



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION I  
2100 RENAISSANCE BLVD., SUITE 100  
KING OF PRUSSIA, PA 19406-2713

June 2, 2015

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

Dear Mr. Cox:

A periodic meeting with you and your staff was held on April 16, 2015. 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 Daniel Collins, Lisa Dimmick, and me.

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 June 23, 2015 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](mailto:Monica.Ford@nrc.gov) to discuss your concerns.

Sincerely,

*/RA/*

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

June 2, 2015

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**SUNSI Review Complete: MLF (Reviewer's Initials)**

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

DATE OF MEETING: April 16, 2015

<b>U.S. Nuclear Regulatory Commission (NRC) Attendees</b>	<b>North Carolina Division of Health Service Regulation Attendees</b>
Monica Ford, State Agreements Officer, Region I	W. Lee Cox, Chief, Radiation Protection Section
Daniel Collins, Director, Division of Nuclear Materials Safety, Region I	David Crowley, Manager, Radioactive Materials Branch
Lisa Dimmick, Senior Health Physicist, Agreement State Programs Branch, Office of Nuclear Material Safety and Safeguards	Talytha Moore, Technology Support Specialist

**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 on the Program. 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. This summary is a reflection of that periodic meeting.

**TOPICS COVERED DURING THE MEETING INCLUDED:**

**Program Strengths**

1. Experienced Radiation Control Program Director
  - The radiation control program director came up through the Program and has 22 years of experience with North Carolina State government.

2. Well trained staff
  - Program management also stated that program staff is the most well trained staff in North Carolina State government thanks to the training resources available to the staff.
3. Dedicated Information Technology (IT) Staff
  - The Program has its own IT department which can make changes quickly and deal with IT issues that arise.
4. ~51 years as an Agreement State
  - North Carolina became an Agreement State on August 1, 1964. The experiences and knowledge the Program has gained over the years have helped shape the Program.

#### Program Challenge(s)

1. An underperforming legacy database.
  - The Program has dealt with this challenge by transitioning to the distributed version of Web Based Licensing (WBL). While the transition hasn't solved every database tracking issue, the Program has a plan in place and hopes that eventually modifications to WBL will allow them to track the data they need.
2. Staff morale
  - Staff morale was low at the time of the last IMPEP review due to poor managerial oversight of the program. Since the last IMPEP review the Program has hired a new Branch manager and has implemented monthly staff meetings that the home based inspectors come to the main office to attend.
3. Some licensees being inspected by the same inspector for several inspections
  - Since the Program's inspectors are home based, inspections are variably regionalized based on the work load for that year. This can lead to an inspector performing the same licensee's inspection several times in a row. The Program has decided that it will implement a policy that at least every third inspection will be done by a different inspector from the previous inspection.

#### Feedback on the NRC's Program

The Program was very complimentary of the IMPEP process. However, the Program mentioned that it would be preferential if the IMPEP report could contain language that would help a program get the resources it deemed necessary to have a successful program (in North Carolina's case the discussion specifically revolved around staffing issues from the 2014 IMPEP review). A discussion on this topic during the periodic meeting brought to light other resources that could be used to achieve the same goal, for example a letter of support. The Program also mentioned that it would be helpful if the IMPEP reports tied in information from the State's previous IMPEP reports in order to look for trending.

#### 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 11 technical staff positions totaling 10.5 full time equivalents (FTE), one Branch manager, and one administrative support staff. During the month following the periodic meeting the Program stated that two FTE were reallocated to the branch. This reallocation creates an increase of two technical staff positions from number identified in 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. Since the IMPEP review both of these positions have been filled. This includes the vacant Branch Manager position that was discussed in the IMPEP report. The Program hired a new Branch Manager in December 2014. At the time of the 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 is a new position for the Program which came about from the reallocation mentioned above. One of the two vacancies has been posted and is expected to be filled in the three to four weeks following the periodic meeting. The Program hopes to have the other vacancy filled within four months. 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 has a documented training plan for technical staff. However, as noted in 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." The review team made one recommendation for this indicator. The recommendation is listed below along with its status.

**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 to make it consistent with IMC 1248 following the 2014 IMPEP review. The revised procedure is currently undergoing a second revision and the Program hopes to have the revisions completed within the next four to six weeks. 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.

