



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

May 16, 2016

MEMORANDUM TO: Scott W. Moore, Acting Director  
Office of Nuclear Material Safety  
and Safeguards

Joan W. Olmstead, Assistant General Counsel for  
Reactor and Materials Rulemaking  
Office of the General Counsel

Daniel Collins, Director  
Division of Material Safety, State, Tribal, and  
Rulemaking Programs  
Office of Nuclear Material Safety  
and Safeguards

Kriss M. Kennedy, Deputy Regional Administrator  
NRC Region IV

FROM: Paul Michalak, Acting Chief **/RA/**  
Agreement State Programs Branch  
Division of Material Safety, State, Tribal, and  
Rulemaking Programs  
Office of Nuclear Material Safety  
and Safeguards

SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION  
PROGRAM REVIEW OF TENNESSEE

This memorandum transmits to the Management Review Board (MRB) a proposed final report (Enclosure 1) documenting the Integrated Materials Performance Evaluation Program review of the Tennessee Agreement State Program. The review was conducted by an interoffice team during the period of March 7-11, 2016. The team issued a draft report to Tennessee on April 11, 2016, for factual comment. Tennessee responded to the findings and conclusions of the review by letter dated May 5, 2016, from Debra G. Shults, Director, Division of Radiological Health (ADAMS accession number ML16131A230). Tennessee offered an edit to the recommendation for which the review team accepted.

The review team is recommending that Tennessee's performance be found satisfactory for all indicators reviewed. Accordingly, the review team is recommending that Tennessee be found adequate to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission.

The Management Review Board meeting to consider the Tennessee report is scheduled for **May 24, 2016, 1:00 - 4:00 p.m. EDT**. In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for that meeting is enclosed (Enclosure 2).

If you have any questions prior to the meeting, please contact me at (301) 415-5422.

Enclosures:

- 1) Tennessee Proposed Final Report
- 2) Meeting Agenda

cc: Shari Meghreblian, Ph.D.  
Deputy Commissioner

Debra Shults  
Director, Division of Radiological Health

Sherrie Flaherty, MN  
Organization of Agreement States  
Liaison to the MRB

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DATE	05/12/16	05/12/16	05/16/16

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE TENNESSEE AGREEMENT STATE PROGRAM

MARCH 7-11, 2016

**PROPOSED FINAL REPORT**

## **EXECUTIVE SUMMARY**

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Tennessee Agreement State Program. The review was conducted during the period of March 7-11, 2016, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the States of New Jersey and Louisiana.

Based on the results of this review, Tennessee's performance was found satisfactory for all indicators reviewed. The review team made one two-part recommendation concerning licensing. The review team recommends that the Tennessee Agreement State Program (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.

Accordingly, the review team recommends that the Tennessee Agreement State Program is adequate to protect public health and safety and is compatible with the NRC's Program. Because this review is the second consecutive review with all indicators satisfactory, the review team recommends that the next IMPEP review take place in approximately 5 years and that a periodic meeting be held in approximately 2.5 years.

## 1.0 INTRODUCTION

This report presents the results of the review of the Tennessee Agreement State Program. The review was conducted during the period of March 7-11, 2016, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the States of New Jersey and Louisiana. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6 (MD 5.6), "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of April 28, 2012 - March 11, 2016, were discussed with Tennessee managers on the last day of the review.

The Tennessee Agreement State Program (the Program) is administered by the Division of Radiological Health (the Division). The Division is located within the Bureau of Environment, which is in the Department of Environment and Conservation (the Department). The Division Director reports to the Deputy Commissioner for Environment and Conservation, who in turn reports to the Commissioner of the Department. Organization charts for the State can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML16053A256.

At the time of the review, the Tennessee Agreement State Program regulated 530 specific licensees authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under the Section 274b (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Tennessee.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the State on October 30, 2015. The State provided its response to the questionnaire by electronic mail on February 24, 2016. A copy of the questionnaire response can be found using the ADAMS Accession Number ML16053A262.

