From: Lanzisera, Penny
To: "jnorweck@radiology-inc.com"
Subject: Request for Additional Information for Cabell Huntington Hospital amendment
Date: Tuesday, August 09, 2016 1:58:00 PM

Licensee: Cabell Huntington Hospital
License No. 47-00404-02
Docket No. 03003370
Mail Control No. 591053

With regards to your request to add TheraSphere to your license, please provide the following additional information and or confirmations:

1. Documentation signed by the manufacturer's representative of Nordion (Canada) Inc. (the manufacturer) to support completion of **3** in-vitro cases for each requested authorized user.

2. Confirmation that you procedures developed for TheraSphere will include the following commitments:

Procedures for Administration
Administration of Y-90 microspheres must be performed in accordance with the written directive. The licensee shall record the dose or activity delivered to the treatment site. The record should be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who determined the administered dose or activity and the date.

Written Directives
For the purpose of written directive and medical event reporting requirements in the Y-90 microsphere guidance, "prescribed dose" means the total dose (rad or Gy). Alternatively, prescribed activity (mCi or GBq) may be used in lieu of prescribed dose. If prescribed activity is used in lieu of prescribed dose, activity should be used for all documentation and evaluations.

The written directive shall include the patient or human research subject's name; the date; the signature of an AU for Y-90 microspheres; the treatment site; the radionuclide (including the physical form [Y-90 microspheres]); the manufacturer; the prescribed dose or activity; and, if appropriate for the type of microsphere used, the statement "or dose or activity delivered at stasis."

Termination of Treatment Due to Stasis
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 should be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who determined the administered dose or activity, the date, and the signature of an AU for Y-90 microspheres.

Emergent Patient Conditions

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 should document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive should include the reason for not administering the intended dose or activity, the date, and the signature of an AU for Y-90 microspheres.

Medical Event Reporting

The licensee shall commit to report any event, except for an event that results from intervention of a patient or human research subject, in which:

• the administration of byproduct material results in a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from the use of the wrong radionuclide; or

• the administration of byproduct material: to the wrong individual or human research subject; via the wrong route; or by the wrong mode of treatment; or

• the total dose or activity administered differs from the prescribed dose or activity, as documented in the written directive, by 20 percent or more, except when stasis or emergent patient conditions are documented and resulted in a total dose or activity administered that was less than that prescribed; or

• the administration of byproduct material results in dose or activity to an organ or tissue other than the treatment site, as documented in the written directive, except for shunting when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures.

Additionally, the licensee shall comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

Inventory

The semi-annual physical inventory of microsphere aggregates (e.g., vials) should include:

• the radionuclide and physical form; and

• unique identification of each vial in which the microspheres are contained; and

• the total activity contained in each of the vial(s); and

• the location(s) of the vial(s).

The licensee shall retain each semi-annual physical inventory record for three years.

Labeling

The licensee should commit to the following when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:

• Label vials and vial radiation shields with radionuclide and form (e.g., Y-90 microspheres).

• Label syringes and syringe radiation shields with the radionuclide, form, and therapeutic procedure (e.g., Y-90 microspheres, brachytherapy).

Patient Release

The licensee should commit to develop procedures that describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research subject permits his or her release in accordance with 10 CFR 35.75.

Waste Disposal Issues

In March 2007 NRC staff issued an Information Notice (IN 2007-10) to alert all medical licensees of the presence of radioactive contaminants and possible disposal issues with the two variations of commercially available Y-90 labeled microspheres, TheraSphere® and SIR-Spheres®. Depending on the contaminants, licensees may need to:

- hold the remaining microspheres longer in decay-in-storage in accordance with 10 CFR 35.92; or
- return the microspheres to the manufacturer, if the manufacturer is authorized to receive Y-90 microspheres; or
- transfer the microspheres to an authorized recipient.

We will continue our review upon receipt of this information. Please notify us immediately if your response will be delayed and we will issue the request to remove authorized individuals only pending submittal of the information above. You may submit the above information, signed by management, as a pdf to my email or you may fax the documents to 610-337-5269. Thank you for your assistance.

Penny Lanzisera
Senior Health Physicist
US NRC, Region I