



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD., SUITE 100
KING OF PRUSSIA, PA 19406-2713

October 19, 2016

W. Lee Cox, Chief
Radiation Protection Section
Division of Health Service Regulation
5505 Creedmoor Road
1st Floor
Raleigh, NC 27612

Dear Mr. Cox:

A periodic meeting with you and your staff was held on September 15, 2016. The purpose of this meeting was to review and discuss the status of the North Carolina Agreement State Program.

I have completed and enclosed a general meeting summary, including any specific actions resulting from the discussions. A Management Review Board (MRB) meeting to discuss the outcome of the periodic meeting has been scheduled for January 12, 2017, at 1:00pm. Call in information for the MRB will be provided in a separate transmission.

If you feel that our conclusions do not accurately summarize the meeting discussion, or have any additional remarks about the meeting in general, please contact me at (610) 337-5214 or via e-mail at Monica.Ford@nrc.gov to discuss your concerns.

Sincerely,

Monica Lynn Ford
Regional State Agreements Officer
Division of Nuclear Materials Safety
U.S. NRC Region I

Enclosure:
Periodic Meeting Summary for North Carolina

cc w/encl.: David Crowley, Manager

AGREEMENT STATE PERIODIC MEETING SUMMARY FOR
NORTH CAROLINA'S DIVISION OF HEALTH SERVICE REGULATION
RADIATION PROTECTION SECTION

DATE OF MEETING: September 15, 2016

U.S. Nuclear Regulatory Commission (NRC) Attendees	North Carolina Division of Health Service Regulation Attendees
Monica Ford, Regional State Agreements Officer, Region I	W. Lee Cox, Chief, Radiation Protection Section
James Trapp, Director, Division of Nuclear Materials Safety, Region I (Exit only, by phone)	David Crowley, Manager, Radioactive Materials Branch
Joseph Nick, Deputy Director, Division of Nuclear Materials Safety, Region I (Exit only, by phone)	Louis Brayboy, Licensing Team Lead, Radioactive Materials Branch
	Sharn Jeffries, Inspection Team Lead, Radioactive Materials Branch
	Travis Cartoski, Health Physicist II, Radioactive Materials Branch
	Mark Payne, Division Director, Human Services Division, Department of Health and Human Services (Exit only)
	Emery Milliken, Assistant Division Director II, Human Services Division, Department of Health and Human Services (Exit only)

DISCUSSION:

During the 2014 Integrated Materials Performance Evaluation Program (IMPEP) review of the North Carolina Agreement State Program (Program), the review team found the State's performance satisfactory for the indicators Technical Quality of Inspections, Technical Quality of Licensing Actions, Technical Quality of Incidents and Allegations, and Compatibility Requirements and satisfactory but needs improvement for the indicators Technical Staffing and training, Status of the Materials Inspection Program, and Sealed Source and Device Evaluation Program. The review team made three recommendations regarding program performance. The review team recommended that the Program be found adequate to protect public health and safety but needs improvement and compatible with the NRC's program. The review team also recommended that the State enter into a period of Monitoring. On June 5, 2014, the Management Review Board (MRB) met to consider the proposed final IMPEP report. The MRB disagreed with the review team's finding for the indicator Status of the Materials Inspection Program and directed that the indicator be found satisfactory. The MRB agreed with the findings for the other indicators. The MRB also disagreed with the recommendation to place the State on Monitoring, stating that the team did not identify any performance issues which impacted public health, safety, and security. Overall, the MRB found the Program adequate to protect public health and safety but needs improvement and compatible with the NRC's

program. The MRB directed that a periodic meeting should be held in one year and that the next IMPEP review should take place in approximately four years. Subsequently, a periodic meeting was held with the Program on April 16, 2015. A MRB was held to discuss the April 2015 periodic meeting on June 23, 2015 (ML15160A109). During the June 23, 2015 meeting the MRB agreed with the staff's recommendation to hold a second periodic meeting in 18 months and conduct the next IMPEP review as scheduled in March 2018.

This summary is a reflection of the second periodic meeting.

