UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

June 5, 2023

Joshua Nepute, M.D.
Radiation Safety Officer
Indiana University Health Arnett Hospital
5165 McCarty Ln.
Lafayette, IN 47905

Dear Dr. Nepute:

This letter is regarding your request dated April 25, 2023, to amend your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-32535-02.

The U.S. NRC's guidance document applicable to your request, which I refer to below as "the guidance," is Y-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance, Rev. 10.2. This guidance is available on the U.S. NRC website at: https://www.nrc.gov/docs/ML2108/ML21089A364.pdf

Upon review of the request, I identified the following areas requiring additional or clarifying information:

1. Section 5.1, "Authorized Users," identifies that acceptable training and experience includes current qualification as an Authorized User for medical use in 10 CFR §35.1000 for Y-90 microspheres.

   The request identifies that the proposed Authorized Users, including Daniel Edwards, M.D., and Neil Mascarenhas, M.D., are authorized to serve as an Authorized User of yttrium-90 as SIR-Spheres as permitted by 10 CFR §35.1000 on your U.S. NRC License No. 13-32535-02.

   In addition, please submit a written attestation identifying that the proposed Authorized Users have satisfactorily completed the criteria described in paragraphs A and B of Section 5.1 of the guidance. The attestation may be obtained from an Authorized User who is authorized for the type of Y-90 microspheres for which the individual is seeking authorization.

2. Section 5.2, "Radiation Safety Officer," identifies that a Radiation Safety Officer already listed on a license that includes one type of yttrium-90 microspheres device should be familiar with all radiation safety aspects, including cleaning up spills, associated with all devices used at the facility.

   Therefore, you should complete training addressing the radiation safety aspects associated with the BWXT Medical Ltd., TheraSphere Y-90 Glass Microsphere System.

   As this item is only advisory in nature, no specific response is required.

3. Section 6.2.1, “Termination of Treatment Due to Stasis,” of the guidance identifies that total dose or activity to the treatment site, following termination of treatment due to stasis, is the value of the total dose or activity administered when stasis occurred and the administration was terminated.

   Your procedures do not identify how you will determine the value of the total dose or activity administered to the treatment stie when stasis occurs.

   Please confirm that the value of the total dose or activity administered recorded will be the total dose or activity administered to the treatment site at the time that the treatment is terminated due to stasis.

4. Section 6.9, “Radiation Protection Program Changes,” of the guidance identifies that a licensee currently authorized to use Y-90 TheraSpheres in accordance with the licensing guidance must apply for and receive a license amendment in order to make program changes to conform with subsequent revisions to the guidance.

   You have requested approval for a change process meeting the following conditions specified in Section 6.9 of the Yttrium-90 Microsphere Brachytherapy Source and Devices TheraSphere and SIR-Sphere Licensing Guidance, Rev. 10.2, dated April 20, 2021:

   - the revision is in compliance with the regulations;
   - the revision is based upon NRC’s current guidance for TheraSphere® Y-90 microspheres 35.1000 use posted on the NRC’s Medical Uses Licensee Toolkit Web site;
   - the revision has been reviewed and approved by the licensee’s RSO and licensee’s management;
   - the affected individuals are instructed on the revised program before the change is implemented;
   - the licensee will retain a record of each change for five years;
   - the record will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

   As this item is only advisory in nature, no specific response is required unless changes to your change process commitment or procedures are made in response to this item.

In accordance with 10 CFR §2.390 of the NRC’s “Rules of Practice,” a copy of this letter and its enclosure 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.

To continue review of your request, please submit your response to this letter within 15 calendar days from the date of this letter. In your response, please refer to the license, docket, and control number specified below. I will assume that you do not wish to further pursue this licensing action if I 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, I encourage you to contact me at (630) 829-9737 or via e-mail at Jason.Kelly@nrc.gov.

Sincerely,

Digitally signed by Jason M. Kelly
Date: 2023.06.05 13:24:24 -05'00'
Adobe Acrobat version: 2023.001.20143

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

Docket No.: 030-37189
License No.: 13-32535-02
Control No.: 635546