action to the next as the root causes. Maryland will continue to perform self-assessments of completed licensing actions. The review team recommended, and the MRB agreed, that

this recommendation be closed. The review and MRB note that this recommendation called for a retrospective review of issued licensing actions. The MRB determined that Maryland met the intent of the recommendation. However, to assure quality before a licensing action is issued, the MRB supported a new recommendation for a quality assurance program that reviews licensing actions before they are issued (Section 3.4.c.).

Recommendation: The review team recommends that the State: (1) take measures to ensure that the financial assurance requirements are reviewed as part of significant license actions and during renewals; (2) evaluate the need for financial assurance related to radionuclide production (cyclotron) licensees; and (3) perform a review of the adequacy and validity of financial assurance mechanisms on file with the program (Section 3.4 of the 2011 IMPEP report).

Status: Maryland has a procedure in place that follows NUREG-1757 Volume 3, Revision 1 "Consolidated NMSS Decommissioning Guidance – Financial Assurance, Recordkeeping, and Timeliness." License reviews included an evaluation for the need for financial assurance. Maryland currently has 25 licensees that require financial assurance. The financial assurance mechanisms for these actions are properly organized in a locked cabinet. Maryland maintains an up-to-date financial assurance database of these licensees. In terms of the 2011 IMPEP, one of the two cyclotron licenses has a limiting condition for financial assurance and the other cyclotron licensee provided its revised decommissioning funding plan and a new financial assurance mechanism on November 16, 2015, subsequent to the onsite review. The review team recommended, and the MRB agreed, that this recommendation be closed.

Technical Quality of Incident and Allegation Activities: Satisfactory  
Recommendation: None

Compatibility Requirements: Satisfactory  
Recommendation: None

Sealed Source and Device Evaluation Program: Satisfactory

Recommendation: The review team recommends that, for the 25 obsolete Sealed Source and Device (SS&D) registrations identified in Appendix G, the Program take actions to submit the status of those registrations for inclusion in the National SSD 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 (Section 4.2.2 of the 2011 IMPEP report).

Status: The Program inactivated the 25 obsolete SS&D registrations identified in Appendix G of the 2011 IMPEP report. All of the issues raised during the last IMPEP review have been adequately resolved. The review team recommended, and the MRB agreed, that this recommendation be closed.

Overall finding: Adequate and Compatible

### 3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the NRC regional and Agreement State radioactive materials programs. These indicators are (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

#### 3.1 Technical Staffing and Training

The ability to conduct effective licensing and inspection programs is largely dependent on having a sufficient number of experienced, knowledgeable, well-trained technical personnel. Under certain conditions, staff turnover could have an adverse effect on the implementation of these programs, and thus could affect public health and safety. Apparent trends in staffing must be explored. Review of staffing also requires a consideration and evaluation of the levels of training and qualification. The evaluation standard measures the overall quality of training available to, and taken by, materials program personnel.

##### a. Scope

The review team used the guidance in State Agreements procedure SA-103, "Reviewing the Common Performance Indicator: Technical Staffing and Training," and evaluated Maryland's performance with respect to the following performance indicator objectives:

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Agreement State training and qualification program is equivalent to NRC's Inspection Manual Chapter (IMC) 1248, "Formal Qualifications Program for Federal and State Materials and Environmental Management Programs."
- Qualification criteria for new technical staff are established and are being followed or that qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing of the licensing and inspection programs.
- Management is committed to training and staff qualification.
- Individuals performing materials licensing and inspection activities are adequately qualified and trained to perform their duties.
- License reviewers and inspectors are trained and qualified in a reasonable period of time.

