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

June 15, 2021

Gregory T. Young
Deputy Commissioner
Department of Environment and Conservation
William R. Snodgrass Tennessee Tower
312 Rosa L. Parks Avenue, 2nd floor
Nashville, TN 37243

Dear Mr. Young:

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. The enclosed draft IMPEP report documents the results of the May 3-7, 2021, Tennessee Agreement State review, which was conducted remotely due to travel restrictions associated with the COVID-19 Public Health Emergency. Three in-person inspector accompaniments and one remote accompaniment were performed between April 7 and 15, 2021. The team's preliminary findings were discussed with you and your staff on the last day of the review. The team's proposed recommendations are that the Tennessee 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 this draft report for your review and comment prior to submitting the report to the MRB. Comments are requested within four 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 scheduled to be conducted remotely on August 24, 2021, at 1:00 pm 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 me at Brian.Anderson@nrc.gov, or Geoffrey Warren at Geoffrey.Warren@nrc.gov.

Thank you for your cooperation.

Sincerely,

Signed by Anderson, Brian
on 06/15/21

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:
Draft 2021 Tennessee IMPEP Report

cc: Debra Shults, Director (w/enclosure)
Department of Environment and Conservation
Division of Radiological Health

Beth Shelton, Deputy Director (w/enclosure)
Department of Environment and Conservation
Division of Radiological Health

SUBJECT: LETTER TO G. YOUNG RE: DRAFT 2021 TENNESSEE IMPEP REPORT
DATE June 15, 2021

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE TENNESSEE AGREEMENT STATE PROGRAM

May 3 - 7, 2021

DRAFT REPORT

EXECUTIVE SUMMARY

The results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Tennessee Agreement State Program (Tennessee) are discussed in this report. The review was conducted from May 3 through 7, 2021, by a team of technical staff members assembled from the U.S. Nuclear Regulatory Commission (NRC), the Commonwealth of Kentucky, and the State of Washington. This review was conducted remotely due to travel restrictions associated with the COVID-19 Public Health Emergency. Three in-person inspector accompaniments and one remote accompaniment were performed between April 7 and 15, 2021.

The team found Tennessee's performance to be satisfactory for all performance indicators reviewed. These indicators are: Technical Staffing and Training; Status of Materials Inspection Program; Technical Quality of Inspections; Technical Quality of Licensing Actions; Technical Quality of Incident and Allegation Activities; Legislation, Regulations, and Other Program Elements; and Sealed Source and Device Evaluation Program.

The team did not make any new recommendations for Tennessee during the review. The team determined that the recommendation issued by the Management Review Board for the 2016 IMPEP review should be closed. This recommendation concerned the licensing of waste processors and is discussed further in Section 2.0 of this report.

Accordingly, the team recommends that Tennessee be found adequate to protect public health and safety and compatible with the NRC's program. This is the third consecutive review with all performance indicators being found satisfactory, and as such, the team recommends that the next IMPEP review take place in approximately 5 years with a periodic meeting in approximately 2.5 years.

1.0 INTRODUCTION

The Tennessee Agreement State Program (Tennessee) review was conducted remotely from May 3-7, 2021, by a team of technical staff members from the U.S. Nuclear Regulatory Commission (NRC), the Commonwealth of Kentucky, and the State of Washington. 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). Three in-person inspector accompaniments and one remote accompaniment were performed between April 7 and 15, 2021.

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. In addition, the team considered IMPEP Temporary Instruction 003, "Evaluating the Impacts of the Coronavirus Disease 2019 PHE as Part of IMPEP," dated October 21, 2020, to evaluate the impact of the PHE on the Program. Preliminary results of the review, which covered the period of March 12, 2016, to May 7, 2021, were discussed with Tennessee 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 by e-mail to Tennessee on February 17, 2021. Tennessee provided its response to the questionnaire on April 19, 2021. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML21110A612.

