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

August 26, 2021

Horacio A. Tablada, Deputy Secretary
Maryland Department of the Environment
1800 Washington Boulevard
Baltimore, MD 21230

Dear Mr. Tablada:

The U.S. Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the review of Agreement State and NRC radiation control programs. Enclosed is the draft IMPEP report, which documents the results of the Maryland Agreement State review conducted remotely on July 12-16, 2021. This review was conducted remotely due to travel restrictions associated with the COVID-19 Public Health Emergency. In-person inspector accompaniments were conducted March 10-11, 2020, and May 5-6, 2021. The team's preliminary findings were discussed with you and your staff on the last day of the review. The team is recommending satisfactory for six of the seven performance indicators and satisfactory but needs improvement for Technical Quality of Licensing Actions performance indicator. The team's proposed recommendations are that the Maryland Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program.

The NRC conducts periodic reviews of radiation control programs to ensure that public health and safety are adequately protected from the potential hazards associated with the use of radioactive materials and that Agreement State programs are compatible with the NRC's program. The IMPEP process uses a team comprised of Agreement State and NRC staff to perform the reviews. All reviews use common criteria in the assessment and place primary emphasis on performance. The final determination of adequacy and compatibility of each program, based on the team's report, is made by the Chair of the Management Review Board (MRB) after receiving input from the MRB members. The MRB is composed of NRC senior managers and an Agreement State program manager.

In accordance with procedures for implementation of IMPEP, we are providing you with a copy of the draft report for your review and comment prior to submitting the report to the MRB. Comments are requested within 4 weeks from your receipt of this letter. This schedule will permit the issuance of the final report in a timely manner.

The team will review the response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. The MRB meeting is currently scheduled to be conducted remotely on October 19, 2021, at 1:00 p.m. ET via Microsoft Teams. The NRC will provide you with Microsoft Teams connection information prior to the meeting.

If you have any questions regarding the enclosed report, please contact Kathy Modes at (215) 872-5804 or Kathy.Modes@nrc.gov.

Thank you for your cooperation.

Sincerely,

Signed by Anderson, Brian
on 08/26/21

Brian C. Anderson, Chief
State Agreement and Liaison Programs Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety and Safeguards

Enclosure:
2021 Maryland Draft IMPEP Report

cc: Eva Nair, Program Manager IV
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SUBJECT: LETTER TO H. TABLADA RE: DRAFT 2021 MARYLAND IMPEP REPORT
DATE August 26, 2021

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE MARYLAND AGREEMENT STATE PROGRAM

July 12 - 16, 2021

DRAFT REPORT

Enclosure

EXECUTIVE SUMMARY

The results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Maryland Agreement State Program (Maryland) are discussed in this report. The review was conducted remotely from July 12-16, 2021, due to travel restrictions associated with the COVID-19 Public Health Emergency (PHE). In-person inspector accompaniments were conducted March 10-11, 2020, and May 5-6, 2021.

The team found Maryland's performance to be satisfactory for the following six performance indicators:

- Technical Staffing and Training;
- Status of Materials Inspection Program;
- Technical Quality of Inspections;
- Technical Quality of Incident and Allegation Activities;
- Legislation, Regulations, and Other Program Elements; and
- Sealed Source and Device Evaluation Program.

The team found Maryland's performance to be satisfactory, but needs improvement for the Technical Quality of Licensing Actions performance indicator.

The team determined that the recommendations from the 2015 IMPEP review be closed and is recommending two new recommendations related to protection of sensitive information and review of medical licenses.

Accordingly, the team recommends that the Maryland Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. The team recommends that the next IMPEP review take place in approximately 4 years with a periodic meeting in approximately 2 years.

1.0 INTRODUCTION

The Maryland Agreement State Program (Maryland) review was conducted from July 12-16, 2021, by a team of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Colorado. Team members are identified in Appendix A. This review was conducted remotely due to travel restrictions imposed by the COVID-19 Public Health Emergency (PHE). It should be noted that prior to the review, in-person inspector accompaniments were conducted March 10-11, 2020 and May 5-6, 2021. The inspector accompaniments are identified in Appendix B. The review was conducted in accordance with the "Agreement State Program Policy Statement," published in the *Federal Register* on October 18, 2017 (82 FR 48535), and NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated July 24, 2019. Preliminary results of the review, which covered the period of November 7, 2015 to July 16, 2021, were discussed with Maryland managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common performance indicators and applicable non-common performance indicators was sent to Maryland on November 20, 2019. Maryland's June 21, 2021 response to the questionnaire is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML21173A331.

