UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
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March 3, 2020

W. Lee Cox, Chief
Radiation Protection Section
Division of Health Service Regulation
Department of Health and Human Services
1645 Mail Service Center
Raleigh, NC 27699-1645

Dear Mr. Cox:

On February 13, 2020, the Management Review Board (MRB), which consisted of U.S. Nuclear Regulatory Commission (NRC) senior managers and an Organization of Agreement States Liaison to the MRB, met to consider the results of the Periodic Meeting held with the North Carolina Agreement State Program (the Program) on September 23, 2019. Based on the level of effort executed by the Program to deal with concerns raised in regard to performance of Sealed Source and Device Evaluations, the MRB determined that there is no need for a second Periodic Meeting and further that the State did not need to be placed on Monitoring or have their next IMPEP review moved up. Therefore, North Carolina will have their next IMPEP review as scheduled in fiscal year 2022.

The final periodic meeting summary including the MRB's finding is enclosed. If you feel that the summary does not accurately reflect the outcome of the MRB meeting, please contact me at (610) 337-5281 or Monica Ford at (610) 337-5214. I look forward to our agencies continuing to work together in support of the National Materials Program.

Sincerely,

/RA/

James M. Trapp
Division Director
Division of Nuclear Materials Safety
U.S. NRC Region I

Enclosure:
Final Periodic Meeting Summary for North Carolina

cc w/encl.: David Crowley, Manager
Radioactive Materials Branch

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

PERIODIC MEETING WITH THE STATE OF NORTH CAROLINA

TYPE OF OVERSIGHT: NONE

September 23, 2019

Final

PERIODIC MEETING PARTICIPANTS

NRC

- Joseph Nick: Deputy Director, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission (NRC), Region I
- Monica Ford: State Agreements Officer, NRC, Region I

North Carolina Division of Health Service Regulation

- W. Lee Cox, Chief, Radiation Protection Section
- David Crowley, Manager, Radioactive Materials Branch
- Louis Brayboy, Radioactive Material Licensing Supervisor, Radioactive Materials Branch
- Travis Cartoski, Radioactive Material Inspections and Security Supervisor, Radioactive Materials Branch

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. The meeting was held on September 23, 2019. The meeting was conducted in accordance with the Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-116 "Periodic Meetings between IMPEP Reviews," dated June 3, 2009 and 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 North Carolina Agreement State Program is administered by the Radiation Protection Section, within the Division of Health Service Regulation. The Division of Health Service Regulation is part of the Department of Health and Human Services.

At the time of the meeting, the North Carolina Agreement State Program regulated approximately 458 specific licenses authorizing possession and use of radioactive materials. The North Carolina Agreement State program is 100 percent fee funded. All licensing fees collected go into a dedicated fund specific for the North Carolina Agreement State Program's use. Surplus money remaining at the end of each fiscal year is maintained in a non-reverting fund and can be used for emergency response and future decommissioning as needed.

The North Carolina Agreement State Program last underwent an Integrated Materials Performance Evaluation Program (IMPEP) review in March 2018. A Management Review Board (MRB) meeting to discuss the outcome of the IMPEP review was held on June 7, 2018. Based on the findings presented, the MRB found the North Carolina Agreement State Program's performance satisfactory for the performance indicators: Technical Staffing and Training, Status of Materials Inspection Program, Technical Quality of Licensing Actions, Technical Quality of Inspections, Technical Quality of Incident and Allegation Activities, and Compatibility Requirements and satisfactory but needs improvement for the indicator Sealed Source and Device Evaluation Program. The MRB found the North Carolina Agreement State Program adequate to protect public health and safety and compatible with the NRC's program. One recommendation to improve program performance was made under the indicator Sealed Source and Device Evaluation Program. Additionally, the MRB directed that a periodic meeting should be held in approximately 18 months and include an extended discussion on North Carolina's Sealed Source and Device evaluation program. The 2018 final IMPEP report states that "Depending upon the progress noted at the time of the periodic meeting, the MRB may choose to direct a period of Monitoring, a follow-up IMPEP review, a second periodic meeting, or alter the timing of the next full IMPEP review."

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. Each of these indicators were discussed during the September 2019 periodic meeting.

