

# Comment Resolution Document

## North Carolina IMPEP Review FY2022

Email from David Crowley, David Crowley  
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North Carolina Department of Health and Human Services  
Dated June 21, 2022 - **ML22208A169**

Comment No.	Location	Comment	Accepted
1	Section 1.0, Introduction	The report stated NC had 671 specific licenses, but this accounted for our accelerator licenses.	Accepted
2	Section 2.0, Previous IMPEP Review and Status of Recommendations	The IMPEP report generally captures strong improvements made by the Program with respect to the Sealed Source and Device (SS&D) indicator. Given the strides made over the review period, we believe that NC has established one of the strongest SS&D programs in the National Materials Program (NMP). The Program has recovered from having just one qualified reviewer, to three. We have implemented new procedures and reviewed SS&D actions using a team approach. In the absence of a center of excellence, NC has coordinated assistance to and from other state programs.	Not Accepted
3	Section 2.0, Previous IMPEP Review and Status of Recommendations	The Program can still make progress with respect to SS&D, but the extent of comments during this IMPEP focused on proper retention of email correspondence and formatting consistencies on the SS&D certificates. As such, we request that the prior three-part recommendation be closed entirely and a new one created.	Not Accepted

4	Section 2.0, Previous IMPEP Review and Status of Recommendations	Additionally, the Program strongly believes a finding of “satisfactory” more appropriate given the significant progress made with the SS&D program and the integration of NC to support the NMP’s SS&D efforts.	Not Accepted
5	Section 3.0, Common Performance Indicators	In section 3.1 <u>Technical Staffing and Training</u> , part b. <u>Discussion</u> , the report suggests there are two administrative staff, but there is only one. That leaves a branch manager, two supervisors, one administrative staff, and eleven technical staff for a total of fifteen full-time equivalents.	Accepted
6	Section 3.0, Common Performance Indicators	Regarding the longest standing vacancy, it is worth noting that the length of time for this vacancy was not due to the COVID-19 public health emergency (PHE). Posting and filling this position was delayed as the Program deliberated about the most critical needs for which this position might be utilized. Ultimately, the decision was made to move forward with hiring the position as allocated.	Not Accepted
7	Section 3.0, Common Performance Indicators	With respect to current vacancies, the Program had a license reviewer leave after the on-site IMPEP review. This individual left to pursue other opportunities, higher pay, and greater job flexibility. In total, the Program has three vacancies: a branch manager, a license reviewer, and an inspector position. The Program is in the process of hiring for all of these vacancies.	Accepted
8	Section 3.0, Common Performance Indicators	Two hires began around the week of the on-site IMPEP review. It is estimated that they will take between 1.5-2 years to complete qualification. Therefore, the statement about expecting all hires to be fully qualified in the next 4-9 months does not match the Program’s estimation regarding the length of time for these new hires to complete qualification.	Accepted
9	Section 3.0, Common Performance Indicators	In section 3.2 <u>Status of Materials Inspection Program</u> , part b. <u>Discussion</u> , there is acknowledgement about the impacts of the PHE and the Temporary Instruction (TI) 003. The Program believes it is worth pointing out that regardless of the TI, the approximately 1% overdue number of inspections is acceptable per SA-101’s criteria. The inspection efforts made over this past review period were phenomenal, especially when considering the PHE and the level of inspector turnover.	Accepted

10	Section 3.0, Common Performance Indicators	In section 3.3 <u>Technical Quality of Inspections</u> , part b. Discussion, the Program greatly appreciates the inspector accompaniment phase of the IMPEP reviews. These accompaniments add much of the value by offering real time observations of the inspection activities.	Not Accepted
11	Section 3.0, Common Performance Indicators	During this round of accompaniments, the IMPEP reviewer noted a potential knowledge gap with respect to emerging medical technologies (10 CFR 35.1000) as compared to more established therapy devices (10 CFR 35.600). With respect to this deficiency, the Program has reached out to the NRC for guidance or resources available to provide remedial training to technical staff. Additionally, the Program is conducting a site visit and training day to a local facility who operates Leksell Gamma Knife Perfexion and Icon devices (35.1000). This trip will be used to showcase features of the device, treatment planning, written directives, dose verification, and roles by various individuals at the facility.	Not Accepted
12	Section 3.0, Common Performance Indicators	The Program supports the recommendation identified in section 3.3 <u>Technical Quality of Inspections</u> , part c. Evaluation, and believes the above corrective actions will satisfactorily address the deficiency. Also, we appreciate that the evaluation points out, despite the knowledge gap, that most of the health and safety and all of the security requirements were addressed correctly.	Not Accepted
13	Section 3.0, Common Performance Indicators	In section 3.4 <u>Technical Quality of Licensing Actions</u> , part b. Discussion, the Program generally agrees with the observations and findings described. However, we ask that the second to last sentence be removed from this section, the one regarding the secure storage concerns of financial assurance (FA) instruments. The safe which stores these files is left locked and only opened for quick periods to conduct FA reviews and document updates. The safe is notoriously difficult to open, so it was opened in the morning that the IMPEP team indicated they would review FA documents. As this concern was generated to facilitate the IMPEP review, we do not feel it is fair to notate it within the IMPEP report. Furthermore, the safe is in a badge-only accessible portion of the building and adjacent to the license reviewers' offices.	Accepted
14	Section 4.0, Non-Common Performance Indicators	In section 4.1 <u>Legislation, Regulations, and Other Program Elements</u> , part b. Discussion, page 8, the report suggests 46 compatibility comments and further breaks it down to category types: 22-NRC, eight-B, 10-C, 3-H&S, and 2-multiple, but this adds up to 45. Either one comment is not accounted for appropriately or it should be changed to 45 compatibility comments.	Accepted

