



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**
Division of Health Service Regulation

ROY COOPER • Governor
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May 1, 2018

Paul Michalak, Chief
Agreement State Programs Branch
Division of Material Safety, State, Tribal, and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards

Dear Mr. Michalak:

The North Carolina (NC) Agreement State Program (hereafter "the Program"), as implemented by NC Radiation Protection Section's (RPS) Radioactive Materials Branch (RMB), greatly appreciates the assessment conducted by the Integrated Materials Performance Evaluation Program (IMPEP) team in March of 2018. It is a wonderful example of the collaboration within the National Materials Program (NMP). The insights provided during the on-site portion of the IMPEP as well as those highlighted by the draft report will strengthen the Program.

Both David Crowley, RMB Manager, and I, will attend the Management Review Board (MRB) in person on June 7, 2018 at 1:00 p.m. ET at the Nuclear Regulatory Commission's (NRC) Headquarters Office in Rockville, Maryland. Below are a list of comments regarding the draft report which were provided to the Program on April 4, 2018. Thank you for your consideration.

1.0 INTRODUCTION

- Page 1, Paragraph 3: There is no portion of RPS that performs duties of the Program outside of RMB, thus "performs the majority of responsibilities" is inaccurate and leads reader to consider another entity.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

- Page 2, Paragraph 1: The revised manual is utilized by all staff, not only those newly hired or going through qualifications. The manual is implemented for all technical staff and every member of RMB has their own individual qualification journal to track initial or refresher training.
- Page 2, Paragraph 4: RMB has always strived to complete inspections within the month they are due, at least operationally; this was not a result of the 2014 IMPEP and therefore "since the last IMPEP review" does not reflect accurately the longstanding

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goals of the Program. It would be fair to state “since the last IMPEP” in reference to newly developed queries and reports within the distributed version of NRC’s Web-Based Licensing (WBL) System.

- Page 3, Paragraph 2: It is true that a new revision of the Sealed Source and Device (SS&D) Procedure was implemented February 2018; however, the Program wrote a new procedure following the 2014 IMPEP and before attending the 2014 MRB. The new policies and procedures surrounding SS&D were subject to discussion at both of the periodic meetings throughout this past review period. The February 2018 revision strengthened many items, but given additional issues discovered in this 2018 IMPEP it will require further enhancements.
- Page 3, Paragraph 3: RMB fulfilled all portions of the recommendation as described in the 2014 IMPEP Report and as communicated during the periodic meetings in April 2015 and September 2016. From the previous IMPEP, it was told to RMB management that the issues stemmed from an accounting of records and lack of understanding for how they should be stored. This was addressed very early on in the recent IMPEP period and staff improved the policies and procedures for creating SS&D records and then retaining them consistently. Please note, that the adequacy of the Program’s SS&D reviews were never questioned or discussed previous to this 2018 IMPEP.
- Page 3, Paragraph 3: Saying “continued weaknesses” suggests previous issues were not addressed; it would be more correct to state that the IMPEP team identified additional weaknesses, therefore opening a new recommendation.

3.0 COMMON PERFORMANCE INDICATORS

- Page 4, Paragraph 2: The 14.5 full time equivalent could be more clearly stated as being a manager, three team leads (for licensing, security and response, and inspections), an administrative assistant that coordinates reciprocity activities and uploading license actions, an environmental consultant that serves as both quality assurance reviewer and rule writer, three license reviewers, three inspectors, a hybrid inspector and license reviewer, an environmental program coordinator, and a half time person to function as general license coordinator. Note that all except the administrative assistant and manager are classified as health physicists.
- Page 4, Paragraph 4: The reorganization became effective April 26, 2018.
- Page 7, Paragraph 3: There was groundwork laid to get the transition moving from a locally-hosted WBL to the NRC-hosted WBL, but it didn’t actually begin until the final week in March 2018. It appears the comment is meant to reference a special add-on feature that the Program developed to the locally-hosted WBL. This feature enables staff to select non-compliances real time and automatically generate reports and non-compliance letters. However, it did have some hurdles and nuances such that it was left up to the inspectors to decide which method they wanted to utilize to achieve a satisfactory inspection record (notes, findings, letters, etc.); therefore, in certain cases the old style inspection forms were still utilized. Given the transition to NRC-hosted WBL, this add-on feature will disappear entirely and the inspection team will revert to the old forms until something is established within the new WBL version.

- Page 7, Paragraph 4: Stating that a method may result in an outcome that was not observed by the IMPEP reviewer introduces a subjective interpretation of how the Program conducts business; request that only statements backed by actual observations are included. It is accurate to state the Branch Manager was asked about the method of documentation and answered that there exists a potential weakness, but it should also be added that through training, procedures, and accompany feedback that thorough preparation is emphasized to inspectors to review all past inspection files over the last routine inspection period. It may be some form of weakness of the WBL platform; however, the Program works diligently to overcome it and not let it impact the quality of inspection activities.
- Page 7, Paragraph 6: The statement “North Carolina replaced their security inspector” could suggest that there was some performance issue which required the transition. This was not the case as it was due to a retirement and subsequently filling the vacancy. The retiring individual never performed Part 37 inspections as departure from the Program occurred a few months prior to its effective date. Additionally, all case files were reviewed by the Branch at the time of being conducted; it was a manner in which the security inspector stored certain sensitive documents that made inspection notes inaccessible.
- Page 7, Paragraph 6: Again an IMPEP reviewer comments on a method of database entry that could lead to confusion with inspection dates; however, none were observed. This is something that RMB staff review carefully to avoid errors and many levels of process control were created to ensure it does not happen. Request that the subjective nature of comment be removed and that acknowledgement be granted to the steps taken by the Program. Finally, if the content remains then it should be moved to Section 3.2 Status of Materials Inspection, as it is pointed more towards the accurate tracking and completion of inspections in a timely manner rather than the technical competency displayed while conducting an inspection or documenting any findings.
- Page 7, Paragraph 6: Please note that the RMB’s security inspector (as well as past inspector) served on NMP working groups regarding Part 37 requirements, policy and enforcement. The Program enforces requirements as laid out in the rule and licensing commitments, not according to guidance or best practices. In the particular case mentioned, there were other physical measures placed above the drop down ceiling to adequately prevent access even though the wall was not continuous in and of itself.