The Maryland Agreement State Program is administered by the Radioactive Materials Division of the Radiological Health Program (RHP). The RHP is located within the Air and Radiation Administration of the Maryland Department of the Environment (the Department). Organization charts for Maryland are available in ADAMS (Accession Number ML21189A270).

At the time of the review, Maryland regulated 528 specific licenses authorizing possession, and use of radioactive materials. The review focused on the radiation control program as it is carried out under Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Maryland.

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

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on November 6, 2015. The final report is available in ADAMS (Accession Number ML16028A314). The results of the review and the status of the associated recommendations are as follows:

Technical Staffing and Training: Satisfactory
Recommendation: The review team recommended that Maryland develop, update and implement a training and qualification program that meets the essential elements of NRC 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 2015 IMPEP review resulted in a determination that the licensing training program did not contain all the essential elements to be fully compatible with IMC 1248. In February 2016, the licensing supervisor revised the Maryland Licensing Procedure which incorporated the essential elements of the individual self-study guides, on the job

training modules, and defined minimum training, and specialized training requirements. These were incorporated into qualification journals for the license reviewers.

The team reviewed Maryland's procedures and staff qualifications journals, and interviewed staff and management. Maryland has several new staff who are working toward full qualification. Based on the team's review, the team determined that Maryland has developed a training program that has the essential elements of IMC 1248. The team recommends that this recommendation be closed.

Status of Materials Inspection Program: Satisfactory
Recommendation: None

Technical Quality of Inspections: Satisfactory
Recommendation: None

Technical Quality of Licensing Actions: Satisfactory
Recommendation: The review team recommended 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: After the 2015 IMPEP team found inconsistencies between licensing actions with the same codes and proof-reading errors, the licensing supervisor initiated a proof-reading checklist, and in January 2017 started a root cause review of condition errors in the same type of licenses. The review involved taking the licenses under the same code and developing a spreadsheet of the existing conditions. As a result, a proof-reading checklist and templates were developed for the six most common licenses. In 2019, a formal procedure was established for quality control incorporating the use of the checklist and templates. During this IMPEP review, the team observed the use of the checklists and common license templates.

The team recommends that this recommendation be closed.

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

Legislation, Regulation, and Other Program Elements: Satisfactory
Recommendation: None

Sealed Source and Device Evaluation Program: Satisfactory
Recommendation: None

Overall finding: Adequate to protect public health and compatible with the NRC's program.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the NRC and Agreement State radiation control 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 could affect public health and safety. Apparent trends in staffing must be assessed. Review of staffing also requires 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 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.
- 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.
- Agreement State training and qualification program is equivalent to NRC Inspection Manual Chapter (IMC) 1248, "Formal Qualifications Program for Federal and State Material and Environmental Management Programs."
- Qualification criteria for new technical staff are established and are followed, or qualification criteria will be established if new staff members are hired.
- 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

At the time of the IMPEP review, Maryland was comprised of seven technical staff members and one administrative staff member which equaled seven full-time equivalents (FTE) for the radiation control program. There were three vacancies at the time of the review, so when fully staffed, the program has ten FTE. During the review period, nine staff members left the Maryland Agreement State Program, and ten staff members were hired. The positions were vacant between 28 days to 463 days. Although the length of the vacancies represent the time to permanently fill each position, all positions were promptly filled in an acting capacity until a permanent person was named.

Vacancies in Maryland were due to staff retirements from State service, staff moving from contractual positions to permanent positions, and staff leaving for other opportunities. Many of the positions in Maryland were filled by promoting internally which subsequently left vacancies in the position being vacated. In 2017, a new Program Manager was hired. The Division Chief was filled internally with a promotion in 2017 and again in 2018. In 2019, both the section heads for licensing, and inspection were promoted internally. The number of days the positions remained opened was largely due to a government wide hiring freeze. Since the previous IMPEP, Maryland approved salary increases and attracted highly qualified candidates. Although Maryland experienced a significant amount of turnover and some vacancies were not immediately

filled with permanent replacements, there was no adverse impact on the program, and Maryland continued to maintain health, safety, and security.