Tennessee is administered by the Division of Radiological Health (the Division). The Division is located within the Bureau of Environment, which is in the Tennessee Department of Environment and Conservation (the Department). The Division Director reports to the Deputy Commissioner of the Department, who in turn reports to the Commissioner of the Department. Organization charts for Tennessee at the time of the review are available in ADAMS using the Accession Number ML21110A383.

At the time of the review, Tennessee regulated 499 specific licenses authorizing possession, and use of radioactive materials. The review focused on the radiation control 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 Tennessee.

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 the Tennessee's performance.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review was performed on March 7-11, 2016. The final report is available in ADAMS using the Accession Number ML16153A003. The results of the review and the status of the associated recommendation are as follows:

Technical Staffing and Training: Satisfactory
Recommendation: None

Status of Materials Inspection Program: Satisfactory
Recommendation: None

Technical Quality of Inspections: Satisfactory
Recommendation: None

Technical Quality of Licensing Actions: Satisfactory

Recommendation: Following the 2016 IMPEP review, the review team recommended, and the MRB agreed, that the State (1) review all waste processor licenses to ensure standard license conditions are appropriately applied and consistently used, and (2) continue to develop and finalize the licensing guidance for the unique activities associated with waste processors.

Status: In response to the recommendation from the 2016 IMPEP review, Tennessee: (1) reviewed all the waste processor license conditions and standardized those that were common to the licensees. The standardized common license conditions were adopted as licenses were amended. The team reviewed all the active waste processor licenses and found that the standardized common license conditions were present and used consistently and (2) developed waste processor licensing guidance and procedures, and a checklist for major licensing actions such as new licenses and renewals. The team noted that the checklist was consistently used for new license and renewal actions. Overall, the team found that Tennessee responded promptly, comprehensively, and appropriately to address this recommendation.

The team concluded that this recommendation should be closed.

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

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

Sealed Source and Device Evaluation Program: Satisfactory
Recommendation: None

Overall finding: Adequate to protect public health and safety, 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 Tennessee'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

When fully staffed, the Division is composed of 59 staff members, which equates to 30 full-time equivalents for the radiation control program. The 59 staff members include staff in both the radioactive materials program and the X-ray program, as well as management, and administrative staff. At the time of the previous review, there were nine vacancies in the Division. During the review period, 12 staff members left the Tennessee program and 10 staff members were hired. At the time of the review, there were 11 vacancies, which had been vacant from 1 to 48 months. Two of these 11 vacancies were in the X-ray program. Although Tennessee had several vacancies at the time of the review, it has not experienced performance issues or suffered adverse impacts. Tennessee solicited for five of the nine openings in the materials program during the week after the IMPEP review.

Tennessee has a training and qualification program compatible with the NRC's IMC 1248. The team noted that qualified staff received the 24-hour refresher training as detailed in the NRC IMC 1248.

Tennessee has four regional field offices that are responsible for conducting radioactive materials inspections throughout the State. Inspectors in the qualification process can accompany inspectors from other field offices in order to gain experience in areas not routinely inspected in their respective field offices. All materials licensing operations are performed out of the central office in Nashville.

The team noted that although the PHE has reduced the number of in-person training opportunities, there have been no adverse impacts to the qualification process. Tennessee's staff continues to enroll in NRC virtual classes, when available. Tennessee

has also taken advantage of NRC on-line training classes, which the Organization of Agreement States worked with the NRC to provide.

c. Evaluation

The team determined that, during the review period, Tennessee met the performance indicator objectives listed in Section 3.1.a. Based on the criteria in MD 5.6, the team recommends that Tennessee'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 Tennessee'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 frequencies prescribed in IMC 2800.
- 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

Tennessee performed 608 Priority 1, 2, and 3 inspections, and 63 initial inspections during the review period. All Priority 1, 2, 3, and initial inspections were completed on time. The team determined that Tennessee's inspection frequencies are the same for similar license types in IMC 2800.

