From: Weidner, Tara
To: Hisel, Gregory (ghisel@stfranciscare.org)
Subject: St. Francis amendment request
Date: Wednesday, January 27, 2016 7:52:00 AM

Licensee: St. Francis Hospital and Medical Center
License Number: 06-00854-03
Docket Number: 03001246
Mail Control Number: 589611
Dear Mr. Hisel,
Please reply back to this email to confirm receipt?
This is in reference to your license amendment request dated November 30, 2015, requesting to add the use of Nordion TheraSpheres to License No. 06-00854-03.
In order to continue our review, we need the following additional information. Please review the Microsphere Brachytherapy Sources and Devices guidance which may be found on the NRC website prior to preparing your response.

The Microsphere Brachytherapy Sources and Devices Licensing Guidance Revised June 2012 describes the required training and experience for authorized users (AU) of Y-90 TheraSpheres. It is my understanding that Erik Bee, M.D. is an interventional radiologist. Therefore, please provide documentation of his training described in A.3. of the Training and Experience section of the guidance.

In addition, proposed AUs must have successfully completed training in the operation of the delivery system, safety procedures, and clinical use of Y-90 TheraSpheres. In your request you provided a Certificate of Attendance from Mount Sinai Medical Center. Please provide the following documentation:

a. A syllabus from the course Dr. Bee attended indicating that the operation of the delivery system, safety procedures, and clinical use of Y-90 TheraSpheres was covered, and
b. Specify who performed the training,
    1. an AU who is authorized for TheraSphere use, or
    2. a TheraSphere manufacturer.
c. If the training was provided by an AU, you will need to provide a license listing the AU for TheraSphere use and documentation that the Dr. Bee has completed at least three supervised, hands-on cases of TheraSphere use under the supervision of the AU.
d. If the training was provided by a Y-90 manufacturer, provide documentation that Dr. Bee has completed at least three hands-on in-vitro simulated cases. Also, confirm that Dr. Bee will complete at least the first three hands-on patient cases in the physical presence of a manufacturer representative and confirm that you will submit documentation from the manufacturer to NRC Region I within 30 days of when the three patient cases have been satisfactorily completed.

In your letter dated November 30, 2015 you stated that the total possession limit for Yttrium-90 TheraSpheres would be 3 Ci. Please state the maximum required possession limit of TheraSpheres per vial and in total.

In your request you stated that, “Training for use, quality control, safety, and emergency response will be provided to AUs and other involved staff as appropriate (e.g. medical physicists, radiation safety staff) by the manufacturer.” Please confirm that this covers all individuals that prepare, measure, and perform dosimetry calculations.
Please confirm, in writing, the following for your proposed TheraSpheres program:

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

We will 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 will be prepared within 24 hours after the completion or termination of the administration and will 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.

We 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) will include:

i. the radionuclide and physical form; and
ii. unique identification of each vial in which the microspheres are contained;and
iii. the total activity contained in each of the vial(s); and4) the location(s) of the vial(s).

We will retain each semi-annual physical inventory record for three years.

We will 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.

We will follow the additional guidance applicable when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:

iv. We will label vials and vial radiation shields with radionuclide and form (e.g.,Y-90 microspheres).
v. We will label syringes and syringe radiation shields with the radionuclide,form, and therapeutic procedure (e.g., Y-90 microspheres, brachytherapy).

We will report any event, except for an event that results from intervention of a patient or human research subject, in which:

vi. 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
vii. the administration of Y-90 microspheres results in a dose
    1. 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

2. 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
3. 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, we will comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

Confirm that if the physical conditions of use exceed those reported in the Sealed Source and Device Registry certificate, you will request an amendment for the new conditions.

Please confirm if you wish to be authorized to make minor revisions to your microsphere program. An applicant initially applying for authorization for the medical use of TheraSphere® Y-90 microspheres may request to incorporate into its license a change process similar to 10 CFR 35.26. Such a change process can allow some future changes to radiation safety programs provided that the change process requires the following conditions be met for revisions to the radiation safety program:

a. the revision is in compliance with the regulations; and
   - the revision is based upon NRC's current guidance for TheraSphere® and SIRSpheres® Y-90 microspheres 35.1000 use posted on the NRC Web site; and
   - the revision has been reviewed and approved by the licensee's Radiation Safety Officer and licensee's management; and
   - the affected individuals are instructed on the revised program before the change is implemented; and
   - the licensee will retain a record of each change for five years; and
   - 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.

In March 2007 NRC staff issued an Information Notice (IN 2007-10) to alert all medical licenses of the presence of radioactive contaminants and possible disposal issues with Y-90 labelled microspheres. Please confirm that you have reviewed the Information Notice and will consider the information provided in your waste disposal procedure.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;**then **Licensee Toolkits, see our toolkit index page.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

You may respond to my attention in writing by letter, email (if letter is scanned into a pdf format), or fax (610-337-5269), referencing mail control number 589611.

Please reply to this request as soon as possible. Otherwise, if we do not receive a reply from you by February 20, 2016, we will assume that you do not wish to pursue your amendment. Please feel free to contact me with any questions you may have.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement is not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safetyculture.html. We strongly encourage you to review this

material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.
Thank you in advance for your help.

Tara L. Weidner

Tara L. Weidner
Senior Health Physicist
US Nuclear Regulatory Commission Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406
(610) 337-5272
FAX (610) 337-5269