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

## 2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on April 27, 2012. The final report is available in ADAMS using the Accession Number ML12194A239. The results of the review 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: None

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

Compatibility Requirements: 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 regional and Agreement State radioactive materials programs. These indicators are (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

#### 3.1 Technical Staffing and Training

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

##### a. Scope

The review team used the guidance in State Agreements procedure SA-103, "Reviewing the Common Performance Indicator: Technical Staffing and Training," and evaluated 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.
- Agreement State training and qualification program is equivalent to NRC's Inspection Manual Chapter (IMC) 1248, "Formal Qualifications Program for Federal and State Materials and Environmental Management Programs."
- Qualification criteria for new technical staff are established and are being followed or that qualification criteria will be established if new staff members are hired.

- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing of the licensing and inspection programs.
- Management is committed to training and staff qualification.
- Individuals performing materials licensing and inspection activities are adequately qualified and trained to perform their duties.
- License reviewers and inspectors are trained and qualified in a reasonable period of time.

b. Discussion

The Tennessee Agreement State Program is composed of 50 staff members totaling 30 full-time equivalents (FTE) for the radioactive materials program including vacancies. During the review period, 17 staff members left the program and 8 staff members were hired. Currently there are nine vacancies that have been vacant anywhere from 2 to 20 months. In order to provide staff with better career progression, the Program is converting each vacant position from a health physicist job title to either an environmental consultant, environmental scientist, or environmental manager job title. This conversion requires approval from human resources before the position can be posted with the new job title. Once the Program receives approval from human resources to post the position, the Program must receive approval for funding the position. During the onsite review, the Program received approval from human resources to post six vacant positions. Once funding is approved, the Program will post the six positions. The review team found that the Program training and qualification manual compatible with the NRC's IMC 1248.

c. Evaluation

Although the Program has some positions vacant up to 20 months, the review team did not identify any performance issues associated with these vacancies. During the review period, the Program did not have a backlog in licensing or inspection activities. The team determined that during the review period the Tennessee program met the performance indicator objectives listed in Section 3.1.a.

d. Results

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

3.2 Status of the Materials Inspection Program

Periodic inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety practices. The frequency of inspections is specified in NRC IMC 2800, "Materials Inspection Program," and is dependent on the amount and kind of material, the type of operation licensed, and the results of previous inspections. There must be a capability for maintaining and retrieving statistical data on the status of the inspection program.



a. Scope

The review team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated 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 frequency prescribed in IMC 2800.
- Candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 1220, "Processing of NRC Form 241, Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters, and Inspection of Agreement State Licensees Operating under 10 CFR 150.20."
- Deviations from inspection schedules are normally coordinated between technical staff and management.
- There is a plan to perform any overdue inspections and reschedule any missed or deferred inspections; or a basis has been established for not performing any overdue inspections or rescheduling any missed or deferred inspections.
- Inspection findings are communicated to licensees in a timely manner (30 calendar days, or 45 days for a team inspection, as specified in IMC 0610, "Nuclear Material Safety and Safeguards Inspection Reports").

b. Discussion

Tennessee performed 516 Priority 1, 2, 3, and initial inspections during the review period, of which only one inspection was conducted overdue. The review team sampled 45 inspection reports and found that in each instance, inspection findings were communicated to the licensee within 30 days after the inspection exit. The Program completed more than 20 percent of candidate reciprocity inspections during each year of the review period.

c. Evaluation

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

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that Tennessee's performance with respect to the indicator, Status of the Materials Inspection Program, be found satisfactory.

3.3 Technical Quality of Inspections

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

a. Scope

The review team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated 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 conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.
- For programs with separate licensing and inspection staffs, to verify that procedures are established and followed to provide feedback information to license reviewers.
- For Agreement States, to determine if inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The review team evaluated the inspection reports and enforcement documentation for 45 materials inspections conducted during the review period. The casework included inspections performed by 19 current and former inspectors and covered medical, industrial, commercial, academic, research, and service licenses. The inspection casework and inspector accompaniments were also assessed for implementation of security requirements for risk significant material, as applicable.

