



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

April 4, 2018

Mr. W. Lee Cox, III, Chief  
Radiation Protection Section  
Division of Health Service Regulation  
Department of Health and Human Services  
One Crosspointe Plaza  
5505 Creedmoor Road, 1<sup>st</sup> Floor  
Raleigh, NC 27609

Dear Mr. Cox:

The U.S. Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the evaluation of Agreement State programs. Enclosed for your review is the draft IMPEP report, which documents the results of the Agreement State review held in North Carolina on March 5 – 9, 2018. The team's preliminary findings were discussed with you and your staff on the last day of the review. The team's proposed recommendations are that the North Carolina Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program.

The NRC conducts periodic reviews of Agreement State programs to ensure that public health and safety are adequately protected from the potential hazards associated with the use of radioactive materials and that Agreement State programs are compatible with the NRC's program. The process, titled IMPEP, employs a team of NRC and Agreement State staff to assess Agreement States' and NRC Regional Offices' radioactive materials programs. All reviews use common criteria in the assessment and place primary emphasis on performance. The final determination of adequacy and compatibility of each Agreement State program, based on the team's report, is made by a Management Review Board (MRB) composed of NRC managers and an Agreement State program manager who serves as a liaison to the MRB.

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

The team will review the response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. The MRB meeting is scheduled for Thursday, June 7, 2018, at 1:00 p.m. ET. The NRC will provide invitational travel for you or your designee to attend the MRB meeting at the NRC Headquarters in Rockville, Maryland. The NRC has video conferencing capability if it is more convenient for the State to participate through this medium. Please contact me if you desire to establish a video conference for the meeting.

If you have any questions regarding the enclosed report, please contact me at 301-415-5804.

Thank you for your cooperation.

Sincerely,

*/RA/*

Paul Michalak, Chief  
Agreement State Programs Branch  
Division of Material Safety, State, Tribal, and  
Rulemaking Programs  
Office of Nuclear Material Safety and Safeguards

Enclosure:  
2018 Draft IMPEP Report

SUBJECT: NORTH CAROLINA FY2018 DRAFT IMPEP REPORT

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM  
REVIEW OF THE NORTH CAROLINA AGREEMENT STATE PROGRAM

March 5 – 9, 2018

**DRAFT REPORT**

Enclosure

## EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the North Carolina Agreement State Program. The review was conducted during the period of March 5 – 9, 2018, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Kansas.

Based on the results of this review, the team recommends that North Carolina's performance be found satisfactory for all applicable indicators, except for the non-common performance indicator, Sealed Source and Device (SS&D) Evaluation Program, which the team recommends be found satisfactory, but needs improvement.

The team made two recommendations (see Section 5.0) and believes that the recommendations from the 2014 IMPEP review should be closed (see Section 2.0).

Accordingly, the team recommends that the North Carolina Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. When weaknesses in a program result in, or could result in, less than fully satisfactory performance for one or more performance indicators, the NRC's Management Directive 5.6 states that the Management Review Board (MRB) should consider whether Monitoring by the NRC is warranted. The team discussed whether or not it believed Monitoring was appropriate based on the satisfactory, but needs improvement, finding for the indicator SS&D Evaluation Program. Based on North Carolina's willingness and promptness to correct the deficiencies with its SS&D Evaluation Program and the low volume of actions processed by the staff each year, the team believes North Carolina does not warrant Monitoring. Instead, the team is recommending that a periodic meeting take place in approximately 1 year with the intent to conduct the next IMPEP review in 4 years. The meeting should include an extended discussion on North Carolina's SS&D evaluation program. This timing would give North Carolina time to take actions to address the deficiencies noted in Section 4.2. Depending upon the progress noted at the time of the periodic meeting, the MRB may choose to direct a period of Monitoring, a followup review, a second periodic meeting, or alter the timing of the next full IMPEP review.

## 1.0 INTRODUCTION

This report presents the results of the review of the North Carolina Agreement State Program radioactive materials safety program. The review was conducted during the period of March 5 – 9, 2018, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Kansas. Team members are identified in Appendix A. The review was conducted in accordance with the “Agreement State Program Policy Statement,” published in the *Federal Register* on October 18, 2017, and NRC Management Directive (MD) 5.6, “Integrated Materials Performance Evaluation Program (IMPEP),” dated February 26, 2004. Preliminary results of the review, which covered the period of March 8, 2014, to March 9, 2018, were discussed with North Carolina management on the last day of the review.