##### b. Discussion

The Maryland Agreement State Program is composed of 6 technical staff members (3 each in the licensing and inspection sections), 2 supervisors, 1 administrative staff person, and 1 manager which equals 10 full-time equivalents for the radioactive materials program, including vacancies. Currently, there are two vacancies, one each in

the licensing and inspection sections. At the time of the review, these positions were vacant for 7 and 8 months, respectively, and Maryland had just begun the interview process for the vacant inspector position. The licensing position was on hold pending the outcome of an internal human resource audit. During the review period, four staff members (two inspectors, one license reviewer, and the licensing supervisor) left the program. One license reviewer position was vacant at the beginning of the review period. That position was vacant for approximately 17 months until it was filled in February 2012. Excluding the current vacancies, the other vacant positions during the review period were vacant from 8 to 9 months before they were filled. During the review period, Maryland hired one inspector, one license reviewer, and the licensing supervisor.

Maryland's training and qualification program is not compatible with the NRC's IMC 1248. Maryland should have adopted the essential elements of IMC 1248 within 6 months after it was published on April 19, 2013. The IMC 1248 describes the activities and training that license reviewers and inspectors must complete to become fully qualified to perform the duties of the job. The IMC 1248 identifies formal training classes, including required and specialized training, individual study activities, and on-the-job training activities. The IMC 1248 also added specific refresher training requirements for qualified staff to maintain qualifications. The Program's current staff is fully qualified, however, new staff hired by the Maryland Program must complete a qualification program that is compatible with IMC 1248.

c. Evaluation

The review team determined that during the review period the Maryland program met most of performance indicator objectives listed in Section 3.1.a. However, vacancies were not always filled in a timely manner, and the Program's training and qualification manuals were not compatible with IMC 1248.

The review team was concerned about the length of time that vacancies were open and the extended period of time that the Program has been operating with reduced staffing levels. During the review period, the Program lost an experienced fully-qualified inspector to a position outside of State government, and an experienced fully-qualified license reviewer and the licensing supervisor retired from State government. The Program currently has two positions that have been vacant for over 7 months. Additionally, the licensing supervisor position was vacant for approximately 9 months during the review period. These vacancies and operating with less than a full staff for a significant portion of the review period have impacted the Program's ability to complete licensing actions and inspections in a timely manner.

The workload generated from the licensing and inspection activities associated with 539 licensees, in addition to unplanned incident response and allegation activities, is significant, even at full staffing levels. However, at reduced staffing levels, the review team noted the following impacts to Maryland's administration of the licensing and inspection programs.

In the licensing program, there are currently more licensing actions open and for a longer period of time than during the same period in 2014. Also, the average time to complete a licensing action has increased from 176 days to 206 days in that same period of time.

In the inspection program, Maryland's management made a decision to postpone inspections of lower risk significant activities (e.g., nuclear gauge inspections) to focus the Program's available inspection resources on completing initial inspections of new licensees and higher risk significant priority 1, 2, and 3 licensees, at the required frequency. As documented in Section 3.2 of this report, the Program has an overdue rate of 5 percent for priority 1, 2, 3, and initial inspections. The review team determined that, while 5 percent overdue is still satisfactory, when compared to the 2011 IMPEP overdue rate of 1 percent, there is a declining trend in performing inspections for higher risk significant activities on time.

Maryland has separate training and qualification programs for inspectors and license reviewers, which did not contain the essential elements of IMC 1248. Maryland's inspector qualification program incorporated significantly more of the essential elements than the license reviewer qualification program. In September 2015, both the inspector and license reviewer qualification programs adopted the new refresher training requirements for qualified staff. However, neither program has completely adopted the required and specialized training, individual study activities, or on-the-job training to be considered compatible with IMC 1248. Although, there have not been any new inspectors or license reviewers participating in the qualification program since IMC 1248 was published in April 2013, Maryland is set to hire new staff that will start the training and qualification program. Therefore, the review team recommended, and the MRB agreed, that Maryland develop, update, and implement a training and qualification program that meets the essential elements of IMC 1248 to ensure that new staff are properly trained to license and inspect all Maryland radioactive material license types.

d. Results

The review team strongly considered recommending a Satisfactory but Needs Improvement rating for this indicator because of Maryland's delay in addressing the staffing vacancies. However, the current staff is fully qualified, and the Program's managers addressed resource shortfalls during the review period without sacrificing the technical quality of licensing, inspection, and incident response activities. Therefore, the review team concluded that Maryland demonstrated satisfactory performance during the review period.

