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Division of Health Service Regulation

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June 3, 2014

Duncan White, Chief  
Agreement State Programs Branch  
Division of Materials Safety and State Agreements  
Office of Federal and State Materials and Env. Man. Programs  
US Nuclear Regulatory Commission  
Washington, DC 20555-0001

**SUBJECT: Addendum to North Carolina Response of 2014 IMPEP Report**

Dear Mr. White:

Please accept the following as an addendum to our initial response. Additional time to gather thoughts and complete action items have led to the following information and requests for consideration.

At the end of 2013 North Carolina Radiation Protection Section (RPS) was struggling in two key areas: consistent strong leadership with an emphasis on quality assurance; and staff retention. RPS had lost half of its four license writers during the period, and one of the two remaining license writers had only been employed for one year.

In September of 2013, I took over the management of the radioactive materials branch in addition to my section chief duties. A consultant was also hired to help offset the current staff workload. Unfortunately, these actions and the short period of time before our Integrated Material Performance Evaluation Program (IMPEP) of March 2014 was not enough time to positively impact the program. The bulk of the problems that the IMPEP team identified were administrative. License writers were unsure what they were trained to work on independently, paperwork was randomly kept, the QA review of the license documents was rushed, RAMDATA Access database was corrupted; operational procedures were outdated not including the most current Nuclear Regulatory Commission (NRC) guidance, and there was miscalculation of inspection due dates. A solution to the inspection database should have been a priority. It was not, and that is being resolved. All of this points to the lack of strong, consistent leadership, and I am committed to finding a new manager that has an eye for organization; quality assurance and leadership. I too am to blame for losing control of this typically high performing group. I am committed to being much more engaged and focused on day-to-day operations.

Staff retention is an overall area of concern which we are currently addressing with the Department and Human Resources. I feel certain that we will be able to offer a much more reasonable pay scale in the coming months.

Radiation Protection Section

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While the evaluation uncovered several administrative shortcomings, the indicators related to protecting health and safety were found to have the highest standing. Those indicators were Technical Quality of Inspections and Technical Quality of Incident and Allegation Activities. Our licensees do not hesitate to call us with safety concerns and often we are a helpful tool of support for licensees bringing up radiation safety concerns to their management. Incident and allegation response is and has always been a top priority.

I do want to explain in detail the actions that have been taken place since the IMPEP in an effort to improve performance of the program. Since the IMPEP, staff have created new procedures. The initial assignments were developing updated procedures for: licensing; inspections; training; inspector accompaniments; IC inspections; sensitive information handling; financial assurance; Nuclear Material Event Database (NMED); Sealed Source and Device (SS&D) registry; incident response; and allegation response. Each procedure was re-written by a dynamic team encouraging communication. Meetings were twice a week requiring each team to review each other's procedures. The SS&D procedure was one of the first processes reviewed and rewritten. This new procedure ensures that official SS&D documents are complete and in accordance to NUREG-1556 Volume 3, legible, accounted for, and are readily accessible to those who are determined to have a need to know. Any missing SS&D documents identified during the evaluation have been found and accounted for. All of the above-mentioned procedures initially assigned are already in the testing/training phase to ensure that they are clearly written for someone not familiar with the area. As additional changes are made additional training will take place.

Our consultant has been charged with reviewing all inspection due dates and implementing a new inspection tracking system. We are in the process of manually going through all the inspections completed by inspectors since 2009 and entering corrected inspection dates and due dates into the license tracking system distributed version (LTS-DV) that was offered by the NRC. The LTS-DV, web-based licensing distributed version (WBL-DV) will not be subject to the same corruption issues found in our old Access database. The NRC is maintaining their own copy of this software and providing updates to N.C. and other states at regular frequencies.

Part of our improvement strategy was to place more responsibility on technical staff on actions that might impact data and critical inspection due dates. The new licensing procedures now require that if a license writer creates a new license, he/she must enter a new DRAFT inspection for that license that is due not more than 12 months from the date of issuance. This removes the middle administrative staff that might not recognize a new license when entering data, or understand the significance of ensuring that the due date be calculated not according to the regular frequency but at less than 12 months for the initial inspection. New procedures for separate tracking of due dates for field, security, and home office inspections have also been developed.

We agree and acknowledge the problem of the inspection Access database miscalculating the inspection due dates, and the bad practice of reliance upon non-technical staff for identifying new licenses. Solutions outlined above will prevent those issues from reoccurring. We thank the IMPEP team for helping us make this a top priority. That being said, we are challenging the finding for status of materials inspection program. The finding is "satisfactory but needs improvement" but the data and report show that only 9 percent of the inspections were actually conducted overdue. This outcome is despite the database short comings and bad practices. I believe the IMPEP team was compelled to issue the finding based on the fact that the bulk of overdue inspections were made up of initial inspections. I believe that many of these overdue initial inspections were due to differing approaches of satisfying the guidance outlined in IMC 2800. After hand delivery of a new license which includes touring the facility, interviewing the licensee and relaying license information and compliance expectations, the RPS process for conducting initial inspections included calling the licensee every 6 months until material is obtained. This phone call is documented and the provisions in IMC 2800 Section 05.03 a. 1-5 are met.

The differing approaches are a documented phone call versus an onsite visit. RPS contends that their practice meets the intent of the Inspection Manual Chapter. There may have been an instance where the inspection due date was miscalculated and the staff did not catch it in time, delaying the initial inspection to normal inspection frequency. We contend that this mistake did not occur 10% of the time as only 9% of total inspections (including routine inspections) were calculated to be overdue by more than 25% by the IMPEP team. We now understand that an on-site inspection for initial licenses whether they possess material or not is an NRC practice and expectation. RPS commits to revising their newly developed procedures to come in line with those practices of the NRC. We also understand that this expectation has precedent at other Management Review Board (MRB) findings. Based on this, RPS requests the MRB consider finding this indicator satisfactory with two recommendations that the branch implement procedures and a new tracking system to prevent future degradation of the status of the inspection program into the satisfactory needs improvement category. RPS also asks the MRB to reconsider the finding of adequate to protect public health and safety, but needs improvement. It is requested the MRB consider a finding of adequate, if the decision is to upgrade the status of materials inspection program to satisfactory. This is in step with the Adequacy and Compatibility finding criteria found in IMPEP management directive 5.6.

In conclusion, we would like to thank the IMPEP team and the MRB Chair and members for their time, consideration, and comments. RPS appreciates the in-depth evaluation the IMPEP team performed. It was conducted in a collegial and professional manner, one in which Paul LoHaus and other NRC IMPEP founders had intended. The findings and recommendations have helped us focus our energy to implement desperately needed changes. For the reasons outlined above we respectfully request that the MRB consider modifying the findings. This information is put before you to consider our request that the common performance indicator for status of materials inspection program be found satisfactory, and therefore our program be found adequate to protect public health and safety in accordance with management directive 5.6. This would be due to the fact that two of the indicators would remain as satisfactory, but needs improvement and the rest of the 6 indicators would carry the highest ranking of satisfactory, and our regulations were compatible. We also respectfully request the recommendation for monitoring be reconsidered.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Lee Cox, III". The signature is stylized with a large, sweeping flourish at the end.

W. Lee Cox, III  
Radiation Protection Section Chief

WLC