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

September 12, 2022

David Crowley, Chief
Radiation Protection Section
Division of Health Service Regulation
5505 Creedmoor Road, 1st Floor
Raleigh, NC 27612

Dear David Crowley:

On August 11, 2022, the Management Review Board (MRB), which consisted of U.S. Nuclear Regulatory Commission (NRC) senior managers and an Organization of Agreement States manager, met to consider the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the North Carolina Agreement State Program. The MRB Chair in consultation with the MRB found the North Carolina Agreement State Program adequate to protect public health and safety and not compatible with the NRC's program.

The enclosed final report documents the IMPEP team's findings and summarizes the results of the MRB meeting. Based on the results of the current IMPEP review, the MRB directed that the next periodic meeting take place in approximately 2 years, and the next full IMPEP review to be conducted in approximately 4 years.

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

Sincerely,

Catherine Haney Signed by Haney, Cathy on 09/12/22

Catherine Haney
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, Compliance, Administration,
and Human Capital Programs
Office of the Executive Director for Operations

Enclosure:
Final 2022 North Carolina
Agreement State Program IMPEP
Report

cc: L. Brayboy, Interim Manager
Radioactive Material Branch

SUBJECT: FINAL NORTH CAROLINA AGREEMENT STATE PROGRAM INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REPORT DATED: September 12, 2022

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE NORTH CAROLINA PROGRAM

MAY 2-6, 2022

FINAL IMPEP REPORT

EXECUTIVE SUMMARY

The results of the 2022 Integrated Materials Performance Evaluation Program (IMPEP) review of the North Carolina Agreement State Program (North Carolina) are discussed in this report. The review was conducted in-person from May 2-6, 2022. In-person inspector accompaniments were conducted from April 20-22, 2022.

The team found North Carolina's performance to be satisfactory for five out of seven performance indicators reviewed. The team found North Carolina's performance satisfactory, but needs improvement, for the performance indicator Sealed Source and Device (SS&D) Evaluation Program which remains unchanged from the previous IMPEP review. The team also found North Carolina's performance unsatisfactory for the performance indicator Legislation, Regulations, and Other Program Elements.

The team determined that the 2018 IMPEP review recommendation regarding the SS&D Evaluation Program should remain open with modification and made one new recommendation regarding the Technical Quality of Inspections.

Accordingly, the team recommended and the MRB Chair agreed that the North Carolina Agreement State Program be found adequate to protect public health and safety and not compatible with the NRC's program. Based on this finding, the MRB Chair directed the NRC to conduct the next periodic meeting in approximately 2 years. The team also recommended and the MRB Chair agreed that the next IMPEP review take place in approximately 4 years.

1.0 INTRODUCTION

The North Carolina Agreement State Program (North Carolina) review was conducted from May 2-6, 2022, by a team of technical staff members from the U.S. Nuclear Regulatory Commission (NRC), the State of Texas, and the Commonwealth of Kentucky. Team members are identified in Appendix A. In-person inspector accompaniments were conducted during the week of April 18, 2022. 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 the NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated July 24, 2019. In addition, the team used Temporary Instruction TI-003, "Evaluating the Impacts of the COVID-19 Public Health Emergency as Part of Integrated Materials Performance Evaluation Program (IMPEP)," dated October 21, 2020, to evaluate the impact of the pandemic on the Program. Preliminary results of the review, which covered the period of March 10, 2018, to May 6, 2022, were discussed with North Carolina 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 North Carolina on February 25, 2022. North Carolina provided its response to the questionnaire on April 19, 2022. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) Accession Number ML22109A215.

The Agreement State Program is administered by the Radiation Protection Section (the Section) within the Division of Health Service Regulation (the Division). The Division is part of the Department of Health and Human Services (the Department). Within the Section, the Radioactive Materials Branch (the Branch) administers the radioactive materials program and performs the responsibilities of the Agreement State Program. Organization charts for North Carolina are available in ADAMS, Accession No. ML22111A265.

At the time of the review, North Carolina regulated 521 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) between the NRC and the State of North Carolina.