The team determined that Maryland's training and qualification program is compatible with the NRC's IMC 1248. Temporary Instruction (TI) 003, "Evaluating the Impacts of the COVID-19 Public Health Emergency as part of the Integrated Materials Performance Evaluation Program," states, in part, that license reviewers and inspectors may take longer to become qualified due to the inability to travel to attend training classes needed to complete qualification and inspections being delayed due to social distancing or other factors related to the COVID-19 PHE, provided Maryland continued to maintain health, safety, and security. The team noted that although the COVID-19 PHE has reduced the number of in-person training opportunities, Maryland's staff continues to enroll in NRC virtual classes, when available, and to work with the Organization of Agreement States and the NRC's Technical Training Center to take advantage of NRC on-line training classes.

c. Evaluation

The team determined that, during the review period, Maryland met the performance indicator objectives listed in Section 3.1.a. Based on the criteria in MD 5.6, the team recommends that Maryland's performance with respect to the indicator, Technical Staffing, and Training, be found satisfactory.

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

3.2 Status of Materials Inspection Program

Inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety and security practices. The frequency of inspections is specified in IMC 2800, "Materials Inspection Program," and is dependent on the amount and type of radioactive 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 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 prescribed frequencies (https://www.nrc.gov/materials/miau/mat-toolkits.html).
- 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.

- Candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 2800, and other applicable guidance, or compatible Agreement State Procedure.
- 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 performed 422 Priority 1, 2, 3, and initial inspections during the review period. Maryland conducted less than 2 percent of Priority 1, 2, 3, and initial inspections overdue during the review period. Six of the 372 Priority 1, 2, and 3, and 1 of the 50 initial inspections were conducted overdue. The six overdue inspections were determined to be attributed to data entry errors that caused the next inspection to exceed the target frequency. In response, Maryland implemented a quality assurance program, beginning in 2019, to ensure that data for program codes, and next inspection due dates were accurate. The remaining overdue initial inspection was a Priority 5 inspection of an x-ray fluorescence analyzer (XRF), which is listed as a generally-licensed device even though Maryland issues specific licenses for XRFs. Maryland's inspection frequencies are the same for similar license types in NRC's program.

A sampling of 28 inspection reports indicated that none of the inspection findings were communicated to the licensees beyond Maryland's goal of 30 days after the inspection exit or 45 days after the team inspection exit.

The team noted that Maryland consistently adhered to its reciprocity procedure. Maryland's reciprocity procedure anticipates conducting at least four Priority 1-3 reciprocity inspections each year, based on resource availability. A licensee is a candidate for inspection if it (1) was not inspected the previous year by Maryland, (2) had escalated enforcement, or (3) had a significant Nuclear Material Events Database (NMED) event in the last 2 years. In 2016, Maryland inspected 9 of 23 candidates; in 2017, Maryland inspected 4 of 17 candidates; in 2018, Maryland inspected 4 of 24 candidates; in 2019, Maryland inspected 2 of 24 candidates; in 2020, Maryland inspected 5 of 23 candidates. Review of these inspections indicated that each year Maryland consistently considered all reciprocity applicants as eligible for inspection, based on the specific criteria listed above, and selected these in a performance-based, risk-informed manner, and in a manner consistent with IMC 2800.

c. Evaluation

The team determined that, during the review period, Maryland met the performance indicator objectives listed in Section 3.2.a. Based on the criteria in MD 5.6, the team recommends that Maryland's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

3.3 Technical Quality of Inspections

Inspections, both routine and reactive, provide reasonable 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 an inspection program.

a. Scope

The 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, or senior staff as appropriate, conduct annual accompaniments of each inspector to assess performance, and assure consistent application of inspection policies.
- For Programs with separate licensing and inspection staffs, procedures are established, and followed to provide feedback information to license reviewers.
- Inspection guides are compatible with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated 28 inspection reports and enforcement documentation, and interviewed inspectors involved in materials inspections conducted during the review period. The team reviewed casework for inspections conducted by 6 of Maryland's former and current inspectors and covered medical, industrial, commercial, academic, nuclear pharmacy, radiography, research, and service provider licenses.

