From: Lanzisera, Penny
To: "jkeck3@jhmi.edu"
Subject: Request for Additional Information for Microsphere Use and PET
Date: Friday, February 03, 2017 12:59:00 PM

Licensee: Sibley Memorial Hospital
License No. 08-07398-03
Docket No. 03014754
Mail Control 592730

Mr. Keck,

NRC guidance for microsphere programs may be found at https://www.nrc.gov/docs/ML1535/ML15350A099.pdf. Please review this guidance and provide additional information on the following:

1. Identify the radionuclides, chemical/physical form, requested maximum possession limit, and purpose of use.
2. Evidence to support board certification in diagnostic radiology was submitted; however, it is unclear whether Dr. Akman completed subspecialty certification in interventional radiology by either the American Board of Radiology or the American Osteopathic Board of Radiology; or a year of supervised clinical experience in interventional radiology. Please submit documentation to support completion of this training.
3. Please provide a copy of the permit issued to the preceptor, Dr. Sarin, by The George Washington University Hospital approving him for both Therasphere and SirSphere microsphere use.
4. Please provide confirmation that the AU should 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.
5. As noted in the guidance, the applicant shall commit to follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use, except where replaced by the following licensing commitments for: Training, Procedures for Administration, Written Directives, Medical Event Reporting, Inventory, Labeling, Patient Release, Radiation Protection Program Changes, TheraSphere® Use Outside Humanitarian Device Exemption (HDE) Restrictions, and Waste Disposal Issues. Please provide the requested commitments or procedures for each item noted. The guidance found in the link noted above provides model language for submission of these commitments and procedures.
6. Please confirm that you have reviewed the “Notes to Licensees” section in the guidance and will submit requested information if warranted.

With regards to the PET/CT facility revisions:

1. Please confirm that the shielding will be installed as described in the Shielding Recommendations – Revision 2.
2. Please confirm that the two Prep rooms notated on the diagram are the Injection Rooms described in the shielding report.
3. Please indicate if the Existing Corridor, the Existing Lockers, and the Existing Family

Waiting near the PET/CT scanner and the Prep rooms are controlled or uncontrolled. If access is uncontrolled and available to members of the public during injection holding time; please describe how the 2 millirem in any one hour limit in 10 CFR Part 20 will be met for continuous occupancy (T=1) by a member of the public during the one hour holding time. If these areas will be controlled during procedures, please describe how control will be maintained.

You may submit a signed response by management either via fax to 610-337-5269 or via pdf to my email. Please include the Mail Control No. 592730 in your response. If we do not receive a response within 30 days of this request, we will consider that you no longer require the requested amendments and void your request. Please contact me with any questions and to confirm receipt of this email.

Sincerely,
Penny Lanzisera
Senior Health Physicist
US NRC, Region I