From: Frank Tran
To: llunampcphysics.com
Subject: Request additional information for NRC License No. 21-26740-01
Date: Monday, January 30, 2023 9:05:00 AM

Dear Ms. Luna:

This refers to the license amendment application dated January 12, 2023, for Ascension Genesys Hospital, NRC Materials License No. 21-26740-01. We reviewed the application in accordance with NUREG-1556, Volume 9, Revision 3 and the licensing guidance for using yttrium-90 microsphere in medical dated April 20, 2021. Based on the review, we will need the following.

1. We could not locate the IR Room(s) in the facility diagram. Please resubmit the diagram and indicate the IR Rooms where Y-90 microsphere will be used and the scale or dimensions.

2. Provide the following statement: "We will develop and implement procedures for administration requiring a written directive as specified in 10 CFR 35.41. As Y-90 microspheres are too small to be calibrated in accordance with 10 CFR 35.432, we shall determine and record the activity of each dosage before medical use in accordance with 10 CFR 35.63 and 10 CFR 35.60 even though Y-90 microspheres are listed as sealed sources in their Sealed Source and Device Registries. We commit to following the manufacturer's procedures for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration; determining shunting to non-treatment sites; and determining if a medical event has occurred (e.g., performing pre- and post-vial dose measurements with appropriate instrumentation, evaluating post-treatment imaging)."

3. Provide the following statement: "We commit that if the administration was terminated because of stasis, then the total dose or activity to the treatment site is the value of the total dose or activity administered when stasis occurred and the administration was terminated. The record shall be prepared within 24 hours after the completion or termination of the administration and shall include the name of the individual who determined the administered dose or activity, the signature of an AU for Y-90 microspheres, and the date signed."

4. Provide the following statement: "We will commit that if the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g., artery spasm or sudden change in blood pressure), the AU shall document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive shall include the reason for not administering the intended dose or activity, the signature of an AU for Y-90 microspheres, and the date signed."

To continue the review of your application, we request that you submit the response under a dated and signed cover letter by March 1, 2023. In the cover letter, please refer the license number, docket number and Mail Control No. 634187. We will assume that you do not wish to further pursue this licensing action if we do not receive a reply within the specified timeframe noted above.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, please contact me at 630-829-9623 or reply to this email.

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390 of the NRC's "Rules of Practice," a copy of this correspondence will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Best regards,

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