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 North Carolina's performance.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The 2018 IMPEP review concluded on March 9, 2018. The final report is available in ADAMS, Accession No. ML18164A259. 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: None

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

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

Sealed Source and Device (SS&D) Evaluation Program: Satisfactory, but needs improvement

Recommendation: The 2018 IMPEP team recommended that North Carolina: (1) Improve the thoroughness, completeness, accuracy, and consistency of SS&D reviews and ensure that the reviews address health and safety concerns and product integrity; (2) Improve the concurrence review process to ensure that concurrence reviewers fully assess SS&D evaluations; and (3) Ensure that each SS&D evaluation is properly documented, including all licensee correspondence, deficiency letters and responses, and memos to file. (Section 4.2 of the 2018 IMPEP report).

Status: The 2022 IMPEP team found that North Carolina has improved the thoroughness, completeness, accuracy, and consistency of SS&D reviews and ensured that the reviews address health and safety concerns and product integrity. North Carolina acquired additional hands-on training, increased the number of evaluations needed to become qualified, implemented refresher training, petitioned the National Materials Program to develop a center of excellence for SS&D reviewers, and established a lead SS&D reviewer to take ownership of the program and monitor all review activities.

The 2022 IMPEP team found that North Carolina has improved the concurrence review process to ensure that concurrence reviewers fully assess SS&D evaluations. North Carolina held regular meetings with involved staff and management through the course of evaluations to review evaluations, implemented procedures written prior to the last IMPEP and revised them accordingly after each evaluation, and ensured that only fully qualified individuals acted as primary and concurrence reviewers for evaluations.

The 2022 IMPEP team found that North Carolina had not fully ensured that each SS&D evaluation was properly documented. The correspondence documents referenced in the SS&D registry sheets were not readily accessible but were eventually located during the review. However, in terms of documenting the SS&D evaluation, the team identified several deviations in the content of the SS&D registrations and how these registrations were formatted, compared to the North Carolina adopted procedures in NUREG-1556, Volume 3.

Based on the results of the 2022 IMPEP review the team recommended that North Carolina's performance with respect to the indicator, SS&D Evaluation Program, be found satisfactory, but needs improvement and recommended that the 2018 IMPEP review recommendation remain open, but be modified to read as follows:

- The team recommends that North Carolina take action to ensure each SS&D

evaluation is properly documented to ensure the content and format of information of each evaluation is consistent with the applicable guidance provided in NUREG 1556, Volume 3.

Overall finding from the 2018 IMPEP review: 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, and 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 (SA) procedure SA-103, “Reviewing the Common Performance Indicator: Technical Staffing and Training,” and evaluated North Carolina’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

North Carolina's Agreement State Program is comprised of 11 technical staff members, 1 administrative staff member and 3 managers, which equals 15 full-time equivalents (FTE) for the radiation control program when fully staffed. Currently, there are three vacancies: one inspector, one license reviewer, and a Branch Manager, which is being filled in an acting capacity by the Licensing Supervisor. During the review period, seven staff members left the program and six staff members were hired. The positions were vacant from 6 to 15 months; however, the was no impact on program performance or public health and safety. North Carolina has a training and qualification program compatible with the NRC's IMC 1248, and all qualified licensing and inspection staff completed at least 24 hours of applicable refresher training every two years.

No impacts were noted in this indicator related to the pandemic. The team did note an elevated level of turnover during the review period; however, North Carolina was able to fill vacancies in a timely fashion with highly qualified new hires, all of which have made substantial progress in the State's qualification program and expect to be fully qualified within the next 1.5-2 years.

c. Evaluation

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

d. Management Review Board (MRB) Chair's Determination

The MRB Chair agreed with the team's recommendation and found North Carolina's performance with respect to this indicator satisfactory.

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 SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated North Carolina'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

North Carolina performed 574 priority 1, 2, 3 inspections and initial inspections during review the period. Of these, North Carolina performed 4 of 540 priority 1, 2, and 3 inspections overdue and 3 of 34 initial inspections overdue, or approximately 1 percent overdue overall. These inspections had all been completed by the time of the review, and no priority 1, 2, 3 inspections or initial inspections were overdue at the time of the review.

The team noted that TI 003, "Evaluating the Impacts of the COVID-19 PHE as part of the Integrated Materials Performance Evaluation Program" states, in part, that for inspections that exceed the scheduling window with overdue dates falling inside the defined time frame of the pandemic, the number of overdue inspections should be noted in the report but should not be counted in the calculation of overdue inspections described in SA-101, Appendix A, provided that North Carolina continues to maintain health, safety, and security.