In preparation for the review, a questionnaire addressing the common performance indicators and applicable non-common performance indicator was sent to North Carolina on January 2, 2018. North Carolina provided its response to the questionnaire on February 23, 2018. A copy of the questionnaire response is available in the NRC’s Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML18057A054.

The North Carolina 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, which performs the majority of responsibilities of the Agreement State program. Organization charts for North Carolina are available in ADAMS (Accession Number ML18057A042).

At the time of the review, the North Carolina Agreement State Program regulated 569 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of 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 Agreement State Program’s performance.

## 2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on March 7, 2014. The final report is available in ADAMS (Accession Number ML18057A042). The results of the review and the status of the recommendations are as follows:

Technical Staffing and Training: Satisfactory, but Needs Improvement

Recommendation 1: The review team recommends that the State update its training qualification program to be consistent with NRC Inspection Manual Chapter (IMC) 1248, "Formal Qualification Program for Federal and State Material and Environmental Management Programs" and the State apply this program to all technical staff currently going through the qualification process and all new staff that are hired.

Status: In July 2015, the Branch revised its training and qualification manual to make it consistent with IMC 1248. The revised manual is being used by all staff currently going through the qualification process and will be applied to new staff hired by the Branch. The Branch Manager now meets monthly with staff in the qualification track to review progress and ensure staff is receiving the training, both formal and on-the-job, as needed. The Branch Manager is also tracking all refresher training for qualified staff. Additionally, the Branch has implemented a more restrictive requirement of 40 hours of refresher training every two years for qualified staff.

This team believes that this recommendation should be closed.

#### Status of Materials Inspection Program: Satisfactory, but Needs Improvement

Recommendation 2: The review team recommends that the State implement procedures and a new tracking system to ensure that less than 10 percent of Priority 1, 2, and 3 and initial inspections are completed overdue.

Status: Since the last IMPEP review, North Carolina has actively worked to conduct inspections the month they are due. North Carolina uses the distributed version of the NRC's web based licensing (WBL) system. North Carolina has established new queries and reports in WBL so management can adequately track upcoming inspections. These reports provide information regarding new licenses issued, as well as initial and routine inspection due dates. Additionally, North Carolina has established several inspection frequencies that are more restrictive than the NRC's. Increasing the inspection frequency gives the Branch a greater window to conduct inspections on time in comparison to NRC's inspection frequencies. Lastly, North Carolina established a new role for quality assurance and control reviews of inspection reports. This role was assigned to a senior staff member who is responsible for ensuring that the next inspection due date is captured accurately in WBL by the inspector after completing an inspection. All of these actions taken by North Carolina contributed to the State performing only 3.8 percent of Priority 1, 2, 3, and initial inspections overdue during the current review period.

The team believes that this recommendation should be closed.

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 (SS&D) Evaluation Program: Satisfactory, but Needs Improvement

Recommendation 3: The review team recommends that the State identify, develop and Implement processes to ensure official sealed source and device registry documents are complete, legible, accounted for, and are readily accessible to those who are determined to have a need to know the information.

Status: North Carolina developed and implemented a procedure that provides staff members with instruction on how to review sealed source and device applications and issue certificates. The procedure established roles and responsibilities for the Branch staff and provided instruction on how to receive and upload electronic copies of application material to WBL and to a shared drive. This procedure was implemented in February 2018.

Because North Carolina fulfilled portions of this recommendation, the team believes that this recommendation should be closed; however because of continued weaknesses in North Carolina's SS&D program, the team opened a new recommendation (see Section 4.2).

Overall finding: Adequate to protect public health and safety, but needs improvement, 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, 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 explored. Review of staffing also requires consideration and evaluation of the levels of training and qualification. The evaluation standard measures the overall quality of training available to, and taken by, materials program personnel.

