Maryland
Department of
the Environment

Larry Hogan, Governor
Boyd K. Rutherford, Lt. Governor

Ben Grumbles, Secretary
Horacio Tablada, Deputy Secretary

September 21, 2021

Brian C. Anderson, Chief
State Agreement and Liaison Programs Branch
Division of Materials Safety, Security, State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards
US Nuclear Regulatory Commission (NRC)
Washington DC 20555-0001

RE: Maryland's Response to NRC's 2021 Draft Integrated Materials Performance Evaluation Program (IMPEP) Report

Dear Mr. Anderson:

Please find enclosed the Maryland Department of the Environment's (MDE) response to the draft report and corrective actions regarding the recommendations from the US Nuclear Regulatory Commission's Integrated Materials Performance Evaluation Program (IMPEP) audit conducted July 12-16, 2021. On behalf of the MDE Secretary and the RHP staff, I thank the NRC and the IMPEP audit team for their expertise, professionalism, competence, and patience during the virtual audit.

Maryland firmly supports the IMPEP process and will continue to improve the adequacy and compatibility of our Program as we further our mission to protect both occupational staff and the public against the hazards of ionizing radiation. We are looking forward to discussing the results of the IMPEP audit during the Management Review Board meeting. Should you have any questions regarding this response, please contact Eva Nair at 410-537-3300 or by email at eva.nair@maryland.gov.

Sincerely,

Horacio Tablada
Deputy Secretary

Enclosure: Maryland's Response to NRC's 2021 Draft IMPEP Report

STATUS of CORRECTIVE ACTIONS REGARDING 2021 IMPEP TEAM RECOMMENDATIONS

IMPEP Team Recommendation 1: Maryland will review the qualification of all Radiation Safety Officers (RSO), Authorized Users (AU), and Authorized Medical Physicists (AMP) listed on their medical licenses to ensure that they meet the qualifications in accordance with Maryland's regulations for medical use of byproduct material.

Status: On August 4, 2021, the Radiological Health Program (RHP) had a follow-up conversation with our Regional State Agreement Officer for further clarification and guidance on the criteria for reviewing qualifications. Currently, we are in the process of reviewing our medical licensees based on the clarification and guidance provided. We are reviewing our medical licenses based on inspection frequency. We do not have any Priority 1 medical licenses, so we are working on Priority 2, therapy licenses, followed by Priority 3. Priority 5's will be completed as amendment requests or license renewals are submitted.

We have generated a list of Priority 2 and 3 licenses and are currently evaluating qualifications of the listed RSOs, AUs, and AMPs. All licensees will receive a notice alerting them to this pending quality review. Should documentation be insufficient for any person, the licensee will receive a detailed letter requesting the appropriate documentation be submitted to the Department within thirty (30) days. Reference to another Maryland license will not be considered adequate for this verification of qualifications.

Submitted documentation will be added to the applicable licensee file and amendments will be processed if needed. The RHP staff is using a spreadsheet to ensure that all qualifications are appropriately reviewed and resolved as needed. While Priority 2 and 3 licenses take precedent for their higher risk to health and safety, Priority 5 licenses will also be tracked and updated as amendments and renewals are processed.

If a new RSO, AU, or AMP is added, and a previous Maryland license is referenced as qualification, the RHP staff will research the referenced license to ensure the individual was appropriately qualified before being added to the original license.

IMPEP Team Recommendation 2: Maryland will develop and implement a procedure to ensure protection of sensitive information as it applies to written correspondence with licensees.

Status: We are in the process of finalizing a procedure on marking sensitive information. We plan on implementing this procedure prior to the Management Review Board meeting. The Category 1, 2, and 3 licenses are marked on the top and bottom of the license by stating propriety and confidential. The same procedure will be followed for any correspondence related to security information regarding place of use and isotope and curie limits.

Each page containing security related information will be stamped as "confidential" and "security related information." As denoted in your evaluation, all license folders are locked at the end of the workday. Stamps have been purchased and are being used. A template for licenses has been created which includes "Security Related Information – Withhold under 10 CFR 2.390"

and “Proprietary and Confidential” to be used going forward. A list of Category 1, 2, and 3 licensees has been created and are being checked to ensure that the files are marked accordingly.

RESPONSE to 2021 IMPEP TEAM’s DRAFT REPORT COMMENTS

On Page 7 in item 3.3 “Technical Quality of Inspections”, under Evaluation-1st bullet, it states that management does not promptly review inspection results. For clarification purposes, inspection reports are reviewed by management within 30 days of management’s receipt of the report. This criterion was not met under the COVID-19 public health emergency when access to the office was either severely restricted or altogether not allowed since the hard copy of the inspection needs to be signed.

On Page 7 in item 3.3 “Technical Quality of Inspection”, under Evaluation-2nd bullet, it states that supervisors did not conduct annual accompaniments of each inspector. For clarification purposes, annual accompaniments of each inspector occurred prior to the COVID-19 public health emergency. Operational restrictions imposed during the height of the pandemic prevented accompaniments from taking place for several months.

On Page 8, in item 3.4 “Technical Quality of Licensing Actions”, under Discussion- 1st bullet, it states that financial assurance for the cyclotron was not required. The following has been done to rectify this issue: The licensee was directed to revise their calculation considering the materials identified in the report and determined that financial assurance is required and is in the process of submitting the required information.