The team reviewed inspection reports from 22 routine inspections and 4 reciprocity inspections from the four field offices. All inspection findings were communicated to licensees within Tennessee's goal of 30 days after the inspection exit or 45 days after a team inspection exit.

The PHE did not appear to impact the inspection frequency and the time constraints required to communicate inspection results to the licensees. Inspections continued to be performed in a timely manner and reports continued to be issued timely throughout the PHE.

Tennessee inspected 45 of the 79 reciprocity licenses during the review period, and more than 20 percent of candidates each year (60 percent in 2016, 57 percent in 2017, 59 percent in 2018, 75 percent in 2019, 45 percent in 2020, and 40 percent to date in 2021). Reciprocity inspections are conducted in the State of Tennessee using guidance found in the NRC's IMC 2800. The reciprocity inspections reviewed were consistent with this policy.

c. Evaluation

The team determined that, during the review period, Tennessee met the performance indicator objectives listed in Section 3.2.a. Based on the criteria in MD 5.6, the team recommends that Tennessee'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 Tennessee'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 22 inspection reports and associated enforcement documentation, and interviewed inspectors involved in materials inspections conducted during the review period. The team reviewed casework for inspections conducted by 15 of Tennessee's inspectors and covered medical, industrial, commercial, academic, research, service provider, and reciprocity licenses. Based on its review of inspection documentation, the team found that all inspections were well documented, and inspection findings were consistent with inspection procedures and regulatory requirements.

The team accompanied four inspectors between April 7 and 15, 2021. Three of the four inspector accompaniments were performed in-person and one was performed remotely. The team found that inspectors were well-prepared and thorough, and assessed the impact of licensed activities on health, safety, and security. Inspectors observed the use of radioactive materials, whenever possible. During interviews of licensee staff, inspectors used open ended questions, and were able to develop a basis of confidence that radioactive materials were being used safely and securely. Any findings observed were brought to the user's attention at the time of the inspection and again to the licensee's management during the inspection closeout. All findings and conclusions were well-founded and documented. The inspector accompaniments are identified in Appendix B.

The team found that all supervisory accompaniments were performed at least annually for all qualified inspectors during each year of the review period, and continued to be performed for all inspectors during the PHE.

The team determined that Tennessee has an adequate supply of properly calibrated radiation detection equipment to support the inspection program. Calibrations are performed annually. In all inspection records reviewed, the team found that surveys had been performed with properly calibrated survey equipment. Tennessee also has laboratory services available for sample analysis, when needed.

c. Evaluation

The team determined that, during the review period, Tennessee met the performance indicator objectives listed in Section 3.3.a. Based on the criteria in MD 5.6, the team recommends that Tennessee'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 Tennessee 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 Tennessee'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, Tennessee performed 2,211 radioactive materials licensing actions. The team evaluated 40 of those licensing actions. The licensing actions selected for review included 8 new applications, 18 amendments, 9 renewals, and 5 terminations. The team evaluated casework which included the following license types and actions: waste processing, broad scope medical, broad scope academic, medical diagnostic, and therapy, commercial manufacturing and distribution, industrial radiography, research, and development, nuclear pharmacy, fixed, and portable gauges, self-shielded irradiators, decommissioning actions, financial assurance, bankruptcies, and service providers. The casework sample represented work from all four current license reviewers and two past reviewers.

License reviewers and the licensing supervisor perform license reviews following the guidance provided in the NRC's NUREG-1556 series, "Consolidated Guidance about Materials Licenses" and routinely use the NRC's Pre-Licensing Guidance (PLG). License reviewers also follow Tennessee's procedures and checklists for licensing the waste processors. Tennessee currently has 10 active waste processor licensees with 5 out of the 10 owned by one company, and 2 out of the 10 owned by another company. Seven out of the 10 are authorized to perform bulk surveys for release.

The team found that licensing actions were well documented and properly address health, safety, and security issues. The team also found that deficiency letters were clear and used at appropriate times. License reviewers complete a summary sheet for each licensing action describing the review and the changes made to the license.