##### a. Scope

The team used the guidance in State Agreements procedure SA-103, "Reviewing the Common Performance Indicator: Technical Staffing and Training," and evaluated 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.
- Agreement State training and qualification program is equivalent to IMC 1248.
- Qualification criteria for new technical staff are established and are 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.
- 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 Branch is comprised of 14.5 full time equivalents (FTE) which includes: the Branch Manager; a security and response lead; 4 license reviewers; 4 inspectors; an environmental consultant and quality assurance reviewer, a general license coordinator, an environmental program coordinator; a license reviewer and inspector; and an administrative assistant and reciprocity coordinator. There were no vacancies at the time of the review.

While evaluating this indicator, the team considered the number of staff who have left the Branch over the review period and how those losses could potentially impact the Branch's performance. Over the review period, three staff left the program for various reasons and seven staff were hired, including the Branch Manager. One staff left the Branch in 2014 to pursue an additional degree and two in 2016; one retired and the other left to seek other opportunities. New staff were hired within 5-7 months in each case; however as the Branch increased FTE during the review period, the loss of staff had minimal impact. The team determined that the Branch has sufficient staff to carry out the responsibilities of the Agreement State Program and a good balance between licensing and inspection staffing levels.

As mentioned in North Carolina's response to the questionnaire, the Branch was in the process of reorganizing. This reorganization is meant to increase efficiency in the management of the Branch and provide advancement opportunity for staff; however the reorganization was not completed before the onsite review.

As noted in Section 2.0, North Carolina has implemented a qualification and training manual that is consistent with NRC's IMC 1248. The training program is managed by the Branch Manager who meets regularly, currently monthly, with staff under qualification and guides them through the training process. The Branch Manager also determines when staff are sufficiently trained to work independently while performing licensing and inspection-related activities, including partial qualification for certain activities.

Since implementing the new training and qualification program, staff understand the Branch Manager's expectations in terms of training and are qualified in an appropriate amount of time. At the time of the review, there were three staff members in different stages of qualification, as well as one staffer who achieved full licensing qualification just prior to the review. Several staff are receiving training and experience to become qualified to perform both licensing and inspection in certain cases. Staff spoke highly of the Branch Manager's commitment to training, as well as the Branch's use of team inspections, and peer and mentor reviewing of activities.

c. Evaluation

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

d. MRB Decision

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

3.2 Status of 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 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 team used the guidance in State Agreements procedure 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 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

North Carolina performed 505 Priority 1, 2, 3, and initial inspections during the review period. Of those inspections, 10 Priority 1, 2, and 3 and 8 initial inspections were conducted overdue for a total of 3.8 percent of Priority 1, 2, 3, and initial inspections completed overdue. Section 2.0 discussed some of the steps the Branch took to ensure inspections were conducted on time following the 2014 IMPEP review. North Carolina's inspection frequencies are the same as, and in some instances more frequent than, the NRC's inspection frequencies for similar license types in IMC 2800.

A sampling of 25 inspection reports indicated that 3 inspection findings were communicated to licensees beyond North Carolina's goal of 30 days after the inspection exit. The three findings issued beyond 30 days occurred early in the review period. During the review period, North Carolina updated its procedures and added time frames to its administrative processes to ensure inspection findings are issued timely. Inspection findings sampled in the second half of the review period were all issued within 30 days of the inspection exit.

The team evaluated North Carolina's performance of reciprocity inspections throughout the review period. The team determined that during each year of the review period, North Carolina performed greater than 20 percent of candidate reciprocity inspections.

c. Evaluation

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

d. MRB Decision

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

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 an Agreement State's inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated 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 consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated the inspection reports, enforcement documentation, and interviewed inspectors involved in 30 materials inspections conducted during the review period. The casework reviewed included inspections conducted by eight of North Carolina's inspectors and covered industrial radiography, academic, broad scopes, medical with and without written directives, panoramic irradiators, security, portable gauges, brachytherapy, pharmacies, and high dose rate remote afterloaders. Additionally, a

team member accompanied four program inspectors the week of January 22, 2018. The inspector accompaniments are identified in Appendix B.

The accompanied inspections were of high quality and consistently displayed both technical expertise and courteousness toward licensees. One of the inspections uncovered several non-compliances which were handled in an effective manner. The rest were thorough despite finding no non-compliances.