The IMPEP team members conducted accompaniments of 10 Program inspectors during the weeks of November 16, 2015, and February 22, 2016. The inspectors were accompanied during health, safety, and security inspections of industrial radiography, waste collector, radiopharmacy, medical diagnostic, high dose rate remote after loader, and waste processor licensees. During the accompaniments, the inspectors demonstrated appropriate inspection techniques, knowledge of the regulations, appropriate use of calibrated survey instruments, and conducted performance-based inspections. The inspectors were trained, well-prepared for the inspection, conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspections were adequate to assess radiological health and safety and Increased Controls at the licensed facilities.

The review team noted the Program performed annual supervisory accompaniments for each of the inspectors throughout the review period.

c. Evaluation

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

d. Results

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

3.4 Technical Quality of Licensing Actions

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

a. Scope

The review team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated 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 meet current regulatory guidance (e.g. financial assurance, increased controls, pre-licensing guidance).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and are inspectable.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Applicable guidance documents are available to reviewers and are followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).
- Licensing practices for risk significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled and secured.

b. Discussion

During the review period, the Program performed 2,175 radioactive materials licensing actions. The review team evaluated 30 radioactive materials licensing actions, including 5 new applications, 12 amendments, 7 renewals, and 6 terminations. The casework

sample represented work from all four current license reviewers. The review team also reviewed a sample of financial assurance and decommissioning actions.

The review 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, and service providers.

With the exception of waste processor licensing, license reviewers and the licensing supervisor perform license reviews following the guidance in the NRC's NUREG-1556 series, "Consolidated Guidance about Materials Licenses" and consistently use the NRC's Pre-Licensing Guidance. The State follows other processes for licensing the waste processors. The State has issued 14 waste processor licenses with 6 out of the 14 owned by one company and with 7 out of the 14 authorized to perform bulk survey for release. One licensee is currently undergoing decommissioning. The 2008 IMPEP review team discussed developing guidance or a checklist for licensing unique activities associated with waste processors to ensure consistent and thorough licensing. The 2012 IMPEP review team noted that the State had developed standard license conditions for use in waste processor licensing but had not yet developed written guidance. In reviewing the waste processor license files, the 2016 IMPEP review team identified; (1) standard license conditions are not used consistently; (2) written guidance has not been finalized; and, (3) several licenses authorize storage for greater than 365 days, two of which have an authorization for an indefinite period of time.

c. Evaluation

The team determined that during the review period Tennessee met the performance indicator objectives listed in Section 3.4.a., with exception.

The license reviews for most license types are thorough, complete, consistent, and of acceptable technical quality with health and safety issues properly addressed. The license reviews for the waste processors showed inconsistencies which are attributed to the lack of final guidance, use of checklists, and standard license conditions. Based on this review, the review team is recommending 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.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that Tennessee's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory with one recommendation.

3.5 Technical Quality of Incident and Allegation Activities

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

procedures and actions will be a significant indicator of the overall quality of the program.

a. Scope

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

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

b. Discussion

During the review period, a total of 78 incidents were reported by Tennessee to the NMED database. The review team screened the incidents and selected 18 of the most significant events for review. The casework reviewed included lost/stolen radioactive materials events, damaged equipment incidents, internal and external contamination events, fires at waste processor facilities involving radioactive materials, and shipping incidents involving a Tennessee based common carrier.

When an event occurs and is reported to the Program, management evaluates it to determine what the appropriate response should be. Responses can range anywhere from an immediate response to reviewing the event during the next inspection. For the more significant events, management directed inspectors to respond immediately. The review team also noted that Tennessee staff perform event reviews in accordance with their established procedures.

During the review period, Tennessee also received 20 allegations of which 8 were related to radioactive materials. The review team evaluated all eight materials allegations and found that the Program took prompt and appropriate action in response to the concerns raised. Concerned individuals were notified of the findings in each case. Tennessee's open records laws often make it difficult for the Program to protect alleged's identities, so they have developed alternate methods where alleged's can be notified of outcomes while still protecting their identities. No allegations were referred from NRC to Tennessee during the review period.

c. Evaluation

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

d. Results

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

4.0 NON-COMMON PERFORMANCE INDICATORS

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

4.1 Compatibility Requirements

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

a. Scope

The review team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," and evaluated Tennessee's performance with respect to the following performance indicator objectives:

- The Agreement State program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of radioactive materials under the Atomic Energy Act, as amended.
- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were adopted no later than 3 years after the effective date of the NRC regulation.