Reviews of renewals included an analysis of the licensee's inspection and enforcement history.

The team evaluated the implementation of the PLG and Risk Significant Radioactive Materials (RSRM) checklists. Tennessee conducted pre-licensing visits for unknown entities in accordance with the checklist, and properly implemented the PLG. For applications with RSRM, Tennessee completed the RSRM checklist, and performed on-site security reviews, as necessary. In addition, the team determined that documents containing sensitive security information were marked, handled, and secured appropriately.

c. Evaluation

The team determined that, during the review period, Tennessee met the performance indicator objectives listed in Section 3.4.a. Based on the criteria in MD 5.6, the team recommends that Tennessee's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

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 Tennessee'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 for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the Nuclear Material Events Database (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, 51 incidents were reported to Tennessee. The team evaluated 15 radioactive materials incidents: 5 lost, stolen, or abandoned radioactive materials; 3 equipment failures; 2 contamination events; 2 medical events; 1 potential overexposure; 1 potential release; and 1 fire. Tennessee dispatched inspectors for on-site follow-up for eight of the cases reviewed.

The team found that Tennessee responded appropriately and in accordance with Tennessee's procedures to each of the reported events, whether initiating an immediate on-site inspection, reviewing the event through telephone or e-mail contacts, or deciding to review the case at the next routine inspection. Documentation of these inspections was thorough and issued in a time frame consistent with Tennessee's goals. Enforcement action was taken when appropriate.

The team also evaluated Tennessee's reporting of incidents to the NRC's Headquarters Operations Officer (HOO). The team noted that in each case requiring HOO notification, Tennessee reported the incident within the required timeframe. The team also evaluated whether Tennessee had failed to report any required incidents to the HOO. The team did not identify any missed reporting requirements.

During the review period, 60 allegations were received by Tennessee, of which 28 were related to the materials program. The team evaluated 11 allegations, including 2 allegations that the NRC referred to Tennessee, during the review period. The team found that Tennessee responded to the allegations consistent with the safety consequence of the concern, protected the identity of concerned citizens, and contacted concerned citizens with the results of the review when their identity was known.

c. Evaluation

The team determined that, during the review period, Tennessee met the performance indicator objectives listed in Section 3.5.a. Based on the criteria in MD 5.6, the team recommends that Tennessee'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. Tennessee has not initiated any LLRW disposal activities as described in Section 4.3 of this report, and the NRC retains regulatory authority for the Uranium Recovery Program; 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 Tennessee'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

Tennessee became an Agreement State on September 1, 1965. The Program's current effective statutory authority is contained in Tennessee Code Annotated Title 68, Chapter 202-101 through 202-7-9, of the Tennessee Statutes. The Division of Radiological Health is designated as Tennessee's radiation control agency. No legislation affecting the radiation control program was passed during the review period.

Tennessee's administrative rulemaking process takes approximately 12 to 18 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 State. The team noted that

the State's rules and regulations are subject to "sunset" laws. According to the Program, the sunset laws have never affected their program, or caused any gaps in regulations.

During the review period, Tennessee submitted six proposed regulation amendments to the NRC for a compatibility review. One of the amendments was overdue for State adoption at the time of submission.

- "Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions", 10 CFR Parts 30,40, 70, 170, and 171 that was due for Agreement State adoption by August 27, 2016

The team reviewed program guidance documents that Tennessee uses to meet the requirements of other program elements (e.g., Pre-Licensing Guidance, Inspection Procedures, etc.) that the NRC has designated as necessary for the maintenance of an adequate and compatible program. Tennessee uses NRC guidance documents and remains up to date as new guidance is issued.

c. Evaluation

The team determined that, during the review period, Tennessee met the performance indicator objectives listed in Section 4.1.a, except for:

- 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

During the review period, Tennessee submitted six proposed regulation amendments to the NRC for a compatibility review with one being submitted one year after the due date for adoption. However, this amendment included updates to existing rules that did not affect compatibility. As such, this late submission did not create a conflict or gap in regulation and did not adversely affect the program.