Inspection reports contain a significant amount of information. Additional notes to keep track of when correspondence are issued, as well as how and when the licensee responds, are kept in WBL along with inspection history. At the time of the review, North Carolina was in transition from a locally-hosted WBL to an NRC-hosted version. The NRC-hosted version had been recently implemented and staff was still taking notes using the old form in addition to the new WBL notes form.

When an inspection reveals non-compliance issues, the next inspector copies the non-compliances into a new checklist for use during their inspection. This checklist is used in the preparation of and in the documentation of each new inspection. In the case files reviewed, the section on previous non-compliances was given more than a perfunctory write-up. Inspections are documented so that routine inspection reports are separate from field and security inspections. This separation may result in non-compliance remarks from one inspection not carrying over into other subsequent inspections. Specifically, this segmented approach may result in an issue from a field or security inspection not being noted in preparation for a routine inspection. There were no events where this occurred in the latest inspection period, but it has been noted as a potential weakness by the Branch Manager.

When a licensee receives a non-compliance notice, they are required to respond in a timely manner. Licensee responses are required to identify root causes for each non-compliance. One inspection reviewed as part of this review resulted in the correction of items in a license.

Security inspections are conducted separately from routine inspections in North Carolina. In the course of preparations to adopt Section 10 Code of Federal Regulations (CFR) Part 37 requirements, North Carolina replaced their security inspector. This inspector was known for working independently and keeping notes in his own style. In the transition between inspectors and between security regulations, some previous case files were not reviewed by the Branch. One instance of non-compliances was missed out of thirty reviewed cases. The method that security inspections are put into the database is not as straightforward as it could be, leading to the possibility for due dates to be confused between security and routine inspections. Though the team did not note any inspections that were missed, there was confusion on the due dates for one inspection that had the potential to be missed in the future. Additionally, the team noted that, although North Carolina's interpretation of Part 37 is still protective of material security, some guidance on the security implications of drop-down ceilings had not yet been implemented. After discussing the issue with the security inspector, the guidance documents were to be reviewed and implemented.

The Branch Manager, or in some cases, the lead inspector, accompanies each inspector once per year. Summaries of these accompaniments are created to reflect on what improvements can be made. Based on the team's review of the summaries, previously noted inspection issues have been improving in subsequent years. For example, reminders and pointers from the 2015 summary were noted as good practices by

inspectors in the 2017 summary. Both the Branch Manager and lead inspector are long-tenured inspectors and/or supervisors. Uniquely, all inspections are reviewed by a single designated reviewer who is neither management nor the lead inspector. He provides a summary of non-compliance issues to the entire inspection group approximately eight times per year.

c. Evaluation

The team determined that, during the review period, North Carolina met the performance indicator objectives listed in Section 3.3.a., and recommends that North Carolina's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

d. MRB Decision

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

3.4 Technical Quality of Licensing Actions

The quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, as well as security. An assessment of licensing procedures, actual 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 State Agreements procedure 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., 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 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 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, North Carolina performed 2,265 radioactive materials licensing actions. The team evaluated 22 of these actions. The licensing actions selected for review included two new applications, seven amendments, eight renewals, two terminations, two decommissioning/terminations, and one decommissioning/site closure. The team evaluated casework which included the following license types and actions: broad scope medical; diagnostic nuclear medicine; commercial manufacturing only; commercial distribution – nuclear pharmacies; industrial radiography; research and development; education – broad scope; nuclear pharmacy; gauges; industrial lab; outpatient radiopharmaceutical therapy – radium; brachytherapy only; service and/or repair (including relocation); gamma knife (hospital based); Group I-IV medical cyclotron; decommissioning actions; and financial assurance. The casework sample represented work from five license reviewers including the team leader of licensing.

At the end of 2014, all of North Carolina's licensing documents were made electronically available. In 2015, the Branch began issuing renewal licenses for 10 years if the eligibility criteria stated in the materials license cover letter was met. If the eligibility criteria is not met, the renewal license will be issued for five years. As of March 1, 2016, the Branch had its licensees, who were under the Increased Controls and Fingerprinting Orders, begin implementation of 10 CFR Part 37. The Branch updated their licensing procedures March 2018 and plans to begin using the NRC-hosted version of WBL on April 1, 2018.