- Other program elements, as defined in SA-200 that have been designated as necessary for maintenance of an adequate and compatible program have been adopted and implemented within 6 months of NRC designation.
- The State statutes authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement.
- The State is authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses.
- Impact of sunset requirements, if any, on the State's regulations.

A complete list of regulation amendments can be found on the NRC Web site at the following address: [https://scp.nrc.gov/rss\\_regamendments.html](https://scp.nrc.gov/rss_regamendments.html).

b. Discussion

Tennessee became an Agreement State on September 1, 1965. The Tennessee Agreement State 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 Department is designated as the State's radiation control agency. No legislation affecting the radiation control program was passed during the review period.

The State's administrative rulemaking process takes approximately 12 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 State.

During the review period, Tennessee submitted one final regulation amendment and six proposed regulation amendments to the NRC for a compatibility review. Three of these proposed amendments are now final regulations. During the onsite review, Tennessee submitted these three final regulation amendments to NRC for review. The remaining three amendments will be published for final comment in March 2016. Once these regulations are final, Tennessee will submit them to NRC for review.

At the time of this review, the following two amendments were overdue:

- "Decommissioning Planning" 10 CFR Parts 20, 30, 40, and 70 amendment (76 FR 35512), that was due for Agreement State adoption by December 17, 2015.
- "Requirements for Distribution of Byproduct Material" 10 CFR Parts 30, 31, 32, 40, and 70 amendment (77 FR 43666), that was due for Agreement State adoption by October 23, 2015.

c. Evaluation

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

d. Results

Using the evaluation criteria in MD 5.6, the review team recommends that Tennessee's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

4.2 Sealed Source and Device 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 SS&D reviews and establishes useful guidance for review teams. Three sub elements; technical staffing and training, technical quality of the product evaluation program, and evaluation of defects and incidents regarding SS&D's, will be evaluated to determine if the SS&D program is satisfactory. Agreement States with authority for SS&D evaluation programs that are not performing SS&D reviews are required to commit in writing to having an SS&D evaluation program in place before performing evaluations.

a. Scope

The review team used the guidance in State Agreements procedure SA-108, "Reviewing the Non-Common Performance Indicator: Sealed Source and Device Evaluation Program," and evaluated 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 that qualification criteria will be established if new staff members are hired.
- Any vacancies are filled in a timely manner.
- Management is committed to training and staff qualification.
- Individuals performing SS&D evaluation activities are adequately qualified and trained to perform their duties.
- SS&D reviewers are trained and qualified in a reasonable period of time.

Technical Quality of the Product Evaluation Program

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

Evaluation of Defects and Incidents

- SS&D incidents are reviewed to detect possible manufacturing defects and the root causes of these incidents.



- Incidents are evaluated to determine if other products may be affected by similar problems. Appropriate action and notifications to NRC, Agreement States, and others, as appropriate, should occur in a timely manner.

b. Discussion

Technical Staffing and Training

The SS&D program currently has four fully qualified SS&D reviewers. A fifth reviewer is in the qualification process and is currently qualified for device reviews but not for source reviews. A total of nine staff have attended NRC's SS&D Workshop including those currently qualified, those in the qualification process, as well as four additional staff. At the present time, the SS&D program is fully staffed and the Program believes that current staffing levels are adequate. The SS&D training program is compatible with the training requirements identified in Appendix D to IMC 1248.

Technical Quality of the Product Evaluation

Over the review period, the SS&D program issued 20 actions of which 3 were new applications and 17 were amendments to existing device sheets.

The review team evaluated 17 of these actions including 3 new applications and 14 amendments. The review team determined that in each instance SS&D reviewers evaluated the cases against all applicable guidance and standards. The work performed by the SS&D reviewers was found to be comprehensive and of high quality.