TOPICS COVERED DURING THE MEETING INCLUDED:

Program Strengths

1. Experienced management and staff with a wealth of technical expertise and historical knowledge.
 - a. The Program was able to add two more FTE at the technical staff level since the last IMPEP review.
 - b. Additionally, North Carolina has 52 years of experience as an Agreement State. North Carolina became an Agreement State on August 1, 1964. The experience and knowledge the Program has gained over the years have helped shape the Program.
2. Program Support
 - a. This includes Human Resources, Technical, and Information Technology support to help the Program with any and all items they might identify.
3. Work from Anywhere
 - a. The only requirement is that Program staff need to have internet access. The ability to work from anywhere helps to promote a good work life balance for staff while creating greater effectiveness in servicing the regulated community in case of a needed regional incident response.

Program Challenge(s)

1. Historical Knowledge and Succession Planning
 - a. The Program stated that while it currently has a lot of historical knowledge due to the experience of the staff, it is now focusing on capturing that knowledge in procedures to ensure continuity and consistency in the future. Additionally, the Program recognizes the need to continue to work with State government leadership on strategies for staff retention and succession and to promote career growth opportunities.

Feedback on the NRC's Program

The Program mentioned that it still struggles with the distributed version of web based licensing (WBL). Due to the lack of Agreement State interest in the distributed version of WBL, the NRC has limited the resources needed to maintain the system and focused more on the NRC hosted version. The Program plans to transition to the hosted version of the system within the next 12 months and stated that continued NRC support of the hosted version of WBL would be critical to the Program's continued success.

The Program communicated strong appreciation for the NRC funded training courses. The Program believes that these courses are essential in training new staff.

Lastly, the Program mentioned that it was interested in hosting the next offering of the Sealed Source and Device (SS&D) Workshop as it has several staff who have yet to take this course. After the periodic meeting, this information was provided to the SS&D team leader for consideration.

Organization

The Program is administered by the Radiation Protection Section, which includes the Radioactive Materials Branch, within the Division of Health Service Regulation (the Division). The Division is part of the Department of Health and Human Services. There have been no reorganizations since the 2014 IMPEP review.

Program Budget/Funding

The program is 100 percent fee funded. The money goes into a dedicated fund specific for agency use. Surplus money is maintained in a non-reverting fund and can be used for future decommissioning or clean-up projects as needed.

Technical Staffing and Training (2014 IMPEP: Satisfactory but needs improvement)

At the time of the periodic meeting, the Program consisted of 12 technical staff positions, one Branch manager, one general license (GL) program manager, and one administrative support staff totaling 14.5 full time equivalents (FTE). This is an increase of two FTE from the 2014 IMPEP review.

It was noted in the 2014 IMPEP report that at the time of the review there were two vacant staff positions in the Program. Both vacant positions were filled between the March 2014 IMPEP review and the April 2015 Periodic meeting. At the time of the April 2015 periodic meeting there were another two vacancies in the Program. One resulted from an individual who left the Program shortly after the IMPEP review and the other was a new position created for the Program. Additionally, since the April 2015 Periodic Meeting one individual retired from the Program creating a third vacancy. As of the September 2016 periodic meeting all three vacancies have been filled and the Program is currently fully staffed. The Program also utilizes two contract employees when needed. One contract employee helps with engineering reviews for sealed source and device applications and the other contract employee helps with regulation promulgation. The Program is also considering obtaining additional support for its GL program. Currently 0.5 FTE are dedicated to the GL program; however, the Program is investigating expanding this role to 1.0 FTE.

The Program has a documented training plan for technical staff. Per the 2014 IMPEP report, the training plan had not been updated since 2004 and was not consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1248, "Formal Qualification Program for Federal and State Material and Environmental Management Programs." This resulted in the review team making a recommendation for this indicator.

Recommendation 1: The review team recommends that the State update its training qualification program to be consistent with 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: The Program revised its procedure and finalized the changes in July 2015 to make it consistent with IMC 1248. The revised procedure is being used by all staff currently going through the qualification process and will be applied to new staff hired by the Program. The Branch manager is tracking all refresher training for qualified staff. The Program has implemented a more restrictive requirement of 40 hours of refresher training for qualified staff.