The team found that inspection results were well documented with respect to health, safety, and security. Each inspection report was tailored to the licensee, clearly explained the scope of the licensed program, and described the specific observations made by the inspector. There was sufficient detail documented in each report. At exit meetings, the inspectors routinely identify best practices used by the licensee, recommend the incorporation of the NRC's Safety Culture statement and policy into the licensee's radiation protection program, and reference Maryland's Web site to obtain the latest updates to pertinent information. The team also found that cited violations were supported by the State of Maryland regulations, and that inspection findings led to appropriate, and prompt regulatory actions. Maryland's inspection documentation included the closure of previous violations.

A team member accompanied three inspectors on four in-person inspections which occurred March 10-11, 2020, and May 5-6, 2021. No performance issues were noted during the inspector accompaniments. The inspectors were well-prepared and thorough; assessed the impact of licensed activities on health, safety, and security; and followed Maryland's checklists which were created based upon NRC Inspection Procedures. The inspectors clearly communicated the inspection findings to licensees at the exit meeting.

Temporary Instruction (TI) 003, "Evaluating the Impacts of the COVID-19 Public Health Emergency as part of the Integrated Materials Performance Evaluation Program," states, in part, that supervisory accompaniments of all qualified inspectors may not be able to be performed in each calendar year impacted by the PHE. This was the case for one inspector in 2020. In all other cases, supervisory accompaniments were performed annually.

The team determined that Maryland has a sufficient supply of calibrated radiation survey instruments to support the inspection program. Records indicate that all survey instrumentation is calibrated on an annual basis.

c. Evaluation

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

- Management does not promptly review inspection results.
- Supervisors, or senior staff as appropriate, did not conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.

The team noted that early in the COVID-19 PHE, there were some delays in supervisory reviews of inspection documentation (e.g., March 2020 inspections were reviewed in June 2020 – due to lockdown), which were later corrected. However, licensees were provided inspection results at the conclusion of the inspection and there was no impact on public health and safety.

Based on the criteria in MD 5.6, the team recommends that Maryland's performance with respect to the indicator, Technical Quality of Inspections be found satisfactory.

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

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, as well as security. An assessment of licensing procedures, implementation of those procedures, and documentation of communications, and associated actions between the Maryland licensing staff and regulated community is a significant indicator of the overall quality of the licensing program.

a. Scope

The 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 are consistent with current regulatory guidance (e.g., pre-licensing guidance, Title 10 *Code of Federal Regulation* (CFR) Part 37, financial assurance, etc.).

- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and can be inspected.
- 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 the physical protection of Category 1 and Category 2 quantities of radioactive material (10 CFR Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

b. Discussion

During the review period, Maryland performed over 750 radioactive materials licensing actions. The team evaluated 25 of those licensing actions: 4 new applications, 14 amendments, 6 renewals, and 1 termination. The team evaluated casework which included the following license types and actions: broad scope, medical diagnostic, and therapy, accelerator, commercial manufacturing and distribution, industrial radiography, research, and development, academic, nuclear pharmacy, self-shielded irradiators, service providers, decommissioning actions, and financial assurance. The casework sample represented work from five license reviewers.

The team found 5 of the 25 licensing actions were not correct and did not properly address the health and safety issues. Four were attributed to medical licenses.

- The team identified that Maryland did not require financial assurance for a cyclotron licensee. The team noted that the long-lived activation products were not included in the calculation. The team brought this to Maryland's attention and Maryland agreed to correct this matter. Maryland also informed the team that all of their financial assurance mechanisms were undergoing a review by new legal counsel.

- The team found that Maryland did not follow the guidance for evaluating the training and experience for Radiation Safety Officers (RSOs), Authorized Users (AUs), and Authorized Medical Physicists (AMPs) listed on medical licenses. Based on the information provided to the team, there were four examples:

  - Maryland incorrectly placed an RSO on a medical license.
  - Maryland incorrectly placed an AU on a medical license as the only AU on that license.
  - Maryland incorrectly placed AMPs on a license that did not require AMPs.
  - Maryland incorrectly approved an AU who was only authorized on a diagnostic license, for therapeutic use. Maryland also incorrectly added therapeutic use radioactive materials as storage only on this diagnostic license.