The team found that licensing actions were thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed. The licensing cases reviewed demonstrated that, with isolated exceptions, proper guidance was followed, and deficiency letters and license conditions were well supported by information contained in the licensing files. Terminated licensing actions were well documented, showing appropriate transfer and final status surveys, as appropriate.

c. Evaluation

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

d. MRB Decision

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

3.5 Technical Quality of Incident and Allegation Activities

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

a. Scope

The team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated North Carolina'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 followup actions are taken to ensure prompt compliance by licensees.
- Followup 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, 141 incidents were reported to North Carolina. The team evaluated 10 reportable and 4 non-reportable radioactive materials incidents which included 2 lost/stolen radioactive materials, 6 medical events, 3 damaged equipment, 2 motor vehicle accidents, and 1 contaminated material event. North Carolina dispatched inspectors for onsite follow-up for all of the cases reviewed.

North Carolina has procedures in place for the evaluation and follow-up of incidents and allegations. The team determined that the procedures were compatible with equivalent NRC procedures. When North Carolina receives an incident or allegation the Response Coordinator is responsible for its initial evaluation, determination of whether or not an on-site investigation is required, assigning inspectors to investigate and determining the priority for that inspection, and reporting the event to the NRC as required.

The team determined that initial responses were prompt and well-coordinated and the level of effort was commensurate with the health and safety significance of the event. For all events reviewed, North Carolina notified the NRC's Headquarters Operations Center and entered and/or updated the information in NMED in a timely manner.

During the review period, 16 allegations were received by North Carolina. The team evaluated four allegations, including one allegation that the NRC referred to the State, during the review period. The team determined that North Carolina's follow-up to the allegations was appropriate and that North Carolina provided responses to concerned individuals when contact information was provided. Additionally, the team determined that North Carolina can and does protect the concerned individual's identity to the extent practicable if asked.

c. Evaluation

The team determined that, during the review period, North Carolina met the performance indicator objectives listed in Section 3.5.a., and recommends that North Carolina's

performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

d. MRB Decision

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

#### 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 (SS&D) Evaluation Program; (3) Low-Level Radioactive Waste Disposal (LLRW) Program; and (4) Uranium Recovery (UR) Program. The NRC's Agreement with North Carolina retains regulatory authority for a uranium recovery program; therefore, only the first three non-common performance indicators applied to this review.

#### 4.1 Compatibility Requirements

State statutes should authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health, safety, and security. The State must be authorized through its legal authority to license, inspect, and enforce legally binding requirements, such as regulations and licenses. NRC regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted in a time frame so that the effective date of the State requirement is not later than three years after the effective date of the 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 six months following NRC designation.

a. Scope

The team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," 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, as amended.
- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were adopted no later than three 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 six months of NRC designation.

- The State statutes authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement.
- The State is authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses.
- Impact of sunset requirements, if any, on the State's regulations.

b. Discussion

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

The North Carolina regulations governing radiation protection requirements are located in The North Carolina Administrative Code, Title 15A, Chapter 11, "Regulations for Protection against Radiation" apply to all ionizing radiation. North Carolina requires a license for possession and use of all radioactive material. The State has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

Rulemaking begins with the Branch recommending that the Rules Review Commission (RRC) commence rulemaking. The RRC then directs the Radioactive Materials Control Advisory Committee to develop the rules to be adopted. Depending upon the complexity of the task, it can take one to three years to bring a set of rules to the RRC to be adopted.

The Department must approve the rule and the Office of State Budget must approve an associated Fiscal Impact Statement (FIS). After the Department has approved of the rules and the FIS is approved, the RRC will vote to approve the rules for adoption. After the rules are approved for adoption by the RRC, they are published for public comment and a public hearing is held. Public comments are addressed and rule revisions are made, as necessary. If substantive changes are made a second public comment period and public hearing is held. Once public comments are resolved, the RPC votes to adopt the rules. The RRC from the Office of Administrative Hearings then votes to adopt the rules by the State. Rules become effective on the first day of the month following adoption by the RRC.