All the overdue inspections noted above were impacted by the pandemic and occurred during the pandemic time frame as established by North Carolina. Moreover, the State continued to maintain public health, and safety, and security. Consistent with TI-003, these overdue inspections were not counted in the calculation of overdue inspections, therefore, no inspections were considered overdue.

North Carolina's inspection frequencies are the same, or in some cases more frequent, as those for similar license types in the NRC's program.

A sampling of 23 inspection reports and review of all report timeliness data indicated that three of the inspection findings were communicated to the licensees beyond North Carolina's goal of 30 days after the inspection exit or 45 days after the team inspection exit. The delay in communicating findings to one of the licensees was due to an extended review period for the inspection findings; the other two were due to transitory increases in workload for the inspectors due to staff turnover.

In 2021, North Carolina conducted a risk-informed analysis in response to recent changes to IMC 2800. North Carolina uses this analysis and the associated process changes to identify which reciprocity applicants should be considered candidates for inspection. The team reviewed the criteria in the State's procedure and the reciprocity inspections that it conducted during the review period. The team determined that North Carolina performed reciprocity inspections in accordance with its risk-informed reciprocity procedure.

c. Evaluation

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

d. MRB Chair's Determination

The MRB Chair agreed with the team's recommendation and found North Carolina's performance with respect to this indicator satisfactory.

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 SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated North Carolina'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 23 inspection reports and associated enforcement documentation. The team also interviewed inspectors involved in materials inspections conducted during the review period. The team reviewed casework for inspections conducted by nine of North Carolina's current and former inspectors, covering medical, industrial, commercial, academic, research, and service licenses.

A team member accompanied three inspectors on April 20-22, 2022. The inspector accompaniments were conducted in-person and are identified in Appendix B. The inspectors were thorough and assessed the impact of licensed activities on health, safety, and security.

During one of the accompaniments and through subsequent interviews with staff during the on-site review, the team identified a knowledge gap related to emerging medical technologies. Specifically, an inspector did not recognize that the model of gamma knife being inspected during an inspection accompaniment was licensed as an emerging medical technology. That is, this model was subject to North Carolina's equivalent regulation to Title 10 of the *Code of Federal Regulations* (10 CFR) Section 35.1000 and associated guidance, rather than North Carolina's equivalent regulation to 10 CFR Part 35 Subpart H. Specifically, the team observed during the accompaniment that, the inspector was unfamiliar with the written directive requirements associated with this model of gamma knife and incorrectly used the requirements stated in North Carolina's regulation equivalent to 10 CFR 35.40. The difference in written directive requirements was brought to the inspector's attention during the on-site accompaniment. It is important for inspectors to understand the written directive requirements for medical modalities so that they can ensure that the appropriate information is contained on the written directive and identify medical events licensees may have missed. The team determined that the security portion of the inspection was completed appropriately. The team identified no other performance concerns during the other two inspector accompaniments.

Emerging medical technologies are currently authorized at a limited number of licensed facilities in a North Carolina, potentially making it difficult for inspectors to become familiar with the technology. As an example, only two gamma knife devices of the model discussed above exist in North Carolina. In addition, these technologies are sometimes similar to those licensed under the conventional subparts of 10 CFR Part 35. Therefore, the team determined that additional training would be beneficial to help staff conduct high quality inspections on emerging medical technologies. The team recommends that North Carolina provide additional training to its staff on emerging medical technologies subject to its equivalent to 10 CFR 35.1000, as applicable to its regulatory program.

The team noted that North Carolina maintained sufficient instrumentation for inspectors to conduct independent and/or confirmatory measurements that were calibrated at appropriate intervals and were appropriate for the types of licensed activities inspected.

Supervisory accompaniments of qualified inspectors were performed in all years of the review period except for 2019 and 2020. In 2019, one supervisory accompaniment was missed because of an unexpected medical issue with a staff member. In 2020, only one supervisory accompaniment was performed because inspections were suspended, and limited staff was available during the pandemic. Supervisory accompaniments resumed in 2021 and all qualified inspectors were subsequently accompanied. The team noted that TI-003 states, in part, that if these impacts to supervisory accompaniments were outside of the Program's control, they should not be considered by the IMPEP team when establishing the overall indicator rating. Therefore, the team did not consider the missed supervisory accompaniments that occurred in calendar year 2020 when establishing the overall indicator rating.

c. Evaluation

The team determined that North Carolina met all performance indicator objectives listed in Section 3.3.a, except for the following:

- Emerging medical technology inspections of the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ did not focus on all aspects of licensed activities encompassing health and safety.