15	Section 4.0, Non-Common Performance Indicators	In general, the Program's 2018 IMPEP report more accurately captures the rule promulgation steps and parties involved. This 2022 draft IMPEP report emphasizes the Office of Administrative Hearings' (OAH) role at the very end; this step by OAH is only the final act to make the rules effective and has a limited role in either approving or objecting to the rules on very specific statutory bases such as whether the rule is ambiguous or exceeds the statutory authority of the rule adopting body. The North Carolina Radiation Protection Commission (RPC) is the statutorily authorized body to adopt these rules and is responsible for drafting and promulgating North Carolina's radiation regulations. The RPC approves when the rules are ready for public comment, resolves comments, and approves when to submit a final rule to OAH to be made effective.	Accepted
16	Section 4.0, Non-Common Performance Indicators	Due to the Program's approach to adopt the 10 CFR by reference, we went back and looked for all open comments from prior rule submissions. In doing so, the Program identified comments back to the early 2000's and discussed the intent to clear those with the IMPEP team. Consequently, they are now listed within this IMPEP report. While it is appreciated for completeness, the Program notes these outstanding comments were not included in prior IMPEP reports. Additionally, it does not seem to be standard practice or formatting for IMPEP reports to list out each of the regulatory amendments and outstanding comments within the body of the reports. We suggest this list be removed from the main body of the report and captured in an appendix at the end of the final report.	Not Accepted
17	Section 4.0, Non-Common Performance Indicators	For consideration, many of these comments were generated due to accidentally incorporating "NRC" compatibility rules (particularly our rule 10A NCAC 15.0117—a broad incorporation by reference rule). This additional incorporation has not resulted in confusion with our licensees, cross jurisdictional issues, or any disruptions to the orderly pattern of regulation from what we can discern.	Accepted
18	Section 4.0, Non-Common Performance Indicators	The Program is working with the RPC to prioritize and establish a schedule for rule readoptions. This schedule will bring forward the parts of the 10 CFR which have more significant health and safety or security impacts, or that are overdue for adoption for purposes of compatibility. Though we are targeting the end of 2026 to complete all readoptions, a revised schedule should allow most of our compatibility concerns to be addressed within the next one to two years.	Not Accepted

19	Section 4.0, Non-Common Performance Indicators	In section 4.2 <u>SS&amp;D Evaluation Program</u> , part c. <u>Evaluation</u> , the Program reiterates the comments stated to “2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS.” In summary, the NC SS&D program has made dramatic improvements over the past four years. We have both received help and assisted other states (ex. New Hampshire, Kentucky, and Maryland). Due to this progress and the willingness to work across the NMP, it was surprising to receive a “satisfactory, but needs improvement” largely due to formatting inconsistencies and email management.	Not Accepted
20	Section 4.0, Non-Common Performance Indicators	Throughout section 4.2 <u>SS&amp;D Evaluation Program</u> , there is no mention to the Program’s creation of a technical lead for the SS&D program. This individual is responsible for leading and sustaining the SS&D program, and they will be key for ongoing quality improvements and consistency for SS&D actions. The lead helped in training new SS&D reviewers, collaborated with outside agencies, focused efforts on priority issues (incident response and investigation), updating procedures, and much more.	Not Accepted

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Remarks
Report revised to list the correct number of licenses.
The IMPEP team appreciates the comment and agrees that NC has made some improvements to the SS&D Evaluation Program. However, no changes were made to the report.
The IMPEP team appreciates the comment and agrees that NC has made improvements to address the first two elements of the 2018 IMPEP review recommendation and determined that those elements of the 2018 recommendation could be closed. However, the team observed content and formatting deviations, as well as record keeping issues during the review, and determined that the recommendation be modified to retain the third element of the 2018 recommendation.

<p>The IMPEP team appreciates the comment and agrees that NC has made some improvements to the SS&amp;D Evaluation Program. However, no changes were made to the report.</p>
<p>The IMPEP team appreciates this information. Report revised to reflect the correct number of administrative staff.</p>
<p>The IMPEP team appreciates this information. However, no changes made though, as the comments appears to be informative and the report does not suggest that the vacancy was due to the pandemic.</p>
<p>The IMPEP team appreciates this comment. Report revised to reflect the correct number of vacancies.</p>
<p>The IMPEP team appreciates this comment. Report revised to reflect the referenced qualification completion times.</p>
<p>The IMPEP team appreciates this comment. Report revised to include the overall percentage.</p>

<p>The IMPEP team appreciates this information. However, no changes were made to the report.</p>
<p>The IMPEP team appreciates this information. Its great that North Carolina has reached out to the NRC and is planning to conduct additional training. This is an illustrative topic for discussion during the Management Review Board Meeting.</p>
<p>The IMPEP team appreciates this information. However, no changes were made to the report.</p>
<p>The IMPEP team appreciates this information. Report revised to remove the referenced sentenced.</p>
<p>The IMPEP team appreciates this comment. Report revised to correct the number of compatibility numbers.</p>



<p>The IMPEP team appreciated this comment. Report revised to reference the RPC.</p>
<p>The IMPEP team appreciates the comment. However, the report was not revised. Listing the regulatory amendments and outstanding comments in the Discussion of Section 4.1 is part of the standard practice for IMPEP report writing. Listing regulatory amendments and outstanding comments as a separate appendix is not consistent with IMPEP report writing guidance.</p>
<p>The IMPEP team appreciates the comment. However, no changes were made to the report.</p>
<p>The IMPEP team appreciates this information. However, no changes were made to the report.</p>

The IMPEP team appreciates the comment and agrees that the Program has made some improvements. However, no changes were made to the report.

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