North Carolina requires a review of all regulations promulgated by the State every 10 years. Regulations that are not reviewed and approved prior to the end of the review period automatically expire. The Branch will need to review all radiation protection rules in 2018 and then report to the RRC as to whether the rules are necessary and what, if any, public impact the rules have. The Branch anticipates this review of regulations as an opportunity to improve upon the consistency of and streamline its regulations.

During the review period, the Branch submitted five proposed regulation amendments, and fourteen final regulation amendments, including three revised final regulation amendments, to the NRC for a compatibility review. Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally-binding requirements no later than three years after they become effective. No regulations were late at the time of submission. At the time of the review, there were no amendments overdue for adoption with one exception. The Radioactive Materials Control Advisory Committee

decided to not adopt an amendment to 10A NCAC 15.0117, which primarily contains items that shifted from a different compatibility category to compatibility category “NRC”:

These are NRC program elements that address areas of regulation that cannot be relinquished to Agreement States pursuant to the AEA or provisions of Title 10 of the Code of Federal Regulations. These program elements are designated “NRC” and should not be adopted by Agreement States.

Potential incompatibilities created by not adopting the amended regulations were minimal. Additionally, Branch staff was aware of this issue while adopting other regulations and took steps to address portions of the amended rule. Branch staff plans to address this issue fully during the upcoming review of all regulations.

c. Evaluation

The team determined that, during the review period, North Carolina met the performance indicator objectives listed in Section 4.1.a., and recommends that North Carolina’s performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

d. MRB Decision

The final report will present the MRB’s conclusion regarding this indicator.

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 teams. Under this guidance, three sub elements: Technical Staffing and Training, Technical Quality of the Product Evaluation Program, and Evaluation of Defects and Incidents Regarding SS&D’s, are evaluated to determine if the SS&D program is satisfactory. Agreement States with authority for SS&D evaluation programs who are not performing SS&D reviews are required to commit in writing to having an SS&D evaluation program in place before performing evaluations.

a. Scope

The team used the guidance in State Agreements procedure SA-108, “Reviewing the Non-Common Performance Indicator: Sealed Source and Device Evaluation Program,” and evaluated 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 NRC, Agreement States, and others, as appropriate, occur in a timely manner.

### b. Discussion

#### Technical Staffing and Training

At the time of the review, North Carolina had three staff that perform SS&D reviews and there were no vacancies in North Carolina's SS&D program. During the review period, one SS&D staff member left the program and one staff member was hired.

The Branch Manager keeps an electronic qualification journal for each staff member. The training program for SS&D reviewers, which is part of the Branch's overall Qualification and Training Manual, is equivalent to NRC training requirements listed in IMC 1248, Appendix D, with the exception of establishing the minimum number of completed evaluations a reviewer needs to complete to have signature authority for SS&D reviews. The Branch Manager noted that a number of evaluations was not established so each SS&D reviewer's qualification could be tailored to the specific reviewer-in-training. IMC 1248, Appendix D, suggests directed casework review of at least 20 SS&D actions prior to receiving full SS&D signature authority for all devices with flexibilities, including allowing limited qualification. North Carolina's qualification process requires that the reviewer perform two concurrence reviews on in-house evaluations to receive limited qualification to sign off on certain devices.

During the review period, one staff member received their SS&D qualification. The team identified that while the staff member was in training, he completed his qualification journal, which included individual study activities, specialized NRC courses, and on-the-job training. The staff member performed casework reviews of two amendment actions in-house, as well as a mock review of an historical SS&D case. The team also identified that the reviewer performed concurrence reviews and signed two SS&D actions before he had proper training and qualifications. Although the staff member had completed the SS&D qualification journal, given the types of SS&D manufacturers in North Carolina and the types of devices Branch SS&D reviewers would be likely to review, the team discussed with the Branch Manager whether this level of experience was sufficient. Additional experience could be accomplished via mock reviews of historical cases or via reviews of in-house applications.

Qualified staff members are required to fulfill 40 hours of refresher training every two years. This requirement is greater than the NRC's expectation of 24 hours of refresher training every two years. For this review period, the two experienced reviewers and the single review-in-training all attended the NRC SS&D Workshop in 2017.