Status of Materials Inspection Program (2014 IMPEP: Satisfactory); Technical Quality of Inspections (2014 IMPEP: Satisfactory)

The Program has conducted 280 Priority 1, 2, and 3 inspections since the last IMPEP review. Of those, ten have been completed overdue. The Program has no Priority 1, 2, or 3 inspections currently overdue. The Program has completed 55 initial inspections of which five were completed overdue. It should be noted that the number of initial inspections completed overdue is less than that reported in the 2015 periodic meeting summary (ML15153A624). At the time of the 2015 periodic meeting, the Program ran a report that led them to believe that 10 initial inspections were completed overdue. This was due to inconsistencies in the way initial inspection data was being populated and tracked by the software in the distributed version of WBL. Since the 2015 Periodic meeting the Program has worked with the WBL contractors to address this issue and believes it has been resolved. In preparing for this periodic meeting, the Program realized that only five initial inspections were completed in greater than twelve months after license issuance. These inspections were completed overdue because of a misunderstanding by the Program staff that there was an absolute deadline of one year for initial inspections. Staff were for a period of time incorrectly treating initial inspections as one year +/- 25 percent, similar to routine inspections. This misunderstanding was resolved and is no longer occurring. Based on the numbers provided by the Program during the periodic meeting it is estimated that the Program has completed four percent of Priority 1, 2, 3, and initial inspections overdue since the last IMPEP review.

During the periodic meeting the Program noted that they complete health and safety inspections separate from security inspections. There is no requirement that a Program complete these inspections at the same time, as long as the inspections are not completed by more than +/- 25 percent of their designated inspection frequency.

Pre-licensing visits of new applicants were also discussed. The Program noted that they do not hand deliver licenses and that once the pre-licensing visit is complete the inspector works with the license reviewer to complete the license. The Program also instituted a policy that for any unknown entity the reviewer must independently validate at least three documents submitted in the license application (i.e. training certificates, landlord letters, attestations, etc...). This is meant to protect against fraudulent documents being used to obtain a license. Additionally an invoice is issued to the prospective licensee that must be paid before the completed license can be issued.

Reciprocity inspections were also discussed. At the time of the Periodic meeting the Program was uncertain of the exact number of candidate reciprocity inspections completed, however the

Program stated that they were aware of the NRC's criteria to inspect 20 percent of candidate licensees each calendar year. The inspection team tries to inspect as many reported reciprocity worksites as possible and typically exceed inspections of 50 percent of the licensees that file. The Program is confident that they are exceeding the NRC's criteria for inspection of candidate reciprocity licensees.

The Program has a policy to accompany all staff performing radioactive materials inspections on an annual basis. All inspector accompaniments were performed in CY 2014. Two of those accompaniments were performed by the Inspection team lead since the Branch manager position was not filled until December 2014. All accompaniments have also been completed for calendar year 2015. No supervisory accompaniments have been completed for calendar year 2016, however the Branch manager has plans to complete the supervisory accompaniments of all staff in the fall of 2016.

The Program uses inspection procedures that are consistent with the inspection guidance outlined in IMC 2800. The Program does not issue any final inspection findings in the field. The Program will leave preliminary inspection findings with the licensee in order to allow immediate licensee response when appropriate. All inspection data undergoes a managerial review before being officially issued. Inspection findings are routinely sent to licensees within 30 days of completing an inspection.

The 2014 IMPEP review team made one recommendation for the indicator Status of the Materials Inspection Program.

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: In the 2014 IMPEP report it was noted that the Program faced many challenges with the database that was in place at the time of the review. Shortly after the review was completed the Program did a large data dump into the distributed version of WBL in order to close down the legacy database that was causing so many tracking issues. In implementing the WBL database, issues with data population and with inspection tracking were again identified. At the time of the April 2015 periodic meeting, the Program was working with the NRC contractors for WBL to fix the problems found and to ensure that data fields for the next initial and routine inspections are populated correctly. Since the last periodic meeting, the Program believes that the data issues have been resolved; however, they continues to run reports and do extensive quality checks to ensure that no inspections are missed. The Program has not yet written these quality checks into their procedures but plans to address this portion of the recommendation before the next IMPEP review.