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Maryland's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

3.2 Status of the Materials Inspection Program

Periodic inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good

safety practices. The frequency of inspections is specified in NRC IMC 2800 “Materials Inspection Program” dated November 15, 2010, and is dependent on the amount and kind of material, the type of operation licensed, and the results of previous inspections. There must be a capability for maintaining and retrieving statistical data on the status of the inspection program.

a. Scope

The review team used the guidance in State Agreements procedure SA-101, “Reviewing the Common Performance Indicator: Status of the Materials Inspection Program,” and evaluated Maryland’s performance with respect to the following performance indicator objectives:

- Initial inspections and inspections of Priority 1, 2, and 3, licensees are performed at the frequency prescribed in IMC 2800.
- Candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 1220, “Processing of NRC Form 241, Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters, and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20.”
- Deviations from inspection schedules are normally coordinated between technical staff and management.
- There is a plan to perform any overdue inspections and reschedule any missed or deferred inspections; or a basis has been established for not performing any overdue inspections or rescheduling any missed or deferred inspections.
- Inspection findings are communicated to licensees in a timely manner (30 calendar days, or 45 days for a team inspection, as specified in IMC 0610, “Nuclear Material Safety and Safeguards Inspection Reports”).

b. Discussion

Maryland conducted 302 priority 1, 2, and 3, and initial inspections during the review period. Five percent of those inspections (1 initial inspection and 14 priority 1, 2, or 3 inspections) were conducted overdue. A satisfactory performance rating is warranted when less than 10 percent of inspections are conducted overdue.

c. Evaluation

The review team determined that during the review period Maryland met the performance indicator objectives listed in Section 3.2.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Maryland’s performance with respect to the indicator, Status of the Materials Inspection Program, be found satisfactory.

### 3.3 Technical Quality of Inspections

Inspections, both routine and reactive, provide assurance that licensee activities are carried out in a safe and secure manner. Accompaniments of inspectors performing inspections, and the critical evaluation of inspection records are used to assess the technical quality of a program's inspection capability.

#### a. Scope

The review team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated Maryland's performance with respect to the following performance indicator objectives:

- Inspections of licensed activities focus on health, safety, and security.
- Inspection findings are well-founded and properly documented in reports.
- Management promptly reviews inspection results.
- Procedures are in place and used to help identify root causes and poor licensee performance.
- Inspections address previously identified open items and violations.
- Inspection findings lead to appropriate and prompt regulatory action.
- Supervisors conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.
- For programs with separate licensing and inspection staffs, to verify that procedures are established and followed to provide feedback information to license reviewers.
- For Agreement States, to determine if inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

#### b. Discussion

The review team evaluated the inspection reports, enforcement documentation, and interviewed inspectors for 25 materials inspections conducted during the review period. The casework reviewed included inspections conducted by six (current and former) of Maryland's inspectors and covered medical, industrial, commercial, academic, research, and service provider licenses.

Review team members accompanied four program inspectors during September and October 2015. The inspector accompaniments are identified in Appendix B.

#### c. Evaluation

The review team determined that during the review period Maryland met the performance indicator objectives listed in Section 3.3.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Maryland's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, and security. An assessment of licensing procedures, actual implementation of these procedures, and documentation of communications and associated actions between the Maryland licensing staff and the regulated community will be a significant indicator of the overall quality of the program.

a. Scope

The review team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated Maryland's performance with respect to the following performance indicator objectives:

- Licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Essential elements of license applications have been submitted and elements meet current regulatory guidance (e.g., financial assurance, increased controls, pre-licensing guidance).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and are inspectable.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Applicable guidance documents are available to reviewers and are followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).
- Licensing practices for risk significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled and secured.

b. Discussion

During the review period, Maryland performed 1,754 radioactive material licensing actions. Maryland receives over 400 licensing actions each year and currently has 539 active specific licenses. The review team evaluated 25 radioactive material licensing actions, which included casework for one former license reviewer, two current license reviewers, and the current licensing supervisor. The licensing actions selected included

1 new application, 14 amendments, 4 renewals, 2 terminations, 1 bankruptcy, and 3 financial assurance actions. The review team evaluated casework for several license types and actions: broad-scope, medical diagnostic and therapy, cyclotron, manufacturer and distributor, industrial radiography, research and development, academic, nuclear pharmacy, portable and fixed gauges, panoramic irradiators, service providers, and waste brokers.