Evaluation of Defects and Incidents Regarding SS&Ds

One event involving a leaking line source used in for the calibration of PET/CT devices was reported to the Program during the review period. A total of three of these sources have been manufactured with this being the only leaking source to date. The Program is evaluating the incident for generic implications and the event is still under investigation.

c. Evaluation

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

d. Results

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

4.3 Low-level Radioactive Waste 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 satisfactory for all the performance indicators reviewed. The review team made one two-part recommendation regarding program performance by the State. The review team is recommending 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.

Accordingly, the review team recommends that the Tennessee Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. Based on the results of the current IMPEP review, the review team recommends that the next full IMPEP review take place in approximately 5 years.

## LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Inspection Accompaniments

## APPENDIX A

### IMPEP REVIEW TEAM MEMBERS

<b>Name</b>	<b>Area of Responsibility</b>
Randy Erickson, Region IV	Team Leader Technical Quality of Incident and Allegation Activities Inspector Accompaniments
Donna Janda, Region I	Technical Staffing and Training Compatibility Requirements Inspector Accompaniments
Ryan Craffey, Region III	Technical Quality of Inspections Status of the Materials Inspection Program
Kathy Modes, NMSS	Technical Quality of Licensing Actions Inspector Accompaniments
Nancy Stanley State of New Jersey	Technical Quality of Licensing Actions
James Pate State of Louisiana	Sealed Source and Device Evaluation Program

## APPENDIX B

### INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1  
License Type: Waste Processor  
Inspection Date: 11/17 -18/2015

License No.: R-73014-H24  
Priority: 2  
Inspectors: JM/MA

Accompaniment No.: 2  
License Type: Industrial Radiography  
Inspection Date: 11/19/2015

License No.: R-01092-A16  
Priority: 1  
Inspector: MG

Accompaniment No.: 3  
License Type: Radiopharmacy  
Inspection Date: 02/22/2016

License No.: R-19190-I24  
Priority: 2  
Inspector: GK

Accompaniment No.: 4  
License Type: Medical Diagnostic  
Inspection Date: 02/23/2016

License No.: R-16028-A16  
Priority: 5  
Inspector: AP

Accompaniment No.: 5  
License Type: HDR/Medical Therapy  
Inspection Date: 02/24/2016

License No.: R-79056-L16  
Priority: 2  
Inspector: AG

Accompaniment No.: 6  
License Type: Industrial Radiography  
Inspection Date: 02/25/2016

License No.: R-79313-D20  
Priority: 1  
Inspector: GS

Accompaniment No.: 7  
License Type: Radiopharmacy  
Inspection Date: 02/24/16

License No.: R-71029-C21  
Priority: 2  
Inspector: SB

Accompaniment No.: 8  
License Type: Service Provider/Waste Collector  
Inspection Date: 02/25/16

License No.: R-73021-E25  
Priority: 2  
Inspectors: RM/NM

**Agenda for Management Review Board Meeting  
May 24, 2016, 1:00 p.m. – 4:00 p.m. (ET), OWFN-17-B04**

1. Announcement of public meeting. Request for members of the public to indicate they are participating and their affiliation.
2. MRB Chair convenes meeting. Introduction of MRB members, review team members, State representatives and other participants.
3. Consideration of the Tennessee IMPEP Report.
  - A. Presentation of Findings Regarding Tennessee's Program and Discussion.
    - 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
    - Compatibility Requirements
    - Sealed Source and Device Evaluation Program
  - B. IMPEP Team Recommendations.
    - Recommendation for Adequacy and Compatibility Ratings
    - Recommendation for Next IMPEP Review
  - C. MRB Consultation/Comments on Issuance of Report.
4. Request for comments from Tennessee representatives, OAS Liaison, and State IMPEP team members.
5. Adjournment.

Invitees:

Scott Moore, NMSS	Michelle Sampson, OEDO
Joan Olmstead, OGC	Pamela Henderson, NMSS
Daniel Collins, NMSS	Paul Michalak, NMSS
Kriss Kennedy, RIV	Lisa Dimmick, NMSS
Sherrie Flaherty, MN, OAS	Lizette Roldan-Otero, NMSS
Randy Erickson, RIV	Karen Meyer, NMSS
Donna Janda, RI	
Kathy Modes, NMSS	
Ryan Craffey, RIII	
Nancy Stanley, NJ	
James Pate, LA	