INOVA ALEXANDRIA
HOSPITAL

4320 Seminary Road
Alexandria, Virginia 22304
Tel 703 504-3000

December 27, 2006

K-8

Sam Nunn Atlanta Federal Center
US Nuclear Regulatory Commission Reg. II
Medical Licensing Section
61 Forsyth Street, SW., Suite 23T85
Atlanta, Georgia 30303-6931

03003335

Re: Amendment to NRC No. 45-09358-02

Dear Sirs:

Please accept this letter and attachments as a request to amend our Radioactive Material Licenses as follows:

We are in the process of initiating a New Treatment modality using Yttrium 90 Microsphere in the management of Liver Disease. And therefore, we would like to add Y-90 Microspheres to our licenses. Please see attached information for details.

Thank you for your attention in this matter. If there are questions or you would like to have more information, please contact me at 703-504-3109

Sincerely,

Michael Friedman, MD, RSO

Kathy Barry, RN, MHA, COO,

Attachments: Amendment Information
Sample Written Directive

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NMSS/RGN1 MATERIALS-002

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NRC license # 45-09358-02
Y-90 microspheres for permanent brachytherapy implantation

Byproduct material requested: ANSTO Radiopharmaceuticals and Industrials Model Microspheres resin microspheres in the Sirtex Medical Limited Model SIR-Spheres delivery system, corresponding to Sealed Source and Device Registration No. MA-1229-D-101-S

Maximum activity requested: 500 millicuries (approximately 6 patient doses)

Written Directives:
A written directive form has been developed and will be used to include:

(a) Before implantation: the treatment site, the radionuclide (Y-90 SIR-Spheres) and the prescribed dose (the total dose documented in the written directive).

(b) After implantation but before completion of the procedure: the radionuclide (Y-90) SIRSpheres, treatment site, and the total dose.

(c) When the authorized user uses the medical end point of stasis to determine when to terminate implantation of the microspheres then this will be included in the written directive before implantation. In this case, the written directive will include:

(1) Before implantation: the treatment site, the radionuclide (Y-90 SIR-Spheres), and a prescribed dose of either XXX rad/Gray (or rem/Sieverts) or the dose delivered at stasis; and

(2) After implantation but before completion of the procedure: the radionuclide (Y-90 SIR-Spheres), treatment site, and the total dose. If the implantation was terminated because of stasis, then the total dose is the value of the total dose delivered when stasis occurred and the implantation was terminated.

(d) The written directive will specify the maximum dose that would be acceptable for a specified site (or sites) outside the primary treatment site to which the microspheres could be shunted (such as the lung and gastrointestinal tract).

(e) Procedures for administrations requiring a written directive will, for Y-90 SIR-Spheres administrations, describe how to quantify the total dose to the treatment site as well as the total dose to other sites upon completion of the administration to confirm that the administration is in accordance with the written directive

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Radiation Safety Procedures:
(a) The quarterly physical inventory of sealed sources and brachytherapy sources will include the individual aggregates of the microspheres identifying the radioisotope, the container the aggregate is in, the total activity of the aggregate, and the location of the container.

(b) We will take surveys to ensure that the bremsstrahlung emissions from each patient or human research subject permits his/her release in accordance with 10 CFR 35.75

(c) Vials, syringes and associated radiation shields will be labeled with the radioisotope, form, and therapeutic procedure (i.e., Y-90 SIR-Spheres, brachytherapy).

(d) We will follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use except where license conditions place further restrictions.

(e) We will comply with all requirements of 10 CFR (specifically Parts 19, 20, and 35) and conditions of our NRC license.

(f) We will request an amendment for the new conditions if the physical conditions of use exceed those reported in the SSD certificate.

(g) We have attached our procedure for assaying patient dosages and for determining the activity in millicuries that has been delivered to each patient.

We request authorization to allow future changes to our radiation safety program, with the following conditions being met:

(1) The revision is in compliance with the regulations
(2) The revision is based upon NRC's current guidance for SIR-Spheres yttrium-90 microspheres 35.1000 use posted on the NRC Web site
(3) The revision will be reviewed and approved by our RSO and RSC
(4) The affected individuals will be instructed on the revision before implementation
(5) We will retain a record of each change for five years
(6) The record will include a copy of the appropriate Web site guidance, the old and new procedures, the effective date of the change, and the signature of RSO and RSC chairman approving change

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Procedure for determining dose calibrator settings for Y-90:
1. Procedure will use first three doses of Y-90 SIR-Spheres received at facility.
2. Verify that dose calibrator has current satisfactory accuracy and constancy results.
3. Ensure that well liner is in place and hook type dipper is used.
4. Calculate current activity of Y-90 dose based on radiopharmacy calibration data.
5. Insert Y-90 SIR-Spheres dose device into dose calibrator.
6. Select the OTHER key and adjust the dial setting to the vicinity of 45.
7. Adjust until displayed activity, times ten, agrees with Step 4 result.
8. Repeat three times in succession to check constancy.
9. Record setting for future use.
10. Repeat with second and third doses received to further verify accuracy.

The following Authorized User will be involved in SirSpheres administration.

Authorized User	**Material and Use on Current NRC License**
Stephen J. M. Banks, M.D.	Medical use described in 10 CFR 35.400, Ir-192 in a high dose rate treatment unit.

Training
All authorized users, the RSO and all personnel involved in dose preparation and treatment administration will be provided the specific vendor training in the use of the microspheres and the microsphere delivery system before first use.

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Written Directive for Liver SIRT with Y-90 "SirSphere" Microspheres
Interventional Radiology

Patient Name: _____ Procedure Date: _____
MRN: _____ RT#: _____

PRE- IMPLANT

LIVER Treatment Site: Right Lobe Left Lobe Entire Liver

Chemical/Physical Form of Implant: ***Y-90 microspheres, trade name "SirSpheres"***

Prescribed Y-90 Activity: _____GBq= _____ mCi, ***OR, the activity implanted at time of Stasis.***

LUNG Shunt Fraction (%): _____ **GI Tract** Shunt Fraction (%): _____
Calculated **Liver** dose (Gy): _____ Calculated **Lung** Dose (Gy): _____

Note: Maximum permissible lifetime LUNG Dose is 30 Gy.

Authorized User (Radiation Oncologists): _____ Date: _____

POST- IMPLANT
LIVER Treatment Site: Right Lobe Left Lobe Entire Liver

Chemical/Physical Form of Implant: ***Y-90 microspheres, trade name "SirSpheres"***

Date and Time of Implantation: _____

Total Implanted Y-90 Activity: _____ GBq= _____mCi Stasis reached? _____
Y-90 Activity Implanted in **LIVER**: _____ GBq= _____mCi **LIVER** Dose (Gy): _____
Y-90 Activity Implanted in **LUNGS**: _____ GBq= _____ _mCi **LUNG** Dose (Gy): _____

Patient Identified by:
□Name □SS Number □Relative/Friend
□Birth Date □Physician/Nurse □Hospital/Wristband

Post-Implant Max. Patient Surface Reading (less than 5.4 mR/hr for release): _____ mR/hr

Post-Implant Max. Patient Reading at 1 meter (less than 2 mR/hr for release): _____ mR/hr

Radwaste was properly accounted for and disposed of as per regulations. Operating/procedure room was cleaned
and surveyed with calibrated and op-checked rad survey meter(s) and determined to be free of contamination following the end of the implantation procedure. The delivered activity and radiation doses to the patient conform to the Written Directive.

Medical Physicist: _____ Date: _____

Authorized User: _____ Date: _____