2.1 Technical Staffing and Training
(2018 IMPEP review: Satisfactory)

The North Carolina Agreement State Program is comprised of 14.5 full time equivalents (FTE) which includes a manager, two supervisors, an administrative assistant, and eleven technical staff. Of the eleven technical positions, eight positions are one hundred percent dedicated to the performance of licensing actions, inspections, and sealed source and device evaluations. The other three positions support various other parts of the program such as general licenses and promulgation of regulations. The structure of the North Carolina Agreement State Program has changed slightly since the 2018 IMPEP review. At the time of the IMPEP review North Carolina had three team leads: one for licensing, one for security and response, and one for inspection. North Carolina restructured these positions into two supervisor positions: one for licensing and one for inspection, security, and response. North Carolina is in the process of considering additional changes to the organizational structure of the Agreement State Program which may include adding a Deputy Chief position to the Radiation Protection Section.

At the time of the periodic meeting, two of the eight licensing/inspection positions were vacant. The two technical staff who left, did so to pursue other opportunities in the private sector. One position has been vacant since April 2019 and the other position has been vacant since May 2019. At the time of the periodic meeting, North Carolina was in the process of filing one of the vacant positions. As discussed above, North Carolina is considering creating a Deputy Chief position in the Radiation Protection Section. If approval is granted for the Radiation Protection Section to have a Deputy Chief, the other vacant position will be converted to that position.

North Carolina has a documented training plan for technical staff that is equivalent to the NRC's Inspection Manual Chapter 1248. This training plan includes a requirement that qualified licensing and inspection staff complete 40 hours of refresher training every 24 months. This exceeds the NRC's requirement for refresher training of 24 hours every 24 months for qualified licensing and inspection staff.

2.2 Status of the Materials Inspection Program
(2018 IMPEP review: Satisfactory)

North Carolina has conducted 264 Priority 1, 2, and 3 inspections since the last IMPEP review. None of the inspections were completed overdue. Additionally, North Carolina conducted 20 initial inspections since the last IMPEP review, none of which were conducted overdue. There are no Priority 1, 2, 3, or initial inspections currently overdue for inspection. North Carolina is completing reciprocity requirements in accordance with the requirements stated in the NRC's inspection Manual Chapter 1220. In calendar year 2018 North Carolina inspected 17 of the 22 candidate licensees for a total of 77.3 percent and to date in calendar year 2019 has inspected 6 of the 11 candidate licensees for a total of 54.5 percent.

2.3 Technical Quality of Inspections
(2018 IMPEP review: Satisfactory)

North Carolina has a policy to accompany all staff performing radioactive materials inspections on an annual basis. All inspector accompaniments were performed in

calendar year 2018. One accompaniment has been completed for calendar year 2019 and the rest are scheduled to be completed before the end of the year.

North Carolina uses inspection procedures that are compatible with the inspection guidance outlined in the NRC's Inspection Manual Chapter 2800. Final inspection findings are not issued in the field and currently North Carolina does not have an equivalent form to the NRC's form 591. Preliminary inspection findings may be left with the licensee to allow immediate licensee response when appropriate. All inspection documentation undergoes a quality assurance review before official issuance. Inspection findings are routinely sent to licensees within 30 days of the inspection exit.

2.4 Technical Quality of Licensing Actions
(2018 IMPEP Review: Satisfactory)

North Carolina has approximately 458 specific licensees. All licensing actions are completed in a timely manner. North Carolina has a peer review system for licensing actions and the licensing supervisor self-audits actions routinely. One hundred and sixty-two licensing actions are currently in house consisting of: 48 renewals, 100 amendments, 10 terminations, and 4 new applications. North Carolina's goal is to complete all licensing actions within 30 - 90 days from the date of receipt. The timeframe is dependent on the type of action received. No licensing actions have been in house greater than 6 months.

North Carolina's new licenses are on a five-year renewal term. If at the time of the first renewal the licensee has had no compliance issues, the next renewal term is extended to ten years. Staff has signature authority for licensing actions that they have been qualified to perform. The guidance used by North Carolina is compatible with the NRC's NUREG 1556 Series guidance, Pre-licensing Guidance, and Risk Significant Radioactive Materials Checklist.

2.5 Technical Quality of Incident and Allegation Activities
(2018 IMPEP review: Satisfactory)

North Carolina is aware of the need to maintain an effective response to incidents and allegations. North Carolina has reported 16 events since the last IMPEP review. All reportable events were conveyed to the NRC in the correct manner as stated in State Agreements Procedure SA-300, "Reporting Material Events," except for one. North Carolina reported a radiography stuck source event directly to NMED; however, this event should have been reported to the NRC's Headquarters Operations Officer (HOO) within 24 hours of North Carolina finding out about the event. Once North Carolina was made aware of the need to report the event to the HOO it submitted the event to the HOO for completeness.

