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November 19, 2021

Katie Tapp
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Dr. Tapp:

The OAS Executive Board (Board) appreciates the opportunity to comment on the Nuclear Regulatory Commission's (NRC) the draft of licensing guidance for Alpha Tau's Alpha DaRT™ (Diffusing Alpha-emitters Radiation Therapy), prepared under Title 10 of the *Code of the Federal Regulations* (CFR), Section 35.1000, "Other medical uses of byproduct material or radiation from byproduct material." (RCPD-21-009)

Based on our review of the information, the Board offers the following questions and comments:

1. Sections 6.1 pg. 4, 6.5 and 6.7 pg. 5: Consider listing the commitment requirements from these sections in bulleted lists, like Section 6.2. It would be much more convenient for the license reviewer and the licensee.
2. Section 6.3, pg. 4, and Appendix, pg. 8: If there is no software system for Alpha DaRT™, why would the licensee need to commit to having an Authorized Medical Physicist (AMP) perform additional acceptance testing on modifications to a treatment planning system (TPS) specifically made for Alpha DaRT™? What role does an AMP have in the treatment planning if it is not specified in the licensing guidance except for concerning a TPS?
3. Section 6.5, pg. 5: requires licensees to "commit to perform a removable contamination survey of the patient to ensure no contamination or leakage prior to patient release". A description of how this should be done would be useful.
4. Appendix: The addition of the *Consolidated Technical Analysis* is a valuable supplement to the licensing guidance for the license reviewer and the licensee. Since this is a new addition to a licensing guidance document, we wonder if there would be a way to highlight its presence in the document prior to Section 6?

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RCPD-21-009

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Once again, the Board appreciates this opportunity to comment. We are available should you have any questions or need clarifications to our responses.

Sincerely,

A handwritten signature in blue ink, appearing to read "Augustinus Ong", with a horizontal line underneath.

Augustinus Ong, Chair

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NH Division of Public Health Services/Radiological Health Section

29 Hazen Drive

Concord, NH 03301-6503