SAINT LOUIS
UNIVERSITY

Caroline Building - Room C305
1402 South Grand Blvd.
St. Louis, MO 63104-1085
Fax 314-977-5560
www.slu.edu

Office of Environmental Safety & Services
Environmental Safety: 314-977-8608
Radiation Safety: 314-977-8609

November 1, 2012

U.S. Nuclear Regulatory Commission
Region III
Nuclear Materials Licensing Branch
2443 Warrenville Road
Lisle, IL 60532

Email: Toye.Simmons@nrc.gov

SUBJECT: Response to Request for Additional Information In Regards to Saint Louis University NRC License Amendment Request for Line Item Addition for Yttrium-90 Microspheres; NRC License No. 24-00196-07, Docket No. 030-11789

Dear Ms. Simmons:

This letter is in follow-up to your telephone message this afternoon requesting commitment to follow certain NRC licensing guidance for Therasphere® and SIR-Spheres® Yttrium-90 Microspheres. Specifically, Saint Louis University will follow the license commitments detailed on pages 4 and 5 of the Microsphere Brachytherapy Sources and Devices Licensing Guidance - Therasphere®and SIR-Spheres®, Revised June 2012. Copies of those pages follow this letter.

In answer to your other question, and pursuant to our follow-up phone discussion, I am affirming that we intend to use both Y-90 Sir-Spheres® and Y-90 Theraspheres®. Initially, the Saint Louis University Radiation Safety Committee (RSC) has approved our Nuclear Medicine Authorized User for use of Y-90 Sir-Spheres®. We expect a subsequent application from and RSC approval of our Nuclear Medicine Authorized User for use of Y-90 Theraspheres®. The license amendment letter dated and faxed October 17, 2012 (refaxed on October 31, 2012) is intended to address both uses.

Thank you for your expedited review and approval of this license amendment request. Please contact me if you have additional questions.

Sincerely,

Mark G. Haenchen, M.S., J.D.
Director, Office of Environmental Health and Safety
and Radiation Safety Officer - NRC

attachment

Copies to: Philip O. Alderson, M.D., Vice President for Medical Affairs
Raymond C. Tait, Ph.D., Vice President for Research
Paul M. Loewenstein, B.S., Chairman, Radiation Safety Committee
Felicity J. Beckfield, M.S., Radiation Safety Officer (Associate)

License Commitments - Written Directives, Inventory, Patient Release, Labeling, & Medical Event Reporting

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 the purpose of written directives 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.
- 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 prescribed dose/activity; the manufacturer; and, if appropriate for the type of microsphere used, the statement "or dose/activity delivered at stasis."
- The written directive should specify the maximum dose(s)/activity(ies) that would be acceptable to the specified site(s) outside the primary treatment site due to shunting (e.g. lung and gastrointestinal tract).
- Administration of Y-90 microspheres must be performed in accordance with the written directive. 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/activity, the date, and the signature of an AU for Y-90 microspheres.
- The licensee shall record the administered dose/activity delivered to the primary treatment site and to the other specified site(s). If the administration was terminated because of stasis, then the total dose/activity to the treatment site is the value of the total dose/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 made the assessment, the date, and the signature of an AU for Y-90 microspheres, if terminated due to stasis.
- The licensee shall commit to following the manufacturer's procedures for calculating/documenting the dose to the treatment and other sites, preparing the dose for administration, and performing pre/post vial dose measurements; or submit alternative methods.
- The semi-annual physical inventory of microsphere aggregates (e.g. vials) should include:
  1) the radionuclide and physical form; and
  2) unique identification of each vial in which the microspheres are contained; and
  3) the total activity contained in each of the vial(s); and
  4) the location(s) of the vial(s).

- The licensee shall retain each semi-annual physical inventory record for three years.
- 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/her release in accordance with 10 CFR 35.75.
- The following additional guidance applies when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:
  1) Label vials and vial radiation shields with radionuclide and form (e.g., Y-90 microspheres).
  2) Label syringes and syringe radiation shields with the radionuclide, form, and therapeutic procedure (e.g., Y-90 microspheres, brachytherapy).
- 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:
  1) 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
  2) the administration of Y-90 microspheres results in a dose
     a) that differs from the prescribed dose or the dose that would have resulted from the prescribed activity, as documented in the written directive, by more than 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue, and the total dose/activity administered differs from the prescribed dose/activity, as documented in the written directive, by 20 percent or more; or
     b) that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from an administration to the wrong individual or human research subject, via the wrong route, or by the wrong mode of treatment; or
     c) to an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and by 50 percent or more of the prescribed dose/activity expected to that site from the administration of Y-90 microspheres, if carried out as specified in the written directive
- Additionally, the licensee shall comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).