North Carolina received and responded to 10 allegations since the last IMPEP review. Three of these allegations were transferred by the NRC. North Carolina processed and closed all allegations in a timely manner. North Carolina uses procedures compatible with the NRC's incident and allegation procedures for processing events and allegations.

3.0 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 does not relinquish regulatory authority for UR; therefore, only the non-common performance indicators Compatibility Requirements, SS&D, and LLRW apply.

3.1 Compatibility Requirements

(2018 IMPEP review: Satisfactory)

The current effective statutory authority for the agreement state program is contained in Chapter 104E of the North Carolina General Statutes. In Section 104E-6, the Department of Health and Human Services is designated as the State's radiation control agency.

No regulation amendment changes were overdue for adoption at the time of the periodic meeting, however there are several outstanding comments on final regulations that North Carolina needs to address.

The Program's administrative rulemaking process takes approximately two years from the development stage to the final approval by the Rules Review Commission, after which the rule becomes effective. The public, the NRC, other agencies, and potentially impacted licensees and registrants are offered an opportunity to comment during the process. Comments are considered and incorporated, as appropriate, before the regulations are finalized and approved.

North Carolina regulations are subject to sunset provisions which require a review of all regulations promulgated by the State every 10 years (§150B-21.3A.). Regulations that are not reviewed and approved prior to the end of the review period automatically expire. North Carolina has until 2027 to complete this action.

3.2 Sealed Source and Device Evaluation (SS&D)

(2018 IMPEP review: Satisfactory but needs improvement)

- Technical Staffing and Training

  At the time of the 2018 IMPEP review North Carolina had three qualified SS&D reviewers. To address deficiencies identified during the 2018 IMPEP review, North Carolina sent the three qualified SS&D reviewers and the Branch Manager to the NRC's Headquarters to receive additional training for SS&D reviews. In April 2019, one qualified SS&D reviewer left the program and another qualified SS&D reviewer's workload was shifted to other areas within the program. Currently, North Carolina has only one qualified SS&D reviewer who is actively engaged in the SS&D program. North Carolina is aware that two qualified SS&D reviewers are needed to perform SS&D reviews. North Carolina is working on qualifying an individual currently on staff and will qualify the new hire (see section 2.1) as well. Program management stated that if an SS&D application needs to be completed before they can qualify another individual that North Carolina will work with another Agreement State who retains SS&D authority to perform the review.

- Technical Quality of Product Evaluation Program

  North Carolina has not received any complete SS&D applications (new, amendment, or termination) since the last IMPEP review. One application for a new device was received by North Carolina, however that device is still awaiting FDA approval. Once FDA approval is received North Carolina will proceed with the review. There was one recommendation made for program improvement resulting from the 2018 IMPEP review.

  Recommendation 1: North Carolina should 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 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.

  Status: The 2018 Final IMPEP Report noted in part that: "… at the time of the IMPEP review the team believed that the devices reviewed were safe, however, the team noted that three of the seven SS&D evaluations did not fully address health and safety concerns and indicated repeated examples of issues with respect to thoroughness, completeness, consistency, clarity, technical quality, adherence to existing guidance in product evaluations, and addressing the integrity of the product." As mentioned under the above bullet Technical Staffing and Training, North Carolina sent four of its staff to the NRC's Headquarters for additional SS&D training as a first step in addressing this recommendation and the concerns surrounding this indicator. Additionally, North Carolina has developed a corrective action plan to address this recommendation. The plan lists the following corrective actions:

  - CA(1)a. - Acquire additional hands on training opportunities from NRC SS&D staff, aimed to provide actual SS&D review case studies. Week-long of multiple reviews to practice applying procedures, NUREGS, and technical evaluation. This was to learn the approach and standards expected from NRC SS&D reviewers. (Done)

  - CA(1)b. - Plan to hold regular meets throughout the course of an SS&D action. Meetings will include management, concurrence SS&D reviewer, SS&D staff in training, licensing and inspection staff. Including various perspectives on the review process will help with consistency overtime, not allowing a single reviewer to drift as easily or become complacent in review technique. (In Progress)

  - CA(1)c. - Implement the procedures written prior to last IMPEP, they addressed a lot of these weaknesses but never had the time nor actions to actually demonstrate a use. Review and revise these procedures as necessary after each SS&D action. (In Progress)

  - CA(1)d. - Training, both initial and refresher. Large part about this first recommendation relies on well trained and capable staff. Increasing the amount of actions to become qualified from 3 to 6; also specify that within

those 6 actions there must be something relating to tritium, medical, and gauge devices. Other 3 may include inactivations or amendments of any type. Refresher training will also be required specific to SS&D. (In Progress)