License reviewers and the licensing supervisor perform license reviews following the guidance in the NRC's NUREG-1556 series, "Consolidated Guidance About Materials Licenses." All licenses are signed by the program manager. Licenses are issued for a 7-year period under a timely renewal system.

c. Evaluation

The review team determined that during the review period Maryland met the performance indicator objectives listed in Section 3.4.a.

Since the last IMPEP review, Maryland has improved the technical quality of its licensing actions. License reviewers use the NUREG-1556 series as a guide for completing all licensing actions, perform self-assessments on completed licensing actions, review licenses for financial assurance, and ensure that financial assurance documents are organized and secured in a locked location.

The review team determined that licensing actions were generally thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed. The review team identified missing license components in 7 of the 25 licensing case files reviewed, which were subsequently corrected by the Program. Two licenses were missing both the maximum possession limits for some radionuclides and the standard license condition for transportation. Two additional licenses were missing the maximum possession limits for some radionuclides. One additional license was missing the standard license condition for transportation. One license was missing the standard license condition for incineration of radioactive waste. One license listed a Radiation Safety Officer on a broad-scope license, but the file was missing documentation of the individual's radioactive material training and experience.

In addition, 163 of Maryland's 539 licenses included a license 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. Although Maryland's regulations in Part A Section A-1 of the Annotated Code of Maryland, Environmental Article, differentiates between NRC jurisdiction and Maryland jurisdiction, the review team determined that the license condition needed clarification. The review team shared a license condition with Maryland that would provide clarity on the jurisdictional status at temporary job sites. Maryland plans to modify the temporary job site license condition at the next amendment or renewal of the license.

Because of the above findings identified by the review team in some of the case files, the review team recommended, and the MRB agreed, 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.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Maryland's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

The quality, thoroughness, and timeliness of response to incidents and allegations of safety concerns can have a direct bearing on public health and safety. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal and external coordination, and investigative and follow-up procedures and actions will be a significant indicator of the overall quality of the program.

a. Scope

The review team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated Maryland's performance with respect to the following performance indicator objectives:

- Incident response, investigation, and allegation procedures are in place and followed.
- Response actions are appropriate, well-coordinated, and timely.
- On-site responses are performed when incidents have potential health, safety or security significance.
- Appropriate follow-up actions are taken to ensure prompt compliance by licensees.
- Follow-up inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the Nuclear Material Events Database.
- Allegations are investigated in a prompt, appropriate manner.
- Concerned individuals are notified of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

During the review period, 43 incidents were reported to Maryland. The review team evaluated 14 radioactive materials incidents which included 5 lost/stolen/abandoned radioactive materials, 2 potential overexposures, 3 medical events, 3 damaged

equipment, and 1 leaking sources. Maryland dispatched inspectors for onsite follow-up for 12 of the cases reviewed.

During the review period, 13 allegations were received by Maryland. The review team evaluated 11 allegations, including 8 allegations that the NRC referred to the State, during the review period.

c. Evaluation

The review team determined that during the review period Maryland met the performance indicator objectives listed in Section 3.5.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Maryland's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

#### 4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. The NRC's Agreement with Maryland does not relinquish regulatory authority for a uranium recovery program; therefore, only three non-common performance indicators applied to this review.

