



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
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June 25, 2024

Louis Brayboy, Acting Chief  
Radiation Protection Section  
Division of Health Service Regulation  
Department of Health and Human Services  
1645 Mail Service Center  
Raleigh, NC 27699

Dear Louis Brayboy:

A periodic meeting with you and your staff was held on May 15, 2024. The purpose of this meeting was to review and discuss the status of the North Carolina Agreement State Program. The U.S. Nuclear Regulatory Commission (NRC) was represented by Paul G. Krohn, Director, Division of Radiological Safety and Security, Region I, and me.

I have completed and enclosed a general meeting summary. If you feel that the summary and its conclusion do not accurately reflect the meeting discussion or have any additional remarks about the meeting in general, please contact me at (610) 337-5102 or via email at [shawn.seeley@nrc.gov](mailto:shawn.seeley@nrc.gov) to discuss your concerns.

Sincerely,

Shawn W.  
Seeley

Digitally signed by Shawn  
W. Seeley  
Date: 2024.06.25  
09:01:41 -04'00'

Shawn W. Seeley  
Regional State Agreements Officer  
Division of Radiological Safety and Security  
U.S. NRC Region I

Enclosure:  
Periodic Meeting Summary for North Carolina

cc w/encl: Emery Milliken, Deputy Director,  
NC Division of Health Service Regulation

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**SUNSI Review Complete: SWS**

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NAME		PKrohn		SSeeley	
DATE		06/24/2024		06/25/2024	

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

PERIODIC MEETING WITH THE STATE OF NORTH CAROLINA

TYPE OF OVERSIGHT: NONE

May 15, 2024

Enclosure

## PERIODIC MEETING PARTICIPANTS

### **Nuclear Regulatory Commission (NRC)**

- Paul Krohn, Director, Division of Radiological Safety and Security
- Shawn Seeley, Regional State Agreements Officer

### **North Carolina Department of the Environment**

- Louis Brayboy, Radiation Protection Section, Chief
- Travis Cartoski, Radioactive Materials Branch, Inspection Manager
- Randy Crowe, Radioactive Materials Branch, Licensing Manager
- James Albright, Radioactive Materials Branch, Consultant
- Redeat Mesfin, Radioactive Materials Branch, Health Physicist II
- Chinweokwu Ekwuribe, Radioactive Materials Branch, Health Physicist II
- Bennifer Pate, Radioactive Materials Branch, Health Physicist II
- Caleb Smith, Radioactive Materials Branch, Health Physicist II

## 1.0 INTRODUCTION

This report presents the results of the periodic meeting held between the U.S. Nuclear Regulatory Commission (NRC) and the State of North Carolina (NC). The meeting was conducted in accordance with the Office of Nuclear Material Safety and Safeguards [Procedure SA-116 “Periodic Meetings between IMPEP Reviews.”](#) dated October 29, 2021.

The NC Agreement State Program (NCASP) is administered by the Radiation Protection Section, which is within the Division of Health Services Regulation of the North Carolina Department of Health and Human Services. There have been no changes to the organizational structure since the May 2022 Integrated Materials Performance Evaluation Program (IMPEP). The NCASP regulates approximately 508 specific licenses authorizing possession and use of radioactive materials and is 100 percent fee funded. Fees for radioactive materials licensees have not increased in several years. NCASP may raise fees in FY 2026.

The NCASP underwent an IMPEP review from May 2-6, 2022. A Management Review Board (MRB) meeting to discuss the outcome of the IMPEP was held on August 11, 2022. The team recommended and the MRB agreed that North Carolina’s performance for the five common performance indicators be found satisfactory. There were also two non-common performance indicators reviewed: Legislation, Regulations and Other Program Elements (LROPE) and the Sealed Source and Device (SS&D) evaluation program. The team recommended and the MRB agreed that North Carolina’s performance for LROPE be found Unsatisfactory. The team recommended and the MRB agreed that North Carolina’s performance for the SS&D evaluation program be found satisfactory, but needs improvement. Additionally, the team made a formal recommendation and the MRB agreed that North Carolina take action to ensure each SS&D evaluation is properly documented to ensure the content and format of the information in each evaluation is consistent with the applicable guidance provided in NUREG-1556, Volume 3. Overall, North Carolina was found adequate to protect public health and safety and not compatible with the NRC’s program. The MRB determined the next full IMPEP review should take place in approximately four years (May 2026) and that a periodic meeting should take place in approximately two years (May 2024). This meeting summary reflects the directed periodic meeting at approximately two years and focuses on the radioactive materials program as it is conducted under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of North Carolina.