On Page 8, in item 3.4 “Technical Quality of Licensing Actions,” under Discussion 2nd bullet, the IMPEP team found that RHP licensing staff incorrectly placed an RSO on a medical license. Documentation to add the RSO to license MD-07-013-01 included all the necessary documents, but the Preceptor Attestation Form 313A had the board certification pathway box checked without the proper board certification. While this box was checked, RHP licensing staff verified prior to adding this proposed RSO to the license that the doctor was already approved as an AU on the license and was seeking authorization to be recognized as an RSO. He was qualified under COMAR 26.12.01.01 Section G.50(c)(2) instead of G.50(b) as the check box indicated. RHP has noticed that licensees often have difficulties filling out Form 313A. RHP staff determined that this error did not compromise public health and safety and therefore did not request a revised form. Moving forward, RHP staff will make a stronger effort to guide licensees on how to correctly fill out this form.

On Page 8, in item 3.4 “Technical Quality of Licensing Actions,” under Discussion 2nd bullet, the IMPEP team found that RHP licensing staff incorrectly placed an AU on a medical license as the only AU on that license. RHP recognizes that documentation on file for this AU was insufficient to approve this doctor for parenteral therapeutic administration. As a result of the findings, the licensee was immediately contacted and is currently working with the RHP licensing staff to provide the appropriate Preceptor Attestation Form (correctly completed). The doctor was confirmed to be board certified in Radiation Oncology by the American Board of Radiology and has since provided documentation of his 3 supervised clinical administrations.

On Page 8, in item 3.4 "Technical Quality of Licensing Actions," under Discussion 2nd bullet, the IMPEP team found that RHP licensing staff incorrectly placed AMPs on a license that did not require AMPs. RHP staff verified, prior to adding these AMPs to the license, that they were qualified to be listed as AMPs because they submitted ABR board certification certificates with "AMP Eligible." RHP did not believe that having these AMPs listed was a public health and safety risk. If another licensee had referenced this license to request these AMPs be added, it is the responsibility of the reviewer to evaluate the authorized uses before adding an AMP onto a license. However, RHP understands that this could cause confusion and has since removed the AMPs from the license and will not list AMPs on licenses that do not require AMPs.

On Page 8, in item 3.4 "Technical Quality of Licensing Actions," under Discussion 2nd bullet, the IMPEP team found that RHP licensing staff incorrectly approved an AU for therapeutic use who was only approved for diagnostic use. RHP recognizes that this was an oversight and has since corrected it. The licensee was immediately contacted, and it was verified by the licensee that no therapeutic procedures had been performed. All G.300 materials for therapeutic use and authorized uses for G.300 materials were removed from the license. As recommended by the IMPEP report, RHP staff has met with the Regional State Agreements Officer to clarify the requirements and is currently reviewing the qualifications of all RSOs, AUs, and AMPs on medical licenses.

On Page 9, in item 3.4 "Technical Quality of Licensing Actions", paragraph 2 states that the license reviewers were missing a questioning attitude. We believe this statement is not accurate. This statement did not arise during the exit meeting, so we did not have the chance to discuss this observation or the basis for it with the IMPEP team. The licensing staff routinely communicates with new applicants and existing licensees by phone, email, and fax during the license review process to ensure regulatory requirements are fully met by the applicant before a license is issued. There have been several instances in which the license reviewer contacts the stakeholder, sometimes multiple times, to ensure that required documentation is provided or updated. If the situation demands, RHP will issue a deficiency letter to the applicant to formally document what is needed before a license can be issued. All license submissions are vetted thoroughly before an approval is issued. The license reviewer does not issue a blanket approval based solely on a submission.

On Page 9, in item 3.4 "Technical Quality of Licensing Actions", under Evaluation- collectively the three bulleted statements give the impression that our licensing reviews are inadequate overall. We acknowledge that some of the 25 file sets that were reviewed during the IMPEP were deficient in some respects. And in terms of deficiencies, we offer that some of what have been flagged as deficiencies in this current IMPEP were not designated as such over the past several IMPEPs. As such, we have been operating under the impression that our current practices are consistent with applicable requirements. Regarding the team's statement on the use of guidance documents, we offer that the IMPEP team stated in the report (p.9, 1st paragraph) that "…license reviewers generally performed license reviews following the guidance provided in the NRC's NUREG-1556 series, "Consolidated Guidance about Materials Licenses" and used the current version of the NRC's Pre-Licensing Guidance (PLG). The team evaluated the implementation of the PLG and Risk Significant Radioactive Materials (RSRM) checklists. Maryland conducted pre-licensing visits for unknown entities in accordance with the checklist,

and properly implemented the PLG. For applications with RSRM, Maryland completed the RSRM checklist, and performed on-site security reviews, as necessary."

To ensure our reviews will result in licensees operating in a manner that is most protective of public health, we have implemented a peer review procedure for renewal applications to allow for a more thorough evaluation and discussion of applications until the license reviewer is completely familiar with a particular type of license. This procedure helps to standardize the review process and ensure the technical quality of review meets the health, safety, and security requirements. It also serves as a training measure.

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