##### 4.1 Compatibility Requirements

State statutes should authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health, safety, and security. The State must be authorized through its legal authority to license, inspect, and enforce legally binding requirements, such as regulations and licenses. NRC regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted in a time frame so that the effective date of the State requirement is not later than 3 years after the effective date of NRC's final rule. Other program elements, as defined in Appendix A of State Agreements procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements," that have been designated as necessary for maintenance of an adequate and compatible program should be adopted and implemented by an Agreement State within 6 months following NRC designation.

a. Scope

The review team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," and evaluated

Maryland's performance with respect to the following performance indicator objectives. A complete list of regulation amendments can be found on the NRC Web site at the following address: [https://scp.nrc.gov/rss\\_regamendents.html](https://scp.nrc.gov/rss_regamendents.html).

- The Agreement State program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of radioactive materials under the Atomic Energy Act, as amended.
- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were adopted no later than 3 years after the effective date of the NRC regulation.
- Other program elements, as defined in SA-200 that have been designated as necessary for maintenance of an adequate and compatible program have been adopted and implemented within 6 months of NRC designation.
- The State statutes authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement.
- The State is authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses.
- Impact of sunset requirements, if any, on the State's regulations.

b. Discussion

Maryland became an Agreement State on January 1, 1971. The Maryland Agreement State Program's current effective statutory authority is contained in the Annotated Code of Maryland, Environmental Article, Title 8, "Radiation," and Title 7, "Hazardous Materials and Hazardous Substances." The Department is designated as the State's radiation control agency. Maryland's statutory authority is sufficiently broad for the regulation of byproduct, source, special nuclear materials, and other radioactive materials. Seven supplements of State regulations affecting the radiation control program were passed during the review period.

Maryland's administrative rulemaking process takes approximately 7 months from drafting to finalizing a rule. The public, the NRC, other agencies, and potentially impacted licensees and registrants are offered an opportunity to comment during the process. Comments are considered and incorporated, as appropriate, before the regulations are finalized and approved by the Secretary of the Environment. The review team noted that the State's rules and regulations are not subject to "sunset" laws.

During the review period, Maryland submitted 11 final regulation amendments and 4 proposed regulation amendments to the NRC for a compatibility review.

c. Evaluation

The review team determined that during the review period Maryland met the performance indicator objectives listed in Section 3.4.1.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Maryland's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

4.2 SS&D Evaluation Program

Adequate technical evaluations of SS&D designs are essential to ensure that SS&D's will maintain their integrity and that the design is adequate to protect public health and safety. NUREG-1556, Volume 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," provides information on conducting SS&D reviews and establishes useful guidance for review teams. Three sub elements; technical staffing and training, technical quality of the product evaluation program, and evaluation of defects and incidents regarding SS&D's, will be evaluated to determine if the SS&D program is satisfactory. Agreement States with authority for SS&D evaluation programs who are not performing SS&D reviews are required to commit in writing to having an SS&D evaluation program in place before performing evaluations.

a. Scope

The review team used the guidance in State Agreements procedure SA-108, "Reviewing the Non-Common Performance Indicator: Sealed Source and Device Evaluation Program," and evaluated Maryland's performance with respect to the following performance indicator objectives:

Technical Staffing and Training

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Qualification criteria for new technical staff are established and are being followed or that qualification criteria will be established if new staff members are hired.
- Any vacancies are filled in a timely manner.
- Management is committed to training and staff qualification.
- Individuals performing SS&D evaluation activities are adequately qualified and trained to perform their duties.
- SS&D reviewers are trained and qualified in a reasonable period of time.

Technical Quality of the Product Evaluation Program

- SS&D evaluations are adequate, accurate, complete, clear, specific, and consistent with NUREG 1556, Volume 3.

### Evaluation of Defects and Incidents

- SS&D incidents are reviewed to detect possible manufacturing defects and the root causes of these incidents.
- Incidents are evaluated to determine if other products may be affected by similar problems. Appropriate action and notifications to the NRC, Agreement States, and others, as appropriate, should occur in a timely manner.