Specifically, during the IMPEP inspector accompaniments, the team identified a knowledge gap related to emerging medical technologies. The team determined that even though the device was not identified as an emerging medical technology, many of the health and safety requirements (and all security requirements) were correctly inspected, since many aspects of emerging medical technology guidance reference 10 CFR Part 35 Subpart H. Additionally, the team determined that the other two observed inspector accompaniments were complete and addressed all aspects of health, safety, and security. Therefore, the team did not identify a programmatic weakness in the conduct of inspections by North Carolina.

As such, the team determined that, although one of the bullets in 3.3.a was not fully met, a recommendation to downgrade North Carolina's performance under this performance indicator was not warranted. However, the team recommends that:

- North Carolina provide additional training to its staff on emerging medical technologies subject to its equivalent to 10 CFR 35.1000, as applicable to its regulatory program.

Based on the IMPEP evaluation criteria in MD 5.6, the team also recommended that North Carolina's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

d. MRB Chair's Determination

The MRB Chair agreed with the team's recommendation and found North Carolina's performance with respect to this indicator 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, as well as security. An assessment of licensing procedures, implementation of those procedures, and documentation of communications and associated actions between the North Carolina 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 SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated North Carolina'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 of the *Code of Federal Regulations* (10 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, North Carolina performed 1,682 radioactive materials licensing actions, which included 19 new applications and 91 terminations. The team evaluated 25 of these licensing actions: 4 new applications, 15 amendments, 2 renewals, and 4 terminations. The team evaluated casework that included the following license types and actions: academic and medical broad scope, veterinary, medical diagnostic and therapeutic, commercial manufacturing and distribution, industrial radiography, nuclear pharmacy, portable gauges, financial assurance, and transfers of control. The casework sample represented work from three full-time and two part-time license reviewers.

Since the 2018 IMPEP, North Carolina has updated its licensing procedures to use the NRC's Web-Based Licensing (WBL) system (adopted April 1, 2018). The team found that licensing actions were complete, thorough, and of adequate technical quality, with health, safety, and security issues properly addressed. The licensing cases reviewed demonstrated that proper guidance (including pre-licensing and risk-significant radioactive materials guidance) was followed. All necessary licensee commitments were obtained, and deficiency letters and license conditions were well supported by information contained in the licensing files. The reviewers followed-up such actions in a timely fashion. Terminated licensing actions were well documented, showing appropriate transfer and final status surveys, as appropriate.

Some minor typographical and administrative errors were noted; however, none impacted the technical quality of any action. The most notable of these issues was the occasional absence of documentation confirming that licensees provided adequate financial assurance for future decommissioning activities; however, where applicable, all the licensees did provide adequate financial assurance. The program committed to include the existing financial assurance worksheet in standard checklist templates for all license actions.

No impacts were noted in this indicator due to the pandemic.

c. Evaluation

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

d. MRB Chair's Determination

The MRB Chair agreed with the team's recommendation and found North Carolina's performance with respect to this indicator satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

The quality, thoroughness, and timeliness of response to incidents and allegations of safety concerns can have a direct bearing on public health, 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 SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated North Carolina'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 (HOO) 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, 104 incidents were reported to North Carolina, of which 38 were reported to the HOO. The team evaluated 10 of the 38 radioactive materials incidents reported to the HOO: two lost or stolen radioactive materials, five medical events, two radiography source disconnects, and one stuck radiography source. North Carolina dispatched inspectors for on-site follow-up in a timely fashion for all cases reviewed.

When notified of an incident, program management and staff meet to discuss the incident and determine the appropriate level of response, which could range from an immediate on-site response to reviewing the incident during the next routine inspection. Those determinations are made based on both the circumstances and the health and safety significance of the incident. The team found that North Carolina's evaluation of incident notifications and its response to them was thorough, well balanced, complete, and comprehensive.

The team also evaluated the North Carolina reporting of incidents to the HOO. The team noted that in each case requiring HOO notification, North Carolina reported the incidents within the required time frame. The team also evaluated whether North Carolina had missed any opportunities to report a required incident to the HOO. The team did not identify any such missed reports.