## 2.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the NRC regional and Agreement State radioactive materials programs during an IMPEP review. 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.

2.1 Technical Staffing and Training  
(2022 IMPEP review: Satisfactory)

The NCASP is comprised of 15 full time equivalents which includes 11 technical staff, one administrative specialist, one environmental program coordinator, one environmental consultant, and one Program Manager. The technical staff include five license reviewers and six inspectors. Since the August 2022 periodic meeting two staff were hired into vacant positions and subsequently left the program. Reasons for staff departure vary and include retirement and/or taking higher paying jobs outside of State Government. Additionally, the Section Chief left the Program in April 2023, and the Branch Manager has been acting in that role since May 2023. At the time of the periodic meeting the NCASP had three vacancies.

The NCASP has a qualification journal that is compatible with NRC's Inspection Manual Chapter (IMC) 1248. No changes have been made to the qualification journal since the 2022 IMPEP review. There are currently five technical staff members undergoing qualification training (three inspectors and two license reviewers). Refresher training for qualified staff is being tracked and all staff requiring refresher training are currently meeting the 24 hours every 24 months requirement.

2.2 Status of the Materials Inspection Program  
(2022 IMPEP review: Satisfactory)

The NCASP reported it has conducted 155 Priority 1, 2, and 3 and 22 initial inspections since August 2022. Only one Priority 1, 2, 3 or initial inspections was completed overdue, by one week. This was due to delays out of the control of the program inspection staff. Specifically, the licensee did not receive material until approximately 18 months after license issuance. At the time of the periodic meeting, the program had no inspections overdue.

The NCASP has implemented a risk-informed process for inspection of reciprocity licensees. This process involves analyzing whether the applicant has been inspected by North Carolina within the last two years, has had a major event in the last two years, and reciprocity information obtained from the regulator the license is issued under. Since the 2022 IMPEP review, North Carolina conducted 7 out of 11 candidates in 2022, 8 out of 12 candidates in 2023, and 1 out of 11 candidates to date for 2024.

2.3 Technical Quality of Inspections  
(2022 IMPEP review: Satisfactory)

The NCASP uses inspection procedures that are equivalent with the inspection guidance outlined in IMC 2800 and the NRC's Inspection Procedures for specific modalities. Inspection reports are reviewed by the Inspection Supervisor and by the Division Chief. Inspection findings are routinely sent to licensees within 30 days of completing an inspection. All qualified inspectors received a supervisory accompaniment in calendar year 2022 and 2023. One supervisory accompaniment has been conducted in 2024. The NCASP has a sufficient supply of calibrated and operable radiation survey instruments to support the inspection program.

During the 2022 IMPEP, the team made a formal recommendation and the MRB agreed that North Carolina provide additional training to its staff on emerging medical technologies subject to its equivalent regulation to 10 CR 35.1000, as applicable to its regulatory program. Specifically, since the 2022 IMPEP, the NCASP has annually reached out to their gamma knife licensee for basic training on their ICON system. This training is slated to be moved in-house later this year.

2.4 Technical Quality of Licensing Actions  
(2022 IMPEP Review: Satisfactory)

The NCASP has approximately 508 specific licenses. Since May 2022, 953 licensing actions have been completed. The NCASP has a 30-day metric for processing amendments and a 60-day metric for renewals. There are currently 39 actions in-house and none are outside their established metrics. Additionally, the NCASP is prioritizing work to ensure the actions with the most health, safety, and security significance are completed first.

The NCASP follows the NRC's NUREG 1556 series as guidance when completing licensing actions along with the most current versions of the NRC's Pre-Licensing Guidance and the Risk Significant Radioactive Materials Checklist. License reviewers are responsible for the performance of pre-licensing visits when warranted.

2.5 Technical Quality of Incident and Allegation Activities  
(2022 IMPEP review: Satisfactory)

The NCASP received 11 reportable events since the 2022 IMPEP. These 11 incidents were reported to the NRC in a timely manner. All events were complete and closed in the Nuclear Materials Event Database (NMED) as applicable.

