Ascension

August 12, 2019

Daniel Strohmeyer
USNRC

Thank you for taking the time to review our license amendment for 21-01190-05. Hopefully this additional information is what you are looking for. I am hoping this will clarify everything.

In place the words "the licensee or the applicant – you can substitute our name – St John Macomb Oakland Hospital, Macomb Site #21-01190-05, or we the licensee agree".

License Commitments:
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:

Training - The applicant shall commit to provide training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

Procedures for Administration - The licensee shall commit to following the manufacturer's procedures for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration; determining shunting to non-treatment sites; and performing pre- and post-vial dose measurements; or submit alternative methods. 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 9 • 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.

Radiation Protection Program - Changes This guidance may be revised as additional experience is gained regarding the medical use of TheraSphere® and SIR-Spheres® Y-90 microspheres. A licensee currently authorized to use these products that is committed by license condition to following provisions in a previous revision of this guidance may request a license amendment to commit to following this revision of the guidance instead. The licensee must apply for and receive this license amendment in order to make program changes to conform to this revision of the guidance.

An applicant initially applying for authorization for the medical use of TheraSphere® and SIRSphere® Y-90 microspheres, or a licensee applying for an amendment to conform with this revision of the guidance may request to incorporate into its license a change process similar to 10 CFR 35.26 (we do wish to have the potential for a change process).

Such a change process can allow some future changes to radiation safety programs provided that the change process requires the following conditions to be met for revisions to the radiation safety program:
1. the revision is in compliance with the regulations; and
2. the revision is based upon NRC's current guidance for TheraSphere® and SIR-Spheres® Y-90 microspheres 35.1000 use posted on the NRC Medical Uses Licensee Toolkit;
3. the revision has been reviewed and approved by the licensee's Radiation Safety Officer and licensee's management; and
4. the affected individuals are instructed on the revised program before the change is implemented; and
5. the licensee will retain a record of each change for five years; and
6. 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. If approved, these conditions for use of updated guidance will be incorporated as license conditions in the licensee's license.

In addition, please note we want 500mCi for Y-90 Theraspheres and 1000mCi for Y-90 Sirspheres. To a total possession limit of 1500mCi.

The only Authorized user on our license for this Dr. Nitin Jain – he is previously approved for Sirspheres, please authorize him for Theraspheres. Once he completes the three training cases we will notify you.

Sincerely,

Laura T. Speer-Smith, MS, DABR
SJ Macomb Hospital
21-01190-05
Radiation Safety Officer

Song, Taehoon

From: Strohmeyer, Daniel
Sent: Monday, August 19, 2019 5:58 AM
To: Pavon, Sandy; Song, Taehoon; Tomczak, Tammy
Subject: FW: Re: [ACTION REQUIRED] CN 612551 Ascension McComb
Attachments: Y90 SJMacomb amendment 2019 2.pdf

Categories: Material Licensing

Good Morning,

Please add to ADAMS for the following.

030-02005	21-01190-05	612551

Thank you,
Daniel