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

The Program has conducted 130 Priority 1, 2, and 3 inspections since the last IMPEP review. Of those, five have been completed overdue. Two inspections are currently overdue. The Program performs its health and safety inspections separate from its security inspections. No security inspections have been completed overdue since the last IMPEP review. The Program has completed 16 initial inspections of which it is believed 10 were completed overdue. These inspections were completed overdue because of data tracking errors associated with the distributed version of WBL. The Program is unsure of the reported numbers since they discovered inconsistencies in the way initial inspection data was being populated by the software in WBL. The Program demonstrated the database issues during the periodic meeting. The Program is working with the NRC WBL contractors to correct for these database issues and to ensure proper tracking of inspection due dates (for both routine and initial inspections) and database population. The review team made one recommendation for the indicator Status of the Materials Inspection Program. The recommendation and its status are listed below.

**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 complete 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 new database issues with data population and with inspection tracking were again identified. The Program is working with the NRC contractors for WBL to fix the problems found and to ensure that data for initial and routine inspections is populated correctly, based off of what is initially entered by staff, so that the next inspection date is correct.

The Program uses inspection procedures that are consistent with the inspection guidance outlined in IMC 2800. The Program does not issue any inspection findings in the field. All inspection data is reviewed and signed by the Inspection Coordinator (or if the Inspection Coordinator performs the inspection the review and signature is completed by the Branch Manager). Inspection findings are routinely sent to licensees within 30 days of completing an inspection.

The Program issued 36 reciprocity approvals in calendar year (CY) 2014. Sixteen of those reciprocity candidates provided notification of work to be performed. The Program inspected eight of those 16 reciprocity candidate licensees. In CY 2015 the Program received 36 applications for reciprocity. Eleven of those licensees have sent in notifications of work. The Program has performed zero reciprocity inspections as of the periodic meeting.

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 coordinator since the Branch Manager position was not filled until December 2014.

Technical Quality of Licensing Actions (2014 IMPEP: Satisfactory)

The Program has approximately 600 specific licensees. All licensing actions are worked on 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. The Program has received 540 licensing actions since the last IMPEP review. One hundred and seventy eight actions are currently in house. The longest licensing action has been with the Program for approximately 271 days and is 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 eight events since the last IMPEP review. All reportable events were conveyed to the NRC in the correct manner. The Program is aware that five of the reported events require additional information and that seven of the events have not yet been closed by the State in NMED. The Program is working with Idaho National Laboratory to address these items. The Program uses procedures equivalent to the NRC's allegation procedures for processing allegations. The Program updated these procedures following the 2014 IMPEP review. The Program received and responded to six allegations since the last IMPEP review two of which pertained to material regulated by the Program.

Regulations and Legislative Changes (2014 IMPEP: Satisfactory)

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. No legislative changes affecting the Program have occurred since the last IMPEP review. The Program has one regulation amendment overdue for adoption. The overdue regulation is associated with Regulation Amendment Tracking System Identification Number 2011-2 "Licenses, Certifications, and Approvals for Materials Licensees; Parts 30, 36, 39, 40, 70, and 150." The Program is working on addressing this overdue regulation along with other regulations that are coming due later this year. The Program plans to have final regulations in place by the end of CY 2015.

North Carolina regulations are subject to sunset provisions which require 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 be required to review all radiation protection rules in July 2018 and then report to the Rules Review Committee as to whether the rules are necessary or not necessary and what if any public impact the rule has.

The Program has not yet implemented regulations equivalent to the NRC's Part 37 regulations. The Program plans to have equivalent regulations implemented by the due date in March 2016. If the Program determines that they are unable to meet this deadline they will use a license condition to adopt the NRC's Part 37 regulations by reference. This license condition would then need to be administratively added to approximately 40 licenses.

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.

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. The Program is working to qualify one additional reviewer in the near future. Both qualified reviewers have degrees in a physical science and have attended the NRC's SS&D Workshop.

- Technical Quality of the Product Evaluation Program

Since the last IMPEP review, The Program has processed two SS&D actions. Both actions were amendments to an existing registry.

The review team made one recommendation for this indicator. The recommendation is listed below along with its status.

**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.

**CONCLUSIONS:**

The Program continues to be an effective, well maintained Agreement State program. There are two staff level vacancies at this time. 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, specifically in the area of data tracking, which the Program is aware of and is working with the NRC contractors to resolve. The Program is effectively managing its licensing and inspection activities. The Program is responding to incidents and allegations as appropriate and has one regulation amendment overdue for adoption. There are two qualified SS&D reviewers in the Program and two SS&D actions have been processed since the last IMPEP review.

NRC staff recommends that a periodic meeting be held in 18 months and that the next IMPEP review be conducted as scheduled in March 2018.