Since the 2022 IMPEP, the NCASP received three allegations referred to NC by the NRC. The NCASP performs and documents its investigations into allegations received. Additionally, procedures are in place for receipt and follow-up of both incidents and allegations.

3.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Legislation Regulation and Other Program Elements (LROPE), (2) Sealed Source and Device (SS&D) Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. The NRC's Agreement with NC only includes the non-common performance indicators LROPE and SS&D.

3.1 Legislation, Regulation, and Other Program Elements  
(2022 IMPEP review: Unsatisfactory)

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 (NCGS). In Section 104E-6, the Radiation Protection Section is designated as North Carolina's radiation control agency. The State's rules and regulations are subject to sunset requirements. 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. During the 2022 IMPEP, the review team noted that the NCASP had initiated the process for incorporating the NRC rules by reference. Since the 2022 IMPEP, 14 NRC Parts were incorporated by reference. The NCASP has two more Parts to adopt and expects to have those adopted by May 1, 2025. One Part became effective October 1, 2022; three Parts became effective May 1, 2023; two Parts became effective October 1, 2023; and eight Parts became effective May 1, 2024. The summary data sheet was sent to NMSS via email on May 9, 2024.

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 is comprised of members from the licensee community and appointed by the Governor. 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.

3.2 Sealed Source and Device Evaluation (SS&D)  
(2022 IMPEP review: Satisfactory, but needs improvement)

Technical Staffing and Training

The NCASP has three fully qualified SS&D reviewers. The NCASP has a training and qualification manual for SS&D reviewers that is equivalent to the NRC's IMC 1248 Appendix D. The SS&D staff have also assisted with two reviews for other Agreement State programs. This is to support the National Materials Program (NMP) and there is no expected impact to the NCASP as a result of providing this assistance to the NMP.

Technical Quality of Product Evaluation Program

The NCASP has five SS&D registrants with a total of 17 SS&D registrations. There have been three amendments since the 2022 IMPEP review to inactive SS&D registrations. They have four amendment actions in process.

During the 2022 IMPEP, the team made a formal recommendation and the MRB agreed that NC take action to ensure each SS&D evaluation is properly documented to ensure the content and format of the information in each evaluation is consistent with the applicable guidance provided in NUREG-1556, Volume 3. Since the 2022 IMPEP, the NCASP has altered the naming convention for files, added a note to file for each action, and have been applying these corrections for each action going forward.

Evaluation of Defects and Incidents Regarding SS&Ds

There were several reported failures to one specific sealed source since the 2022 IMPEP. The failure concerned the integrity of the Am-241 source housing due to suspected inadequate maintenance being performed on the devices during servicing by third party vendors. Subsequently, the NCASP conducted an evaluation of Troxler Am-241 sources. It was found that all reported failures were being serviced by third party



service providers, and it could not be confirmed that the recommended maintenance had been performed. A survey of competing manufacturers concluded that they were not finding similar issues with Troxler gauges. An information noticed was issued by NCASP to NC licensees on July 29, 2022.

#### 4.0 TECHNICAL ASSISTANCE REQUEST

The NCASP submitted a Technical Assistance Request (TAR) to the NRC via letter dated May 9, 2024. The request was related to the approval to continue using a non-standard license condition for decay-in-storage (DIS) that differed from the NRC's DIS condition limiting to radionuclides with half-lives less than 120 days. North Carolina's DIS condition extended the list of radionuclides to those with half-lives less than 275 days. As of the date of this letter, the TAR is being assigned to a technical reviewer in accordance with Management Directive 5.7, "Technical Assistance to Agreement States." and SA-1001, "Implementation of Management Directive 5.7 "Technical Assistance to Agreement States."

#### 5.0 SUMMARY

The NCASP has worked to implement and complete corrective actions relative to the two open recommendations and the unsatisfactory indicator from the 2022 IMPEP review. Specifically, the NCASP has made updating the regulations a priority. There were no inspections overdue at the time of the periodic meeting. There were only 11 licensing actions in-house at the time of the periodic meeting. The NCASP responds to incidents and allegations as appropriate. There are three people qualified to perform SS&D evaluations with four actions in-house.

No new concerns were identified during this periodic meeting. Therefore, the next full IMPEP review should be held as scheduled in May 2026.