### Technical Quality of the Product Evaluation

North Carolina has 13 SS&D licensees and completed seven SS&D actions during the review period. The team evaluated all seven of these SS&D actions. The reviews concerned one generally licensed device and two medical sources from two manufacturers in North Carolina. The actions included two applications for new products, four amendments, and one correction. No inactivations were issued by North Carolina during the review period. North Carolina currently has no open SS&D actions and does not have a backlog of SS&D actions.

As discussed in Section 2.0, the team noted that the Branch developed and implemented a procedure to ensure that SS&D documentation is complete and readily available to those with need-to-know. However, this procedure was implemented in February 2018. Therefore, the team could not effectively evaluate the Branch's implementation of the procedure during this review.

The team noted that SS&D reviewers used NUREG-1556, Vol. 3, Rev. 2, as well as internal guidance, when completing SS&D reviews; however implementation, and thus performance, was inconsistent. For example, the team identified that three of the seven SS&D safety evaluations did not fully address health and safety concerns and product integrity. The team identified that SS&D reviewers did not address the following issues in the safety evaluation of a new generally licensed device: (1) a leak test request that exceeded the typical six month frequency; (2) incomplete descriptions of the product design, construction of the product, and on/off indicators, including engineering drawings, (3) incomplete prototype testing documentation; (4) labeling that did not meet the North Carolina regulatory requirements for labeling of generally licensed devices; (5) no discussion of dose limits for generally licensed devices; and (6) incomplete radiation level information for one of the sources involved. In the subsequent amendment for this device, the following items were noted by the team: (1) the labeling was not corrected to meet generally licensed device regulatory requirements; (2) no documentation was found to justify adding models to a series, as discussed in NUREG-1556, Vol. 3, Rev. 2; and (3) the licensee did not submit information regarding changes to the product to accommodate new sources and a new source array. The issues detailed above were not identified during the primary nor the concurrence review for both actions. During the onsite review, North Carolina drafted a letter to send to the licensee requesting the missing information and that the licensee correct the labeling.

The team identified that incorrect and incomplete labeling was a recurring issue in all seven SS&D registrations. In the evaluation of a new medical source, the team found that the Branch did not address health and safety issues related to prototype testing, conditions of normal use, and likely accident conditions. Both reviewers involved noted the inconsistency of the applicant's prototype testing results with the appropriate American National Standards Institute (ANSI) standard, but failed to address the inconsistency with the applicant. Additionally, SS&D reviewers did not request justification for accepting a lower ANSI classification obtained after testing of the product. The labeling for this medical source and another medical source from the same manufacturer evaluated during the review period was also inconsistent with North Carolina's, and thus NRC's, labeling requirements.

The team noted that reference documents and deficiency letters were missing from six of the seven actions that the team evaluated. The team identified that the procedures implemented by the Branch do not encourage the use of memos to file for reviewers to document administrative amendments where safety evaluations are not necessary or to document a reviewer's decision-making process. During the onsite review, the lead SS&D reviewer located the missing reference documents and deficiency letters and added them to the corresponding folders in the Branch's shared drive.

Based on the issues identified above, the team recommends that North Carolina take action to: (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 evaluate the action; and (3) ensure that each SS&D evaluation is properly documented, including all licensee correspondence, deficiency letters and responses, and memos to file.

#### Evaluation of Defects and Incidents Regarding SS&Ds

There were no incidents involving a SS&D registered product reported to the Department during the review period.

#### c. Evaluation

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

- Individuals performing SS&D evaluation activities are adequately qualified and trained to perform their duties.
- SS&D evaluations are adequate, accurate, complete, clear, specific, and consistent with the guidance in NUREG-1556, Volume 3.

The team noted that the concurrence review for two of the seven SS&D evaluations were performed by staff without proper training and qualifications. Additionally, the team discussed with the Branch Manager whether the cases reviewed by the reviewer-in-training were commensurate to the types of devices manufactured or distributed in North Carolina, as well as whether they were sufficient to justify full signature authority.

Although the team believes that all of the devices reviewed are safe, the team noted that three of the seven SS&D evaluations did not fully address health and safety concerns and indicated repeated examples of problems with respect to thoroughness, completeness, consistency, clarity, technical quality, adherence to existing guidance in product evaluations, and addressing the integrity of the product. Due to the inconsistent quality of the reviews performed during the review period, specifically for new products, the team has concerns that without improvement to the SS&D Evaluation Program, North Carolina may fail to identify issues which could impact health and safety.

