St. JOSEPH MEDICAL CENTER
Carondelet Health • a member of Ascension Health

February 6, 2013

Nuclear Regulatory Commission
Medical Licensing Division, Region III
2443 Warrenville Road
Lisle, IL 60532-4351

To Whom It May Concern,

Please amend our Radioactive Materials License #24-02704-01 (St. Joseph Medical Center, 1000 Carondelet Dr, Kansas City, MO 64114) to include the use of SIRTex-Sir-Spheres microspheres and TheraSpheres. Both products are labeled with Yttrium-90.

Product Description Summary

SIR-Spheres

The SIR-Spheres microspheres consist of biocompatible microspheres containing Yttrium-90 with a size of 20-30 microns in diameter. The average number of particles implanted is 30-60 x 10^6 per implant.

TheraSpheres

The TheraSpheres consist of insoluble glass microspheres where Yttrium-90 is an integral constituent of the glass. The mean sphere diameter ranges from 20-30 μm. Each milligram contains between 22,000 and 73,000 microspheres.

The requested possession limits for these 2 products are as follows:

SIR-Spheres

Radioactive Material	Chemical / Physical Form	Maximum Possession Limit	Authorized Use
Yttrium-90	Sealed Source (Australian Isotope) Model SIR-Spheres	132 mCi / vial, not to exceed 189 mCi / vial	To be used in a SIRTex Medical SIR-Spheres brachytherapy system for treatment of malignant hepatic tumors

TheraSpheres

Radioactive Material	Chemical / Physical Form	Maximum Possession Limit	Authorized User
Yttrium-90	Sealed Source (MDS Nordion) Model TheraSpheres	81 - 540 mCi / vial, not to exceed 2.0 Ci	To be used in a MDS TheraSpheres administration system for treatment of malignant hepatic tumors

1. ***However, the use of Y-90 TheraSpheres cannot be initiated until the approved authorized user has completed the three hands-on in-vitro simulated cases under the direct supervision of an approved factory representative. The documentation of completion of these three cases will be provided to the NRC for your review and approval prior to placing an order for the MDS Nordion TheraSpheres.***

2. Following your approval of the amendment for the Y-90 SIR-Spheres and the Y-90 TheraSpheres, the approved authorized user will complete the first three patient cases under the direct supervision, and in the direct physical presence, of an approved manufacturer's representative.

3. Upon completion of the first three patient cases by the Authorized User with each manufacturer's representative present, documentation will be submitted from the manufacturer to the NRC within 30 days of when these three patient cases have been satisfactorily completed.

4. Both the SIR-Spheres and TheraSpheres are labeled with Yttrium-90. The maximum beta energy is 227 MeV with a mean energy of 0.94 - 0.98 MeV. The maximum range in tissue is 11 mm with the mean range being 2.5 mm. These Y-90 labeled microspheres will be introduced into the liver for treatment of metastatic C.A. via a chemotherapy catheter in the left or right hepatic artery. The administration of these Yttrium-90 microspheres is a permanent implant.

5. We are requesting to have our Interventional Radiologist approved as the authorized user for the SIR-Spheres and TheraSpheres.

Radioactive Material Group	Chemical / Physical Form	Authorized Users
35.1000	Sealed Source (Australian Isotope) Model SIR-Spheres	Donald Christopher Walker, M.D.
35.1000	Sealed Source (MDS Nordion) Model TheraSpheres	Donald Christopher Walker, M.D.
Please see the attached RAM license.		

6. The above physician has completed the manufacturer's one-day training session that includes three in-vitro simulated cases in the administration of the Y-90 SIRTex SIR-Spheres (please see the attached SIRTex Certificate of Completion).

   The intravascular catheter will be placed in a fluoroscopic procedure by Dr. Walker.

7. **The Yttrium-90 SIR-Spheres will only be administered by the approved authorized user (Donald Christopher Walker M.D.).**

8. Our institution in conjunction with the manufacturer will provide specific training to all individuals who will be involved in the Y-90 microspheres procedures. Additional training will be administered to all individuals who are involved in the preparation, measurement of doses, performing dosimetry calculations, and administering the doses.

9. The Dr. Walker has completed training on dose calculations for the SIR-Spheres. (please see the attached SIRTex Certificate of Completion).