During the review period, 16 allegations were received by North Carolina. The team evaluated 10 allegations, including 6 allegations that the NRC referred to North Carolina, during the review period. The team determined that the allegations were investigated promptly and that concerned individuals were informed of the results of the investigation and their identities were protected as allowed by law.

No impacts were noted in this indicator due to the pandemic.

c. Evaluation

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

d. MRB Chair's Determination

The MRB Chair agreed with the team's recommendation and found North Carolina's performance with respect to this indicator satisfactory.

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) SS&D Evaluation Program; (3) Low-Level Radioactive Waste (LLRW) Disposal Program; and (4) Uranium Recovery Program. The NRC retains regulatory authority for Uranium Recovery Programs; therefore, only the first three 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 website at the following address: https://scp.nrc.gov/regtoolbox.html.

a. Scope

The team used the guidance in SA-107, "Reviewing the Non-Common Performance Indicator: Legislation, Regulations, and Other Program Elements," and evaluated North Carolina'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 of 1954, 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, "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, 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

North Carolina became an Agreement State on August 1, 1964. The North Carolina Agreement State Program's current effective statutory authority is contained in Chapter 104E of the North Carolina General Statutes (NCGS). In Section 104E-6, the Department is designated as North Carolina's radiation control agency.

The team found that during the previous review period, North Carolina's regulations became subject to "sunset" laws. The details of this requirement are discussed in NCGS 150B known as "The Administrative Procedures Act." The Administrative Procedures Act imposes periodic review of all North Carolina regulations and sets them to expire every 10 years unless they are re-adopted. Under the current sunset period, all regulations must be re-adopted by February 28, 2027, or they will expire.

NCGS 105B also requires a change in how the rules are written. Previously, the Section copied the text from the 10 CFR, made whatever changes it deemed necessary, and placed that text into rules that then went through the rule adoption process. Under NCGS 105B, repeating the text of a federal regulation is no longer permitted, so a complete re-write of the rule is required for readoption.

To adhere to these requirements, the Section and the Radiation Protection Commission settled on incorporating each Part of 10 CFR by reference. The Section began with writing Rule 10A of the North Carolina Administrative Code, Section 15.1301, which incorporates 10 CFR Part 39 by reference. This rule was in the public comment period at the time of the IMPEP review. Other rules are in development, each incorporating different Parts of 10 CFR. The Section expects to fully complete the adoption of the 10 CFR by reference, by the end of 2025.
North Carolina's administrative rulemaking process takes approximately 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. The North Carolina Radiation Protection Commission (RPC) is the statutorily authorized body to adopt these rules and is responsible for drafting and promulgating North Carolina's radiation regulations. The RPC approves when the rules are ready for public comment, resolves comments, and approves when to submit a final rule to Office of Administrative Hearings, to be made effective.

During the review period, North Carolina submitted one proposed regulation amendment, no final regulation amendments, and no legally binding requirements or license conditions to the NRC for a compatibility review. At the time of this review, the following two regulation amendments were overdue:

- "Miscellaneous Corrections – Organizational Changes," 10 CFR 37, 40, 70, and 71 amendment (83 CFR 57321), which was due for Agreement State adoption by December 21, 2021.
- "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," 10 CFR Parts 30, 32, and 35 amendment (83 FR 33046), which was due for Agreement State adoption by January 14, 2022.

Additionally, in reviewing the regulations currently in place in North Carolina, the team noted that there are 45 compatibility comments that have not been addressed. These comments were provided to North Carolina in NRC letters dated May 13, 2014 (ADAMS Accession No. ML14111A021), and September 6, 2017 (ADAMS Accession No. ML17223A370). These comments include:

- Twenty-two comments on regulations whose authority is solely that of the NRC.
- Eight comments on regulations designated as a compatibility category B, which are considered significant under SA-107.
- Eight comments on regulations designated as a compatibility category C.
- Three comments on regulations designated as a compatibility Category H&S.
- Two comments covering multiple sections and compatibility categories, including changes to compatibility category B regulations (also significant under SA-107).

The 45 outstanding comments relate to the following 13 amendments:

- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30, 31, and 32 amendment (65 FR 79162), which was due for Agreement State adoption by February 16, 2004.
- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendment (67 FR 20249), which was due for Agreement State adoption by October 24, 2005.