The team noted that all seven actions completed during the review period were processed before the Branch implemented procedures to ensure the completeness of sealed source and device documentation. Therefore, although the team believes that adherence to these procedures should strengthen the Branch's SS&D evaluations, not enough time has passed for the team to evaluate the effectiveness of their procedures.

During the onsite review, the Branch took steps to correct some of the issues mentioned above, including drafting correspondence to request more information from a licensee and to request changes in labeling. North Carolina's management is aware of the issues with respect to the SS&D Evaluation Program and has conceded that since the last IMPEP review, North Carolina prioritized other areas of their program which encompass the greatest percentage of their activities, such as licensing, inspections, and incident response. North Carolina's management offered several avenues they will consider to improve the SS&D Evaluation Program, such as additional specialized training for all reviewers, round-table reviews of incoming actions, and reaching out to other Agreement States or the NRC for technical assistance.

Because of the issues noted above, the team recommends that North Carolina's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory, but needs improvement.

d. MRB Decision

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

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 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

The team recommends that North Carolina's performance be found satisfactory for five out of six performance indicators reviewed and satisfactory, but needs improvement, for the non-common performance indicator, Sealed Source and Device Evaluation Program. The team made two recommendations regarding North Carolina's performance and believes that the three recommendations from the 2014 IMPEP review should be closed.

Accordingly, the team recommends that the North Carolina Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. When weaknesses in a program result in, or could result in, less than fully satisfactory performance for one or more performance indicators, the NRC's Management Directive 5.6 states that the MRB should consider whether Monitoring by the NRC is warranted. The team discussed whether or not it believed Monitoring was appropriate based on the satisfactory, but needs improvement, finding for the indicator SS&D Evaluation Program. Based on North Carolina's willingness and promptness to correct the deficiencies with its SS&D Evaluation Program and the low volume of actions processed by the staff each year, the team believes North Carolina does not warrant

Monitoring. Instead, the team is recommending that a periodic meeting take place in approximately 1 year with the intent to conduct the next IMPEP review in 4 years. The meeting should include an extended discussion on North Carolina's SS&D evaluation program. This timing would give North Carolina time to take actions to address the deficiencies noted in Section 4.2. Depending upon the progress noted at the time of the periodic meeting, the MRB may choose to direct a period of Monitoring, a followup review, a second periodic meeting, or alter the timing of the next full IMPEP review.

Below is a recommendation, as mentioned in the report, for evaluation and implementation by North Carolina:

The team recommends that North Carolina take action to: (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 evaluate the action; and (3) ensure that each SS&D evaluation is properly documented, including all licensee correspondence, deficiency letters and responses, and memos to file.

## LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Inspection Accompaniments

## APPENDIX A

### IMPEP REVIEW TEAM MEMBERS

<b>Name</b>	<b>Areas of Responsibility</b>
Lance Rakovan, NMSS	Team Leader Technical Staffing and Training Compatibility Requirements
Monica Ford, Region I	Status of Materials Inspection Program Technical Quality of Incidents and Allegations
Jackie Cook, Region IV	Technical Quality of Licensing Actions
Celimar Valentin Rodriguez	Sealed Source and Device Evaluation Program
Jimmy Uhlemeyer, KS	Technical Quality of Inspections Inspection Accompaniments

APPENDIX B

INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: 0021-3
License Type: <i>High Dose Remote Afterloader</i>	Priority: 2
Inspection Date: 01/22/18	Inspector: SJ

Accompaniment No.: 2	License No.: 1117-3
License Type: <i>Industrial Radiography (Security inspection)</i>	Priority: 1
Inspection Date: 01/23/18	Inspector: TC

Accompaniment No.: 3	License No.: 0668-3
License Type: <i>Medical Private Practice</i>	Priority: 5 (3 in NC)
Inspection Date: 01/24/18	Inspector: CH

Accompaniment No.: 4	License No.: 1064-2
License Type: <i>Portable Gauge</i>	Priority: 5 (3 in NC)
Inspection Date: 01/25/18	Inspector: CS