February 16, 2022

Brian Anderson, Chief
State Agreement and Liaison Programs Branch
Division of Materials Safety, Security, State and Tribal Programs
Office of Nuclear Materials Safety and Safeguards

Dear Brian Anderson:

Subject: Comments on the Minnesota Integrated Materials Performance Evaluation Program (IMPEP) Draft Report

Thank you for the opportunity to give comments on the IMPEP team's report following the Minnesota Agreement State Program IMPEP performed in December 2021. Minnesota appreciates the IMPEP review process and the team's assessment of our program. We continue to find value in this process and remain fully supportive of IMPEP and the mission to protect public health and safety.

In general, we agree with the team's findings. We do, however, have concerns about the team's application of SA-300 Reporting Material Events in the Technical Quality of Incident and Allegation Activities, section 3.5, particularly the reporting requirements for low-risk significant incidents of lost material. The IMPEP team informed us during the review that States are to report incidents involving loss of material greater than 10 times 10 CFR Part 20 Appendix C quantities (10 CFR 20.2201 (a)(1)(ii)) within 30 days to the Headquarters Operations Center (HOC) via a telephone call or email.

During this IMPEP review period Minnesota had four events of lost material greater than 10 times 10 CFR Part 20 Appendix C quantities. These were all low risk, lost and unrecovered medical seeds in microcurie quantities. In each case Minnesota followed the guidance in section 2.3 of the Handbook of SA-300 and made the report to NMED. Minnesota did not contact the HOC via phone or email. The IMPEP team identified this as a failure, but we believe that these should not be discussed in the report.

10 CFR 20.2201 states in part that each licensee shall make a report by telephone, within 30 days, when there is the occurrence of any lost, stolen, or missing licensed material in a quantity greater than 10 times Appendix C to part 20 that is still missing. However, Minnesota is not a licensee. We are co-regulators and as part of Minnesota's Agreement with the NRC, "the State

and the Commission agree to keep each other informed of events, accidents, and licensee performance that may have generic implications or otherwise be of regulatory interest." The document describing how we keep the NRC informed of incidents and remain compatible with the NRC is designated as SA-300. SA-300 is a well-vetted procedure by the NRC and Agreement States. It is a procedure that has gone through a rigorous approval process including significant input the from the Agreement States. Section 2.3 of the Handbook in the current version of SA-300 Appendix, clearly states that Agreement States should electronically report events in this category using the local NMED with no mention of additional reporting. Since becoming an Agreement State in 2006, Minnesota has followed the procedure outlined in SA-300 for these types of events by reporting to the NRC within 30 days using our local NMED software.

During this 2021 IMPEP review, the team informed us that Agreement States reporting incidents falling under 10 CFR 20.2201 (a)(1)(ii) are to follow the regulations the same way as the licensees. It is reasonable that timeframes in SA-300 are based on the various regulations and would be the same, but not necessarily the reporting methods. If Agreement States are required to follow the regulations in 10 CFR, then reports to the HOC for events under 10 CFR 20.2201 (a)(1)(ii) would be required. It would also require Agreement States to send written reports for many events to "the appropriate NRC Regional Office listed in Appendix D to Part 20." Because NMED is not mentioned in 10 CFR, reporting to NMED would not be allowed for any event if Agreement States were required to report as licensees. 10 CFR is the requirements NRC has of its licensees. As co-regulators we assume a different relationship with the NRC, as such we have a different set of standards. The standard used for compatibility with the NRC in reporting incidents and allegations is SA-300.

The team noted in the draft IMPEP report that a revision of SA-300 will be forthcoming with clarification on this issue. We see this as a change to the existing requirements in SA-300 and not simply a clarification. Therefore, it should be described as a change in the proposed SA-300 revision and go through the standard review with input from the NRC and Agreement States. If the change is accepted in the next version of SA-300, that is when it should be evaluated in the IMPEP process.

Because these are low risk cases, the current guidance does not specify reporting these to the HOC, and we are reporting these to NMED consistent with the reporting requirements in the current SA-300, at this time it would not be reasonable to hold us to the forthcoming proposed standard. For the evaluation of this IMPEP review, we feel the events under 10 CFR 20.2201 (a)(1)(ii) should be noted as reported in accordance with the current SA-300 procedure and meeting the objectives for the indicator.

If you have any questions concerning Minnesota's response, please contact me at 651-201-5826 or Sherrie Flaherty at 651-201-4522.

Sincerely,

**Mary B. Navara RN, COHN-S, MPH, Manager**
Environmental Health Division
PO Box 64975
St. Paul, MN 55164-0975
Mary.Navara@state.mn.us
www.health.state.mn.us