Based on the criteria in MD 5.6, the team recommends that Tennessee'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 Tennessee'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

Tennessee has two staff members qualified to perform SS&D reviews and two staff members in training. During the review period, three SS&D staff members left the program and two staff members were hired. While this technically indicates a reduction in staffing for the SS&D Evaluation Program, Tennessee considers this staffing level sufficient to handle the current workload. In addition, one of the positions solicited following this review is for a license reviewer who will be trained to perform SS&D reviews. Tennessee has a training program equivalent to NRC training requirements listed in the NRC's IMC 1248, Appendix D. The team determined that the Tennessee is appropriately staffed and trained to carry out the SS&D program.

Technical Quality of the Product Evaluation

Tennessee has 10 active SS&D licensees. The team evaluated 21 of 55 SS&D actions processed during the review period: 2 new applications, 18 amendments, and 1 inactivation. Based on the information reviewed, the team determined that the technical evaluation of the applications was adequate, thorough, complete, clear, specific, and consistent with the guidance in NUREG-1556, Volume 3, Revision 2.

Evaluation of Defects and Incidents Regarding SS&Ds

There were no incidents during the review period related to manufacturing or design of the sources or devices manufactured or distributed by a licensee with a SS&D registered by Tennessee. The team found that Tennessee is aware of the need to review SS&D-related incidents, including those related to SS&D defects, as potentially generic in nature with possible wide-ranging effects.

c. Evaluation

The team determined that, during the review period, Tennessee met the performance indicator objectives listed in Section 4.2.a. Based on the criteria in MD 5.6, the team recommends that Tennessee'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. Although the Tennessee Agreement State Program has LLRW disposal authority, NRC has not required States to have a program for licensing a LLRW 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, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in Tennessee. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Tennessee's performance was found to be satisfactory for all performance indicators reviewed. The team did not make any new recommendations and determined that the recommendation from the 2016 IMPEP review should be closed.

Accordingly, the team recommends that Tennessee be found adequate to protect public health and safety and compatible with the NRC's program. This is the third consecutive IMPEP review with all performance indicators being found satisfactory; and as such, the team recommends that the next full IMPEP review take place in approximately 5 years, with a periodic meeting in approximately 2.5 years.

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Areas of Responsibility**
Geoffrey Warren, Region III	Team Leader Technical Quality of Incident and Allegation Activities Inspector Accompaniments
Farrah Gaskins, Region I	Technical Staffing and Training Technical Quality of Licensing Actions Legislation, Regulations, and Other Program Elements
Anjan Bhattacharyya Commonwealth of Kentucky	Status of Materials Inspection Program Technical Quality of Inspections Inspector Accompaniments
Lizette Roldán-Otero, Region IV	Inspector Accompaniments
Latischa Hanson, Region IV	Technical Quality of Licensing Actions
Kristen Schwab State of Washington	Technical Quality of Licensing Actions
María Arribas-Colón, NMSS	Sealed Source and Device Evaluation Program

APPENDIX B

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: R-33177-H28
License Type: *Medical Institution–Written Directive Required*	Priority: 3
Inspection Date: 04/07/21	Inspector's initials: JH

Accompaniment No.: 2	License No.: R-06017-B29
License Type: *Medical Institution–Written Directive Required*	Priority: 3
Inspection Date: 04/08/21	Inspector's initials: AD

Accompaniment No.: 3	License No.: R-90053-L30
License Type: *Mobile Medical Service–Written Directive Not Required*	Priority: 3
Inspection Date: 04/12/21 – 4/14/21 (remote)	Inspector's initials: AW

Accompaniment No.: 4	License No.: R-95009-K26
License Type: *Industrial Radiography Temporary Job Sites*	Priority: 1
Inspection Date: 04/15/21	Inspector's initials: CS