- CA(1)e. - Petition National Materials Program to develop centers of excellence for SS&D reviewers. These individuals may assist with certain processes or technical questions when reviewers have them; additionally, may be able to act as primary or concurrent reviewers when there is insufficient staffing at a local SS&D program. (Not Started)

- CA(1)f. - Identify and establish a lead SS&D reviewer to take ownership over the program and monitor all reviewer activities. Not a supervisory position, but a functional lead with focused responsibility on the success and continuous improvement for the SS&D program. (Not Started)

- CA(2)a. - Regular scheduled meetings as stated in CA(1)b. will verify that the reviews were thorough, followed procedures, used correct checklists, asked appropriate questions and that everyone feels confident in moving an SS&D towards acceptance. (In Progress)

- CA(2)b. - Implement procedures, NUREGs, and checklists as stated in CA(1)c. (In Progress)

- CA(2)c. - Ensure that the proper individuals are signing the certificates as stated in procedures, only fully qualified individuals may act as primary and concurrence signatures on certificates. (In Progress)

- CA(3)a. - Before any new SS&D action is issued, both the primary and concurrence reviewer must review the files associated with the action. Only when all documents are present on the shared (s:) drive and in WBL may they submit to management for final approval and activation of the SS&D. Management will also review that all necessary documents are present in both electronic record locations. (In Progress)

- CA(3)b. - Implement procedures, NUREGs, and checklists as stated in CA(1)c. (In Progress)

- CA(3)c. - Ensure documentation is discussed in refresher training required in CA(1)d. (In Progress)

Once staff completes an SS&D evaluation, North Carolina will evaluate the action to determine if the corrective actions listed above are addressing the recommendation. Changes to the corrective action plan will be made as appropriate based on the review of completed SS&D actions until all three items are addressed.

- Evaluation of Defects and Incidents Regarding SS&Ds

  In August 2019, North Carolina was informed by the NRC of an event involving a portable gauge with a potentially faulty weld. North Carolina is in the process of

working with the manufacturer who holds a North Carolina license and SS&D registration to investigate the cause of the failure and to determine whether a potential generic issue exists. Additionally, the NRC informed North Carolina that it had issued an Information Notice in 1996 for a similar issue (IN 96-52). North Carolina stated that it will update the NRC of its findings once the investigation is complete.

3.3 Low-Level Radioactive Waste Disposal (LLRW) Program
(2018 IMPEP review: Not reviewed)

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 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.

4.0 SUMMARY

The North Carolina Agreement State Program has lost two staff since the last IMPEP review. One position is in the process of being filled and the other is potentially going to be converted to a Deputy Chief position for the Radiation Protection Section. Despite losing two staff in 18 months, no Priority 1, 2, 3, or initial inspections were completed overdue during the review period, reciprocity inspections are being completed, no backlog of licensing actions exists, and incidents and allegations are being followed-up on appropriately.

The only indicator that received a less than satisfactory rating during the 2018 IMPEP review was the non-common performance indicator Sealed Source and Device Evaluation Program. At the time of the September 2019 periodic meeting, a discussion was held with North Carolina regarding actions taken to address concerns involving this indicator. North Carolina discussed the additional training received by four staff members at the NRC's Headquarters and its value and shared its corrective action plan for addressing the open recommendation. However, since no SS&D applications (new, amendment to existing, or termination) had been completed by North Carolina since the 2018 IMPEP review, the NRC staff was unable to fully evaluate North Carolina's efforts to address the recommendation. Therefore, the NRC staff recommended to the MRB that a second periodic meeting be conducted in March 2021 (approximately 18 months after the September 2019 periodic meeting) to specifically focus on North Carolina's SS&D Evaluation Program.

5.0 MRB MEETING

An MRB meeting was held on February 13, 2020, to discuss the Periodic Meeting that was held with the North Carolina Agreement State Program on September 23, 2019. The MRB

discussion included a status of the overall Agreement State Program along with an expanded discussion of North Carolina's evaluation of SS&Ds. The MRB disagreed with the NRC staff's recommendation that a Periodic Meeting be held in 18 months (see Section 4.0). Instead, the MRB determined that based on the work done by North Carolina to address concerns involving its performance of SS&Ds that there was no need for a second Periodic Meeting and further that the State did not need to be placed on Monitoring or have their next IMPEP review moved up as stated for consideration as a result of the 2018 IMPEP review. Therefore, the MRB determined that the next IMPEP review for the North Carolina Agreement State Program be held as scheduled in fiscal year 2022.