- “Medical Use of Byproduct Material – Minor Corrections and Clarifications,” 10 CFR parts 32 and 35 (72 FR 45147, 54207), which was due for Agreement State adoption by October 29, 2010.
- “Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements,” 10 CFR Parts 30, 31, 32, and 150 amendment (72 FR 58473), which was due for Agreement State adoption by December 17, 2010.
- “Requirements for Expanded Definition of Byproduct Material,” 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendment (72 FR 55864), which was due for Agreement State adoption by November 30, 2010.
- “Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent,” 10 CFR Parts 19 and 20 amendment (72 FR 68043), which was due for Agreement State adoption by February 15, 2011.
- “Decommissioning Planning,” 10 CFR Parts 20, 30, 40, and 70 amendment (76 FR 35512), which was due for Agreement State adoption by December 17, 2015.
- “Licenses, Certifications, and Approvals for Materials Licensees,” 10 CFR Parts 30, 36, 39, 40, 70, and 150 amendment (76 FR 56951), which was due for Agreement State adoption by November 14, 2014.
- “Requirements for Distribution of Byproduct Material,” 10 CFR Parts 30, 31, 32, 40 and 70 amendment (77 FR 43666), which was due for Agreement State adoption by October 23, 2015.
- “Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions,” 10 CFR Parts 30, 40, and 70 amendment (78 FR 32310), which was due for Agreement State adoption by August 27, 2016.
- “Domestic Licensing of Special Nuclear Material – Written Reports and Clarifying Amendments,” 10 CFR Part 70 amendment (79 FR 57721, 80 FR 143), which was due for Agreement State adoption by January 26, 2018.
- “Safeguards Information - Modified Handling Categorization, Change for Materials Facilities,” 10 CFR Parts 30, 37, 73, and 150 amendment (79 FR 58664, 80 FR 3865), which was due for Agreement State adoption by January 28, 2018.
- “Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements,” 10 CFR Part 71 amendment (80 FR 33987), which was due for Agreement State adoption by August 15, 2020.

North Carolina is working on a readoption of its rules to incorporate by reference all parts of 10 CFR required for compatibility. This is being done to address NCGS 105B. North Carolina stated that once it became aware of the requirements being put in place by NCGS 105B, it decided to focus solely on the adoption of the 10 CFR by reference. As each 10 CFR Part is adopted by reference, the State intends to address any associated comments at that time.

The team reviewed guidance documents that North Carolina 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. All changes to these documents were made within 6 months of the NRC’s changes and were determined to be compatible.

c. Evaluation

The team determined that, during the review period, North Carolina met several of the performance indicator objectives listed in Section 4.1.a. However, the new regulatory process in North Carolina has created significant delays in addressing regulatory changes. Because of the requirements put in place in 2017 under NCGS 105B, North Carolina focused on adoption of all compatible parts of the 10 CFR by reference, which is expected to be complete by the end of 2025. As a result, certain actions have lagged:

- Two regulations requiring adoption by the Agreement State for purposes of compatibility or health and safety (Category H&S) were not adopted within 3 years after the effective date of the NRC regulation. Of these two, one consists of minor corrections and the other involves several important changes to 10 CFR Parts 30, 32, and 35.

- North Carolina has 45 outstanding comments covering 13 regulation amendment changes. These comments are reflected in NRC letter transmitting the results of the review of final regulations in May 2014 and September 2017. Of those 45 comments, several are significant and impact regulations designated as compatibility category B.

North Carolina reviewed the outstanding comments, determined that there were no public health and safety gaps created by the delay in adopting the amendments to the regulations. North Carolina would have implemented license conditions to address any such gaps had one been identified. North Carolina also confirmed that they would continue to review new comments for public health and safety gaps until the rule in question is adopted by reference.

North Carolina's delay in implementing adopting these regulations and addressing these compatibility comments may create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of radioactive materials under the Atomic Energy Act of 1954, as amended. The current plan to address these issues extends through 2025. Based on the IMPEP evaluation criteria in MD 5.6, the team recommended that North Carolina's performance with respect to the indicator, Legislation, Regulations, and Other Program Elements, be found unsatisfactory.

d. MRB Chair's Determination

The MRB Chair agreed with the team's recommendation and found North Carolina's performance with respect to this indicator unsatisfactory.

4.2 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&Ds, 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 SA-108, "Reviewing the Non-Common Performance Indicator: SS&D Evaluation Program," and evaluated North Carolina'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

North Carolina has three staff qualified to perform SS&D reviews. Currently, there are no vacancies. During the review period, one of the SS&D staff members left the program and one staff member was hired. The position was vacant for 6 months. North Carolina has a training program equivalent to the NRC training requirements listed in the NRC's IMC 1248, Appendix D.

