From: Lanzisera, Penny
To: Mink, Michael
Cc: ralph.sgambato@greenwichhospital.org
Subject: Request for Additional Information for Microsphere program
Date: Tuesday, August 06, 2019 1:44:00 PM

Licensee: Greenwich Hospital Association
License No. 06-09522-01
Docket No. 03001276
Mail Control 612640

Mr. Mink,

To support the request dated June 25, 2019, to add microsphere use to the license, please provide the following additional information:

1. Please provide documentation from Sirtex that Dr. May completed 3 supervised hands-on patient cases.
2. Please provide documentation from the New York Presbyterian Hospital's RSC Chair or RSO documenting that Dr. May was approved for 10 CFR 35.200 uses.
3. Microsphere brachytherapy treatment is usually conducted using a multi-disciplinary team approach. Please confirm that the AU will consult, as necessary, with individuals with expertise in: cancer management (e.g., radiation or medical oncology), catheter placement, radiation dosimetry, and safe handling of unsealed byproduct material.
4. Please confirm that you will follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use (e.g., 10 CFR 35.406 for source accountability and inventory), except where replaced by your commitments made in your June 25, 2019 letter.
5. Please describe receipt and storage areas for microspheres.
6. Please provide examples of emergent patient conditions referenced in your letter (e.g., artery spasm or sudden change in blood pressure).
7. Please describe disposal options for long-lived contaminants found in waste that do not meet 10 CFR 35.92 decay-in-storage criteria (e.g., Sr-90 identified with an appropriate radiation detection survey meter). For instance, will you: (i) return the microspheres to the manufacturer, if the manufacturer is authorized to receiveY-90 microspheres; or (ii) transfer the microspheres to an authorized recipient.
8. Please indicate if you would like to adopt future changes to the microsphere program in accordance with revisions to NRC guidance. If so, please confirm that your change process will include the following criteria: i) the revision is in compliance with the regulations; ii) the revision is based upon NRC's current guidance for SIR-Spheres® Y-90 microspheres posted on the NRC Medical Uses Licensee Toolkit; iii) the revision has been reviewed and approved by your Radiation Safety Officer and management; iv) the affected individuals are instructed on the revised program before the change is implemented; v) you will retain a record of each change for five years; and vi) 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 management that reviewed and approved the change.

Please reply either via signed pdf sent to my email or via facsimile to 610-337-5269 within 30 days. Please include Mail Control No. 612640 in your reply. If we do not receive a reply

within 30 days, we will consider that you no longer require the request and void your request. Thank you for your assistance.

Penny Lanzisera
Senior HP, US NRC, Region I