  The team informed Maryland that by incorrectly approving individuals on a license as either RSOs, AUs, or AMPs, this could perpetuate the error with another Agreement State, or the NRC. The team acknowledged that approving RSOs, AUs, and AMPs for medical licenses is challenging due to all of the Board certifications and training and experience necessary. Maryland requested that their Regional State Agreements Officer assist them with gaining a better understanding of the process.

The team noted that license reviewers generally performed license reviews following the guidance provided in the NRC's NUREG-1556 series, "Consolidated Guidance about Materials Licenses" and used the current version of the NRC's Pre-Licensing Guidance (PLG). The team evaluated the implementation of the PLG and Risk Significant Radioactive Materials (RSRM) checklists. Maryland conducted pre-licensing visits for unknown entities in accordance with the checklist, and properly implemented the PLG. For applications with RSRM, Maryland completed the RSRM checklist, and performed on-site security reviews, as necessary.

The team also noted that reviews of renewals included an analysis of the licensee's inspection and enforcement history. The team found that license reviewers were missing a questioning attitude and had a reliance on licensee submissions. The team noted that certain licenses did not have any markings on them.

The team noted that Maryland issued one exemption for relief from quarterly radiation safety committee meetings to one licensee due to the COVID-19 PHE.

c. Evaluation

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

- Licensing action reviews were not thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Applicable guidance documents were available to reviewers, but were not being followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).
- Documents containing sensitive security information were not properly marked, handled, controlled, and secured.

The team noted that there were several technical errors in licensing and that the guidance was not followed. Most of the errors dealt with medical licenses approval of RSOs, AUs, and AMPs. Therefore, the team made the following recommendation: Maryland review the qualifications of all Radiation Safety Officers, Authorized Users, and Authorized Medical Physicists listed on their medical licenses to ensure that they meet the qualifications in accordance with Maryland's regulations for medical use of byproduct material.

The team noted that licenses did not have markings on licenses which authorized risk significant radioactive material. All license files are locked in the Maryland office at the end of each workday. Access to files is limited to staff and Maryland's attorneys. However, written work products (e.g., licenses, deficiency letters, and Notices of Violation) are mailed to licensees without any marking. Licenses with Category 1, 2, and 3 quantities of radioactive material are currently not marked. If there was a security violation as part of an inspection, then the information on the Notice of Violation would need to be properly marked. Therefore, the team made the following recommendation: Maryland develop and implement a procedure to ensure protection of sensitive information as it applies to written correspondence with licensees.

Based on the IMPEP evaluation criteria in MD 5.6, the team recommends that Maryland's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory, but needs improvement with the two proposed recommendations.

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

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, safety, and security. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal, and external coordination, timely incident reporting, and investigative and follow-up actions, are a significant indicator of the overall quality of the incident response and allegation programs.

a. Scope

The 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, 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 (HOC) for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the NMED and closed when all required information has been obtained.
- Allegations are investigated in a prompt, appropriate manner.
- Concerned individuals are notified within 30 days, of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

During the review period, 50 incidents were reported to Maryland. The team evaluated 16 radioactive materials incidents: 3 contamination events, 3 equipment failures, 2 lost and recovered radioactive material events, 2 patient waste events, 2 scrap yard radiation monitoring alarm activations, 2 transportation events, 1 medical event, and 1 damaged equipment event. Maryland dispatched inspectors for on-site follow-up for all the cases reviewed.

When notified of an incident, management, and staff meet to discuss the incident and determine the appropriate level of response, which can range from an immediate response to reviewing the incident during the next routine scheduled inspection. Those determinations are made based on both the circumstances and the health and safety significance of the incident. The team found that Maryland's evaluation of incident notifications and its response to those incidents was thorough, complete, and comprehensive.

The team also evaluated Maryland's reporting of incidents to the NRC's HOC. The team noted that in each case requiring HOC notification, Maryland reported the incidents within the required timeframe. The team also evaluated whether Maryland had failed to report any required incidents to the HOC. The team did not identify any missed reporting requirements.

During the review period, 8 allegations were received by Maryland. The team evaluated all 8 allegations, including 2 allegations that the NRC referred to the State, during the review period.