During the review period, two individuals successfully completed their SS&D reviewer qualifications. In the SS&D reviewer training program, North Carolina has increased the number of mentored casework files from three cases to six cases and requires that three of the cases include one each of a medical device, a gauge, and a tritium application.

North Carolina has implemented a team approach to reviewing SS&D actions. Review staff meet and discuss the SS&D application prior to issuing the first deficiency letter. This process ensures all SS&D review staff remain current in reviewing applications and aids the training of new SS&D review staff.

During the time when North Carolina had only one qualified SS&D reviewer, they used qualified SS&D reviewers from the NRC and two other Agreement States as concurrence reviewers. Only qualified reviewers signed the SS&D registry sheets.

Technical Quality of the Product Evaluation

North Carolina has five SS&D licensees. The team evaluated nine of ten SS&D actions processed during the review period. These actions included three amendments, one correction, and five inactivation's. The team did not review the one transfer to another Agreement State.

North Carolina uses the NRC's NUREG-1556, Volume 3, as its standard operating procedure for performing the SS&D reviews.

During the 2022 IMPEP review of the SS&D amendments and inactivation's, North Carolina requested additional information from the applicant to update and complete the registration certificate contents. The additional information included in the amended SS&D registry sheets addressed deficiencies in the prior registry sheets.

The February 2018 changes to the review process procedures ensured that the SS&D evaluations addressed the health and safety concerns and product integrity.

The team found that the SS&D reviewers do not always follow the criteria in NMSS Procedure SA-108 and North Carolina's incorporation by reference of NUREG-1556, Volume 3. The team identified several deviations in the content of the SS&D registrations and how the SS&D registrations were formatted, compared to the procedures in NUREG-1556, Volume 3, that were adopted by the State.

The content deviations in North Carolina SS&D registrations may impact the clarity of information provided to the user of the SS&D included the following:

- One SS&D registry sheet had the incorrect "principal use code" listed, as identified in the NUREG.
- Two of the four registry sheets for generally licensed devices did not have the general license criteria identified in the safety analysis summary, as identified in the NUREG.

The format deviations in North Carolina SS&D registrations that may impact the clarity of information provided to the user of the SS&D included the following:

- In six of nine SS&D actions reviewed, the format of the SS&D page one information was inconsistent with the format specified in the NUREG. Specifically, the sealed source model numbers were combined with the isotope and activity of the devices instead of being called out in separate sections.
- In three of the five actions for inactivation, the document headers stated that the registrations were amended when they were a newly issued inactivation certificate.
- Two of the five actions for inactivation retained the radiation profiles in an attachment instead of including it in the body of the SS&D under "External Radiation Levels."

The above deviations in the content and formatting of the SS&D registrations affect the clarity of the SS&D product evaluation that license reviewers use to license the possession and use of the product. More than a few, but less than most, of the

registrations do not summarize the product evaluation and provide license reviewers with adequate information to license possession and use of the product.

North Carolina maintains SS&D documents of record as electronic files located on their computer network drive and uses WBL as a backup for records retention. While the State has access to WBL, the State does not currently use WBL for tracking SS&D actions.

Three of the three SS&D amendment evaluations did not have all the referenced correspondence documents used for the amendment readily available, especially for the dates listed in the reference section of the registry sheet. The documents identified by date in the references section become part of the enforceable commitments and documentation used in the product evaluation. The documents were eventually located and added to the electronic file folder for the SS&D action.

Based on the issues identified above, the team recommended that North Carolina take action to ensure that each SS&D evaluation is properly documented and the content and format of information of each is consistent with NUREG 1556, Volume 3.

Evaluation of Defects and Incidents Regarding SS&Ds

The team evaluated the one closed incident involving a North Carolina SS&D registered product during the review period. The incident was not caused by a manufacturing or design deficiency of the North Carolina SS&D registered product.

As a result of the incident investigation finding, North Carolina issued an Information Notice to portable gauge service providers to highlight the specific device safety inspection points during maintenance activities as identified in the current SS&D. A copy of the Information Notice is on North Carolina's webpage.

