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November 15, 2018

Said Daibes
Office of Nuclear Materials Safety and Safeguards
U. S. Nuclear Regulatory Commission
Washington, DC 20555

**OPPORTUNITY TO COMMENT ON DRAFT GERMANIUM-69/GALLIUM-68
PHARMACEUTICAL GRADE GENERATORS LICENSING GUIDANCE (RCPD-18-006)**

Dear Mr. Daibes:

The Organization of Agreement States (OAS) Executive Board (Board) reviewed the above document and offers the following comments.

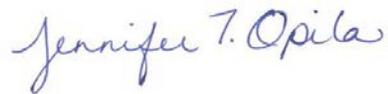
1. Page 1 Line 2: “Future Ge-68/Ga-68 radionuclide generators will be addressed in revisions to the licensing guidance.” It is unclear which set of generators this guidance addresses and which it does not. Which generators are included in this guidance, or is it covering all current and future generators?
2. Page 3 below the commercial nuclear pharmacy table: According to the OAS representative on the Working Group, the paragraph which stated that the eluate of the Ge-68/Ga-68 generator is not a pharmaceutical grade material was removed. The Board believes that this paragraph should remain. The licensing guidance makes a direct comparison to the T-99m generator, which does produce a pharmaceutical grade eluate, albeit arguably without proper labelling. The Board believes that by omitting this paragraph, it may cause confusion resulting in some license reviewers thinking that Ge-68 is an approved radiopharmaceutical. While this may eventually be the case, it is not currently.
3. On page 4 of 11, under Guidance option 4 the guidance says: “identify each AU...and provide documentation of his/her training and experience...” “NRC Form 313A (AUD)...or other formats may be used to document this training and experience.”

On page 5 of 11, if a potential authorized user has used option 4 (starting on page 4) to detail their training and experience, the guidance says they have to “obtain written attestation, signed by a preceptor AU...that the individual...is able to independently fulfill the radiation safety-related duties as an AU for the authorized use of a Ge-68/Ga-68 generator.”

The current NRC Form 313A (AUD) does not have the statement that the individual is able to “Fulfill the radiation safety-related duties as an AU for the authorized use of a Ge-68/Ga-68 generator.” Will the NRC revise the form to include this as an additional check-off box/statement for those people to whom it would be applicable? Or would someone need to send in a supplemental preceptor attestation statement created by the licensee?

We appreciate the chance to comment on this guidance and stand ready to address any questions you may have.

Sincerely,

A handwritten signature in blue ink that reads "Jennifer T. Opila". The signature is written in a cursive, flowing style.

Jennifer T. Opila, MPA
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