10. Dr.Walker has the following experience as an Interventional Radiologist:

    - **2008-2009** Interventional fellowship -
      Cornell NYP Medical Center - New York, NY
      Sloan Kettering Memorial Cancer Center - New York, NY

    - **2009-2012** Mori, Bean & Brooks
      Baptist Med Center - Jacksonville, FL
      Baptist South Med Center - Jacksonville, FL
      Baptist Beaches Med Center - Jacksonville, FL
      Memorial Med Center - Jacksonville, FL
      Orange Park Med Center- Jacksonville, FL

    - **2012-Current** Alliance Radiology
      St Joseph Med Center - Kansas City, MO
      St Mary Med Center- Kansas City, MO

    CAQ Interventional Radiology (Certificates of Added Qualification)

11. The applicant shall commit to follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use.

12. 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.

13. Semi-annual Leak Testing of the microspheres will not be performed based on the NRC criteria in 10 CFR 35.67(f).

14. 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."

    1. Patient name and verification of identity,
    2. Date of treatment,
    3. Authorized User's signature,
    4. Radionuclide and physical form,
    5. Prescribed dose/activity or dose/activity delivered at stasis,
    6. Maximum acceptable dose/activities to sites outside the primary site,
    7. Estimated dose that will result due to shunting,
    8. Review and verification of Administered Dose by the AU (please see the Written Directive Form 116B).
    9. Treatment site and Manufacturer

15. 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.

16. If the treatment is terminated because of stasis, the total dose/activity to the treatment site is the value of the total dose/activity administered when stasis occurred. A record of that dose will be prepared within 24 hours after the completion or termination of administration (please see section C of the Written Directive - Dose Delivered at Stasis). This record will be signed by the AU (please see the Written Directive Form 116B - Dose Delivered at Stasis).

17. We commit to following the manufacturer's procedures for calculating and documenting the dose to the treatment and other sites (please see the manufacturer's dose determinations formulas). We will prepare the dose for administration in accordance with the manufacturer's procedures. This dose record will include the pre and post vial dose measurements (please see the manufacturer's dose preparation procedures and Form 116B).

18. In accordance with the NRC guidance, we will perform a semi-annual inventory of microspheres vials. This inventory will include:

    1. The radionuclide and physical form,
    2. Vial identification,
    3. Total remaining activity in each vial,
    4. Location of the vials.

    These semi-annual inventory records will be maintained for three years (please see the attached inventory record form).

19. The radiation dose to the radiologist and staff members during the administration is minimal, however, all personnel will be required to wear dosimetry badges (please see the attached personnel dosimetry data provided by the manufacturer).

20. In accordance with the NRC guidance, the vials, radiation shield, syringe shield and syringes will be labeled with the radionuclide, the form, and the therapeutic procedure (i.e., Y-90 microspheres, brachytherapy).

21. We will commit to reporting any event if the administered byproduct materials result 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 if the administration of Y-90 microspheres results in a dose 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 on the Written Directive by 20% or more.

or 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 patient** via the **wrong route of administration**, or by the **wrong mode of treatment.**

or 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% 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 (please see the attached Medical Event reporting Form 116A).

22. When the patient is hospitalized following the procedure, s/he will be housed in radiology recovery room. The patient will be surveyed with a GM survey meter at surface, 1 meter, and 2 meters to determine if any additional radiation safety measures need to be implemented for the nursing personnel (please see the enclosed nursing instructions).

23. Area surveys and wipe tests will be acquired in the interventional radiology suite following administration of the dose. These records will be maintained for three years (please see the enclosed example).

24. Waste will be kept in the Radioactive Storage Room. Please see the enclosed floor plan that identifies this waste storage room.

25. 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.

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

Should you have any questions, please contact our Health Physics Specialists, Marcia West or Renee Carlson at 816.807.8090. Your attention in this matter is greatly appreciated.

Sincerely,

Patrick M. O'Toole, M.D., R.S.O

CardinalHealth

Cardinal Health
Medical & Health Physics
816.841.5093 Phone
816.974.1443 Fax

Fax

To: Sara Forster **From:** Marcia West

Fax: 630-595-1078 **Pages:** 7

Phone: **Date:** 2-11-13

Re: Control # 579532.

☑ Urgent ☒ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

Sara

Here is the information you requested for control # 579532.

Please let us know if you need any other information

Marcia West