North Carolina was actively investigating an open incident involving a North Carolina SS&D registered product. The team did not evaluate the ongoing incident investigation.

c. Evaluation

The team determined that, during the review period, North Carolina met the performance indicator objectives listed in Section 4.2.a, except for:

- Some SS&D evaluations were not adequate, accurate, complete, clear, specific, and consistent with the guidance in NUREG-1556, Volume 3.

The team identified several issues with applying the SS&D registration formats in accordance with North Carolina's procedure that incorporates NUREG-1556, Volume 3. These inconsistencies affected the clarity of the product evaluation and their ability to provide license reviewers with adequate information to license the possession and use of the product.

In 2018 the team recommended that North Carolina: (1) improve the thoroughness, completeness, accuracy, and consistency of SS&D reviews and ensure that the reviews address health and safety concerns and product integrity; (2) improve the concurrence review process to ensure that concurrence reviewers fully assess SS&D evaluations; and (3) ensure that each SS&D evaluation is properly documented, including all licensee correspondence, deficiency letters and responses, and memos to file.

The team found that North Carolina has improved the thoroughness, completeness, accuracy, and consistency of SS&D reviews and ensured that the reviews address health and safety concerns and product integrity. The team determined that this part of the recommendation could be considered closed.

The team found that North Carolina has improved the concurrence review process to ensure that concurrence reviewers fully assess SS&D evaluations. The team determined that this part of the recommendation could be considered closed.

The team found that North Carolina has not fully ensured that each SS&D evaluation is properly documented. North Carolina is not always consistent with the SS&D content and format in NUREG-1556, Volume 3. The team determined that this part of the recommendation should not be considered closed, and that the original recommendation should be modified to retain this part only.

Based on the IMPEP evaluation criteria in MD 5.6, the team recommended that North Carolina's performance with respect to the indicator, SS&D Evaluation Program, be found satisfactory, but needs improvement.

d. MRB Chair's Determination

The MRB Chair agreed with the team's recommendation and found North Carolina's performance with respect to this indicator satisfactory but needs improvement.

4.3 LLRW Disposal Program

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

5.0 SUMMARY

North Carolina's performance was found to be satisfactory for five out of seven performance indicators reviewed. The team found North Carolina's performance satisfactory, but needs improvement, for the performance indicator SS&D Evaluation Program. The team found North Carolina's performance unsatisfactory for the performance indicator Legislation, Regulations, and Other Program Elements.

The team made the following new recommendation for the performance indicator, Technical Quality of Inspections:

- North Carolina provide additional training to its staff on emerging medical technologies subject to its equivalent to 10 CFR 35.1000, as applicable to its regulatory program.

The team also recommended that the 2018 IMPEP review recommendation regarding improvements to the SS&D Evaluation Program should remain open with the following modification:

- North Carolina take action to ensure each SS&D evaluation is properly documented to ensure the content and format of information of each evaluation is consistent with the applicable guidance provided in NUREG 1556, Volume 3.

Accordingly, the team recommended and the MRB Chair agreed that North Carolina be found adequate to protect public health and safety and not compatible with the NRC's program. Based on this finding, the team recommended that the NRC conduct two periodic meetings, one approximately 18 months and another in approximately 36 months, with the next full IMPEP review take place in approximately four years. However, based on discussion during the MRB meeting, the MRB Chair directed the NRC to conduct the next periodic meeting in approximately 2 years. The MRB Chair also agreed with the team’s recommendation that the next IMPEP review take place in approximately four years.

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Areas of Responsibility**
Ryan Craffey, Region III	Team Leader Technical Staffing and Training
Monica Ford, Region I	Technical Quality of Inspections Inspector Accompaniments Legislation, Regulations, and Other Program Elements
Leo Wardrobe, Region IV	Status of Materials Inspection Program Technical Quality of Incident and Allegation Activities
Anjan Bhattacharyya, Commonwealth of Kentucky	Technical Quality of Licensing Actions
Karl Von Ahn, State of Texas	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.: 074-1457-2
License Type: Gamma Stereotactic Radiosurgery	Priority: 2
Inspection Date: 04/20/2022	Inspector's initials: CS

Accompaniment No.: 2	License No.: 019-1117-3
License Type: Industrial Radiography	Priority: 1
Inspection Date: 04/21/2022	Inspector's initials: TM

Accompaniment No.: 3	License No.: 051-1523-1
License Type: Medical Institution Limited Scope	Priority: 3
Inspection Date: 04/22/2022	Inspector's initials: KB