Technical Quality of Licensing Actions (2014 IMPEP: Satisfactory)

The Program has approximately 580 specific licensees. All licensing actions are completed in a timely manner. Since the last IMPEP review the Program has implemented a peer review system for licensing actions and holds weekly licensing meetings in order to discuss any issues that arise during the processing of licensing actions. Sixty-one licensing actions are currently in house. The longest licensing action has been with the Program for approximately 165 days and is a renewal. The Program receives most of their licensing actions electronically and encourages licensees to submit their requests this way. Typically, the Program averages

around 30 days to process an amendment and around 60 days to process a renewal. Staff has signature authority for licensing actions that they have been qualified to perform. The guidance used by the Program is equivalent to the NRC's NUREG 1556 Series guidance.

Technical Quality of Incidents and Allegations (2014 IMPEP: Satisfactory)

The Program is aware of the need to maintain an effective response to incidents and allegations. At the time of the periodic meeting the Program had reported twenty-one events since the last IMPEP review. All reportable events were conveyed to the NRC in the correct manner. The Program received and responded to five allegations since the last IMPEP review. One of these allegations was transferred to the Program by the NRC. The Program processed and closed all of the allegations in a timely manner. The Program uses procedures equivalent to the NRC's incident and allegation procedures for processing events and allegations.

Regulations and Legislative Changes (2014 IMPEP: Satisfactory)

The current effective statutory authority for the program 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 Program has six regulation amendments overdue for adoption. These regulation amendments were submitted to the NRC in proposed format only. The Program will resubmit the regulations for the NRC's review once they are set as final regulations.

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, 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. The Program will be required to review all radiation protection rules to determine if they are 1) necessary with substantive public interest, 2) necessary without substantive public interest, or 3) unnecessary. The Program must then post these initial determinations and invite the public to comment. Once comments are addressed all of the gathered information needs to be submitted to the Rules Review Commission. The Program will need to complete this process in calendar year 2018.

Sealed Source and Device (SS&D) Evaluation Program (2014 IMPEP: Satisfactory but needs improvement)

- Technical Staffing and Training

SS&D evaluation responsibilities are distributed between two qualified reviewers. Both qualified reviewers have degrees in a physical science and have attended the NRC's SS&D Workshop. The Program is working to qualify two additional reviewers in the near future.

- Technical Quality of the Product Evaluation Program

Since the last IMPEP review, the Program has processed four SS&D actions. All actions were amendments to existing registries. Additionally, staff will track incidents related to SS&Ds issued by the Program. Inspectors also ask the manufacturers of SS&Ds about incidents during inspections so that the Program is aware and to look for any generic issues with a device.

The 2014 IMPEP review team made one recommendation for this indicator.

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: The Program rewrote their SS&D procedures following the 2014 IMPEP review. The revisions included changes to the SS&D review process that will help ensure the Program has complete and legible SS&D information that is accounted for. The Program has also moved into a new office space since the last IMPEP review. This move allowed the Program to consolidate all of the Program's files (Licensing, SS&D, Financial Assurance ...) into one location so that they are readily accessible for those that have a need to know. SS&D files are also contained electronically on a shared drive and in the Program's distributed version of WBL.

CONCLUSIONS:

The Program continues to be an effective, well maintained Agreement State program. There were no vacancies at the time of the review. The Program is working on addressing the three recommendations from the previous IMPEP review. Use of the distributed version of WBL has provided some challenges for the Program and they plan on switching to the hosted version of WBL within the next year. The Program is effectively managing its licensing, inspection, and SS&D activities and is responding to incidents and allegations as appropriate. Six regulation amendments are overdue for adoption.

Based on the information provide during the periodic meeting as captured above, the NRC staff recommends that the next IMPEP review be conducted as scheduled in March 2018.