#### b. Discussion

##### Technical Staffing and Training

At the time of the review, Maryland had three staff members qualified to perform SS&D reviews. The program plans to train another staff member to be fully qualified to perform SS&D evaluations, and hire another person who may be trained to perform SS&D evaluations. During the review period two SS&D staff members left the program and one staff member was hired. The team noted that the license reviewer position, which would also be one of the SS&D reviewer positions, has been vacant since April 1, 2015. Maryland has a training program equivalent to NRC training requirements listed in IMC 1248, Appendix D.

##### Technical Quality of the Product Evaluation

Maryland has five SS&D licensees. The review team evaluated 23 of 49 SS&D actions processed during the review period. These actions included a new evaluation and 48 inactivations.

##### Evaluation of Defects and Incidents Regarding SS&D's

No incidents involving SS&D registered products were reported to the Program during the review period. Consequently, the review team did not evaluate incidents related to the SS&D program. The review team confirmed that procedures are in place should an SS&D-related incident occur. The Program is aware of the need to review such incidents as potentially generic in nature with possible wide-ranging effects.

#### c. Evaluation

The review team determined that during the review period Maryland met the performance indicator objectives listed in Section 4.2.a.

#### d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Maryland's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

#### 4.3 Low Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement," to allow a State to seek an amendment for the regulation of LLRW. Although Maryland has the authority to regulate LLRW, there are no plans for a commercial LLRW disposal facility in Maryland. Accordingly, the review team did not review this indicator.

#### 5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Maryland's performance was found satisfactory for all seven performance indicators reviewed. The review team made two recommendations regarding the performance of the State and determined that the four recommendations from the 2011 IMPEP review should be closed.

Accordingly, the review team recommended, and the MRB agreed, that the Maryland Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. Based on the results of the current IMPEP review, the review team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately 4 years with a periodic meeting mid-cycle.

Below are the review team's recommendations, as mentioned in the report, for evaluation and implementation by Maryland:

1. The review team recommends that Maryland develop, update, and implement a training and qualification program that meets the essential elements of IMC 1248 to ensure that new staff are properly trained to license and inspect all Maryland radioactive material license types.
2. 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.

## LIST OF APPENDICES

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| Appendix B | Inspection Accompaniments |

## APPENDIX A

### IMPEP REVIEW TEAM MEMBERS

| <b>Name</b>                | <b>Area of Responsibility</b>  |
|----------------------------|--|
| Binesh Tharakan, Region IV | Team Leader<br>Technical Staffing and Training   |
| Steve Seeger, Tennessee    | Status of Materials Inspections  |
| Donna Janda, Region I      | Technical Quality of Inspections<br>Inspector Accompaniments                           |
| Kathy Modes, NMSS          | Technical Quality of Licensing Actions   |
| Latischa Hanson, Region IV | Technical Quality of Incident and<br>Allegation Activities<br>Inspector Accompaniments |
| Stephen Poy, NMSS          | Compatibility Requirements<br>Sealed Source and Device Evaluation Program              |

## APPENDIX B

### INSPECTION ACCOMPANIMENTS

The following inspection accompaniments were performed prior to the on-site IMPEP review:

|   |                        |
|---|------------------------|
| Accompaniment No.: 1                            | License No.: 05-002-04 |
| License Type: High Dose Rate Remote Afterloader | Priority: 2            |
| Inspection Date: 09/22/15                       | Inspector: RM          |

|   |                        |
|---|------------------------|
| Accompaniment No.: 2  | License No.: 03-001-03 |
| License Type: Medical Institution, Written Directive Required | Priority: 3            |
| Inspection Date: 09/29/15                                     | Inspector: KB          |

|  |                        |
|--|------------------------|
| Accompaniment No.: 3                   | License No.: 27-014-01 |
| License Type: Self-Shielded Irradiator | Priority: 5            |
| Inspection Date: 09/30/15              | Inspector: AJ          |

|                                      |                        |
|--------------------------------------|------------------------|
| Accompaniment No.: 4                 | License No.: 25-022-01 |
| License Type: Industrial Radiography | Priority: 1            |
| Inspection Date: 10/29/15            | Inspector: AG          |