From interviews and review of available documents, incidents, and allegations are initially communicated with management to determine the appropriate response after receiving initial report. In each incident, the team found that the inspector discussed the incidents, and worked with the licensee to ensure corrective actions were taken to prevent reoccurrence. Allegations were reviewed promptly, and alleger's identities were protected.

The team noticed that the documentation of the allegations and incidents were maintained in Maryland's actions database with additional documentation generated maintained on paper in a secured file cabinet. Four of the sixteen incidents and three of the eight allegations reviewed did not document final review and signature by a RHP supervisor in accordance with Maryland's allegation and incident procedures. The individual who would have documented the final review and signature is no longer with the program. The team also noted that the incident procedure referenced former employees in an "emergency call down list," and will need to be updated. The team noted that the areas for improvement in this matter revolve around documentation and not performance. Maryland committed to revising their allegation and incident procedures to address the above.

c. Evaluation

The team determined that, during the review period, Maryland met the performance indicator objectives listed in Section 3.5.a. Based on the criteria in MD 5.6, the team recommends that Maryland's performance with respect to the indicator, Technical Quality of Incident, and Allegation Activities, be found satisfactory.

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Legislation, Regulations, and Other Program Elements; (2) Sealed Source and Device (SS&D) Evaluation Program; (3) Low-Level Radioactive Waste (LLRW) Disposal Program; and (4) Uranium Recovery Program. The NRC retains regulatory authority for LLRW Disposal, and Uranium Recovery Programs; therefore, only the first two non-common performance indicators applied to this review

4.1 Legislation, Regulations, and Other Program Elements

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 State's agreement with the NRC. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of adequate 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. The 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 the NRC's final rule. 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 Program Element Table indicating the Compatibility Categories for those program elements other than regulations can be found on the NRC Web site at the following address: https://scp.nrc.gov/regtoolbox.html.

a. Scope

The team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Legislation, Regulations, and Other Program Elements," 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 website at the following address: https://scp.nrc.gov/regtoolbox.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.
- Sunset requirements, if any, do not negatively impact the effectiveness of the State's regulations.

b. Discussion

The Maryland Agreement State Program's current effective statutory authority is contained in the Annotated Code of Maryland, Environmental Article, Title 8, "Radiation." The Department is designated as the State's radiation control agency. No legislation affecting the radiation control program was passed during the review period.

Maryland's administrative rulemaking process takes approximately seven months from drafting to finalizing a rule. The public, 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 Radiation Control Advisory Board periodically reviews the programs and policies of the Department that relate to radiation and the Board also consults with and advises the Secretary of the

Environment on matters related to radiation. There are new members on the Radiation Control Advisory Board due to term limits that expired. The team noted that the State's rules and regulations are not subject to "sunset" laws.

During the review period, Maryland submitted seven proposed regulation amendments, five final regulation amendment(s), five revised final regulation amendments, and one submission of non-standard licensing conditions to the NRC for a compatibility review. None of the amendments were overdue for State adoption at the time of submission and no amendments were overdue at the time of this review.

c. Evaluation

The team determined that, during the review period, Maryland met the performance indicator objectives listed in Section 4.1.a. Based on the criteria in MD 5.6, the team recommends that Maryland's performance with respect to the indicator, Legislation, Regulations, and Other Program Elements, be found satisfactory.

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

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

Adequate technical evaluations of SS&D designs are essential to ensure that SS&Ds 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 the SS&D reviews and establishes useful guidance for teams. In accordance with MD 5.6, three sub-elements: Technical Staffing and Training, Technical Quality of the Product Evaluation Program, and Evaluation of Defects and Incidents Regarding SS&D's, are 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 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 qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, 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 the guidance in NUREG-1556, Volume 3.

Evaluation of Defects and Incidents

- SS&D incidents are reviewed to identify 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, occur in a timely manner.

b. Discussion

Technical Staffing and Training

Maryland has one staff qualified to perform SS&D reviews and two staff members that will be trained as SS&D reviewers after they qualify as license reviewers. Currently, there are two vacancies and when filled, the new employees may be trained to conduct SS&D reviews. During the review period, two of the SS&D staff members left the Maryland Agreement State Program and two staff members transferred from the Radiation Machines Division to the Licensing Section. Maryland's training program is equivalent to the NRC training requirements listed in the NRC's IMC 1248, Appendix D.