4.0 NON-COMMON PERFORMANCE INDICATORS

- Page 12, Paragraph 3: The NC Administrative Code (NCAC) reference is incorrect; it should be Title 10A, Chapter 15.
- Page 12, Paragraph 4: The Rules Review Commission (RRC) does not enter the process until much later as they are the legal review that must approve language and authority prior to passing a rule. Instead, the report should state rulemaking begins with the Program recommending to the NC Radiation Protection Commission (RPC) that rules are due for revisions. The RPC then directs the Radioactive Materials Control Advisory Committee to commence rule development. There are many steps the rules must be

brought to in order to be passed (State Budget, Department, RPC, RRC, etc.); suggest leaving the last statement to end at “it can take one to three years for adoption.”

- Page 12, Paragraph 5: Public comments are resolved and the rules are presented to the RPC in a final version. The RPC then votes to submit rules for the Office of Administrative Hearings RRC to review the final rule. The process concludes with the RRC holding a hearing to review the rule and to decide if they accept to pass the regulation (as written and submitted by the RPC), then it will become effective on the first day of the following month.
- Page 14, Paragraph 5: Performing two tertiary reviews for the purpose of SS&D qualification was the practice for at least a decade or more (as long as anyone employed now can recall); it always seemed to satisfy IMPEP reviews previously. The Program does not believe it practicable to perform near the NRC’s casework numbers with the limited SS&D activity conducted within the State. RMB acknowledges the need and plans to increase the casework to provide reviewers with sufficient knowledge and confidence while performing SS&D reviews.
- Page 15, Paragraph 3: The procedure passed in February 2018 was simply a re-embodiment of the procedures and policies put in place immediately following the 2014 IMPEP. Same comment as noted above for Page 3, Paragraph 2.
- Page 16, Paragraph 1: Future SS&D processes are being worked out to include better documentation and rationale on decision making points throughout the reviews. Additionally, a challenge board will be utilized that reviewers and concurrence reviewers must present their products to and all questions must be answered and recorded to the satisfaction of that board before approving an action. This group shall be comprised of at a minimum: management, a license reviewer, an inspector, and an administrative person for recording. They must be unique to the SS&D reviewers themselves. Should a specific device or source require outside expertise (i.e. medical or engineering) then an expert representative to that discipline will be found to participate as a non-voting resource to the challenge board. All records of this meeting shall be added as a memo to the SS&D file.
- Page 16, Paragraph 2: The Program accepts the weaknesses found in the SS&D program and appreciates the recommendation made by the IMPEP reviewers. Many processes and procedural adaptations shall take place, for example the above mentioned challenge board, to ensure that all of the concerns mentioned in the report are addressed completely and as quickly as practicable to provide only the highest quality results.
- Page 16, Paragraph 6: In the cases where a concurrence signature was provided by a SS&D reviewer in training, it was also reviewed by a second qualified SS&D reviewer; so in total three members reviewed independently. Apparently at the time this signature error occurred the procedures were not yet clear enough and the training was inadequate. This will be remedied in procedure, training, and by careful review of implementation.
- Page 16, Paragraph 8: Same as previous comments; there were new procedures dating back to 2014. The Program agrees that the latest revisions are much stronger than what served most of the review period and should go a long way to resolve the

recommendation in this IMPEP report. That said, there will be numerous areas to continue enhancing the procedures and implementation of RMB's SS&D program as a result of this review.

- Page 17, Paragraph 1: Suggest that the report utilize keyword "now" in context to management being aware of the issue; up until this IMPEP review the only real obvious weakness was with respect to storage and recordkeeping of the SS&D files. SS&D comprises less than half a percent of the total workload conducted by RMB; therefore, the Program first focused on enhancing other more significant sectors (i.e. inspections, licensing, and incident response). Being in a stronger position with respect to these other areas now allows the Program a shift to hone in on SS&D needs.

5.0 SUMMARY

- Page 18, Paragraph 1: The Program understands why the IMPEP team recommended that a periodic meeting take place in one year. In reality, that timeline is compressed to much less than one year due to the normal IMPEP process of MRB meetings and final report submittal. The Program would like the team to consider recommending the standard two year periodic meeting to give the Program appropriate time to develop and implement an improvement strategy. It would also afford more metrics for the IMPEP team to make an informed decision on performance. The Program is also suggesting the team consider that a full review of the SS&D indicator be conducted during that periodic meeting.

Respectfully,



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