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October 17, 2019

Sarah Lopas
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Ms. Lopas:

The Organization of Agreement States (OAS) Executive Board (Board) is pleased for this opportunity to review the draft SECY paper “Training and Experience Requirements for Administration of Radiopharmaceuticals requiring a Written Directive” (RCPD-19-011). This is a rare opportunity to objectively consider a best path forward on a business practice that evolved with different perspectives. The Board greatly appreciates the level of effort put forth by NRC staff to engage all stakeholders and regulatory partners; that effort and diligence rings clearly while reading this draft SECY paper. The Board offers the following comments.

The draft SECY accurately captures discussions of policy statements, stakeholder positions, and future options. As their decision will affect all Agreement States, the Board feels it necessary to reemphasize our position on various approaches.

Approach 1: Removal of Prescriptive Training and Experience Requirements and NRC Review and Approval of Authorized Users

The Board believes that Approach 1 is in line with the Board’s comment letters submitted to date, with the following clarifications:

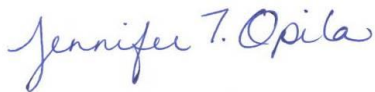
- Option 1a: The Board does not support the use of any medical specialty board to credential use of radiopharmaceuticals without evidence that these boards provide the same level of radiation mastery as existing specialty boards.
- Option 1b: The Board does not support Licensee Credentialing, as the Agreement States would then be obliged to review procedures to ensure that physicians are adequately trained to determine proper administration of radiopharmaceuticals. An additional con to capture the licensing burden seems appropriate.
- Option 1c: The Board endorses this option because the medical specialty boards would be recognized by the NRC. The Board agrees that this option provides flexibility to accommodate emerging and future radiopharmaceuticals and that it may motivate additional medical specialty boards to seek NRC recognition.

Approach 2: Maintain or Enhance the Existing Training and Experience Framework

- Option 2a: Add a con to the status quo approach such that the current regulation may not ensure that administration of radiopharmaceuticals is being appropriately supervised. Once the radiopharmaceutical is onsite, the Board believes the training requirements should emphasize handling, storage and disposal by those who are actually administering the material. The Board's emphasis is on how the drug is being administered in accordance with a physician's prescription, and in accordance with radiation safety practices, not whether the physician is competent to make decisions on what drug to administer. That should be left to the medical specialty boards.
- Option 2a: Add a con that current administrative and technical reviewer burden on regulatory agencies for approving authorized users is substantial and there is little evidence of any value added to this effort level. Case in point, less than 5% of medical events reported in 2017 and 2018 even mentioned inadequate training as a possible reason of the event. Freeing up time on status quo type authorized user actions would allow more thorough review elsewhere (i.e., procedures and practices aimed at ensuring safe handling and accurate delivery of nuclear medicine therapies and licensing guidance for complex emerging radiopharmaceuticals).
- Option 2b: Add a con addressing the complexities it will contribute to an already confusing set of training and experience pathways. Under the existing system there are a high percentage of errors made in authorized user documentation, this will further exacerbate those issues.
- Option 2d: Add a con for potential gaps in responsibility over certain radiation aspects generated by this team approach.

We appreciate the opportunity to provide these comments and stand ready to answer any questions you may have.

Sincerely,



Jennifer T. Opila, OAS Past-Chair for

Terry Derstine
OAS Chair
Radiation Protection Program Manager
Pennsylvania Department of Environmental Protection
Southeast Regional Office
2 E. Main Street
Norristown, PA 19401