Effective July 1, 2021, the staff from Maryland have started working in the office 2 days per week, which will facilitate the training of staff for SS&D reviews. Since there is only one qualified SS&D reviewer, the team discussed the need for Maryland staff to seek assistance from an Agreement State or the NRC in order to obtain the required concurrence evaluation.

Technical Quality of the Product Evaluation

Maryland has four SS&D licensees. The team evaluated all five SS&D actions processed during the review period: one new application, two amendments, and two inactivations. The SS&D evaluations were thorough, of acceptable technical quality, and addressed product integrity under normal and likely accident conditions. Health and safety issues were properly addressed, and registrations clearly summarized the product evaluation. As part of its technical evaluations, Maryland contracts with an engineering firm to assist with engineering evaluations.

The Maryland SS&D reviewers used the NUREG-1556, Volume 3 checklist for the SS&D actions when appropriate to ensure that all health and safety aspects have been adequately addressed. The checklists are signed and dated by the lead reviewer and a concurrence reviewer. The concurrence review provides an additional "quality check" to the safety evaluation process.

Evaluation of Defects and Incidents Regarding SS&Ds

The team evaluated all five incidents involving SS&D registered products during the review period. None of the five incidents were related to manufacturing or design of the sources/devices manufactured or distributed by a licensee with a SS&D registered by Maryland.

c. Evaluation

The team determined that, during the review period, Maryland met the performance indicator objectives listed in Section 4.2.a. Based on the criteria in MD 5.6, the team recommends that Maryland's performance with respect to the indicator, Sealed Source, and Device Evaluation Program, be found satisfactory.

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

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

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 Regulatory Authority and Assumption Thereof by States Through Agreement," to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need for an amendment. Although, the Maryland has authority to regulate a LLRW disposal facility, the NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in Maryland. Accordingly, the team did not review this indicator.

5.0 SUMMARY

Maryland's performance was found to be satisfactory for six out of the seven performance indicators reviewed and satisfactory, but needs improvement, for the Technical Quality of Licensing Actions performance indicator.

The team made two new recommendations and determined that the two recommendations from the 2015 IMPEP review should be closed. The new recommendations are:

- Maryland will review the qualifications of all Radiation Safety Officers, Authorized Users, and Authorized Medical Physicists listed on their medical licenses to ensure that they meet the qualifications in accordance with Maryland's regulations for medical use of byproduct material.

- Maryland will develop and implement a procedure to ensure protection of sensitive information as it applies to written correspondence with licensees.

Accordingly, the team recommends that Maryland 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 team recommends that the periodic meeting take place in approximately 2 years and the next full IMPEP review take place in approximately 4 years.

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Areas of Responsibility**
Kathy Modes, NMSS	Team Leader Inspector Accompaniments Legislation, Regulations, and Other Program Elements
Farrah Gaskins, Region I	Team Leader in Training Technical Staffing and Training
Dennis O'Dowd, Region III	Status of Materials Inspection Program Technical Quality of Inspections
Shirley Xu, NMSS	Technical Quality of Licensing Actions
Ramon Li, State of Colorado	Technical Quality of Incident and Allegation Activities
Tomas Herrera, NMSS	Sealed Source and Device Evaluation Program

APPENDIX B

INSPECTOR ACCOMPANIMENTS

The following inspector accompaniments were performed prior to the remote IMPEP review:

Accompaniment No.: 1	License No.: MD-31-001-02
License Type: *Blood Irradiator*	Priority: 3
Inspection Date: 3/10/2020	Inspector's initials: AM

Accompaniment No.: 2	License No.: MD-13-028-02
License Type: *High Dose Rate (HDR) Afterloader*	Priority: 2
Inspection Date: 3/11/2020	Inspector's initials: DF

Accompaniment No.: 3	License No.: MD-41-001-03
License Type: *HDR Afterloader*	Priority: 2
Inspection Date: 5/5/2021	Inspector's initials: DF

Accompaniment No.: 4	License No.: MD-27-072-01
License Type: *Medical Private Practice, Written Directive Required*	Priority: 3
Inspection Date: 5/6/2021	Inspector's initials: JR