February 21, 2006
Inova Fairfax Hospital
3300 Gallows Road
Falls Church, Virginia 22042-3300

U. S. Nuclear Regulatory Commission
Region I (ATTN: Sandra Gabriel)
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

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Licensee: Inova Fairfax Hospital
License No.: 45-17128-01
Docket No.: 03012235
Control No.: 138392

Inova Fairfax Hospital provides the additional information to our amendment request (dated Jaunuary 23, 2006):

(1) Inova Fairfax Hospital is requesting authorization for the following yttrium-90 microsphere delivery system:

ANSTO Radiopharmaceuticals and Industrials Model Microspheres resin microspheres used in the Sirtex Medical Limited Model SIR-Spheres delivery system (Sealed Source and Device Registration No. MA-1229-D-101-S)

(2) Item 5: Radioactive material in our current NRC license should be modified to add the following:

Item 5
Radioactive material

Byproduct, source, and/or special nuclear material	Chemical and/or physical form	Maximum amount that licensee may possess at any onetime under this license
Yttrium-90 microsphere	As identified in 10 CFR 35.1000	500 mCi

138392

NMSS/RGN1 MATERIALS-002

(3) All authorized users, all Intravascular Radiologists performing this treatment, the Radiation Safety Officer, and all other individuals 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.

(4) A written directive form will be developed that addresses all of the items outlined in our original amendment request, and will include the prescribed dose in the "Before Implantation" section.

Note: Inova Fairfax Hospital intends to use the Written Directive form developed by the Wake Radiology Oncology Services (copy attached). As experience is gained, we intend to modify this form to better fit our requirements.

(5) Any storage or transport devices (vials or vial shields) that are not labeled by the manufacturer will be labeled with the radioisotope, form, and therapeutic procedure by Inova Fairfax Hospital staff.

(6) Attached is a copy of our procedure for assaying patient dosages and for determining the activity in millicuries that has been delivered to each patient.

Note: This procedure is the guidance supplied by SIR-Tex. As experience is gained, we intend to modify this form to better fit our requirements.

(7) As Inova Fairfax Hospital gains additional experience in the use of yttrium-90 microspheres, we reserve the right to make future changes in your radiation safety program provided that the following conditions are met:

(a) The revision is in compliance with the regulations
(b) The revision is based upon NRC's current guidance for TheraSphere and SIRSpheres yttrium-90 microspheres 35.1000 use posted on the NRC Web site
(c) The revision has been reviewed and approved by the licensee's radiation safety officer and licensee's management
(d) The affected individuals are instructed on the revised program before the change is implemented
(e) The licensee will retain a record of each change for five years
(f) The record will include a copy of the appropriate Web site 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

(8) Inova Fairfax Hospital will also adopt a portion of the SIRTex Training Program for Physicians and Institutions, specifically Section 1.17: Dose Calibrator Calibration. This procedure will be used to assay the dosages of Y-90 (copy attached)

If you have any questions concerning this request, please contact Gary F. Talkington, Radiation Safety Officer, at (703) 776-3394 or Gary.Talkington@inova.com.

Thank you for your time and attention in this matter.

Colleen Cohen

Colleen Cohen
Senior Director, Outpatient and Ambulatory Services
Inova Fairfax Hospital/Inova Fairfax Hospital for Women and Children

Wake Radiology Oncology

Written Directive

Pre Treatment Dose Calculations - ^{90}Y-Microspheres

WAKE RADIOLOGY
ONCOLOGY SERVICES, PLLC

Demographics

Patient Name: _____ WROS# _____

Scheduled Procedure Date: _____ WakeMed# _____

Diagnosis _____

Calculations

					Ft	In	metric
Treatment Volume:	**Whole Liver**		Whole (for record)	Height			0.00 m
Liver + Tumor Volume		cc		Weight (lb)			0.0 kg
Tumor volume		cc					
Lung Shunt		%	Assumed lung mass	1 kg		**BSA**	**0.00 m^2**
Desired Liver Dose		Gy	Maximum lung dose	30 Gy		Tumor /Liver Mass Ratio	#DIV/0!
MAA Uptake ratio (tumor/liver)		:1	Tumor Percentage of liver	#DIV/0!		T/N (p.41 SirSphere manual)	#DIV/0!

Emperical Method	#DIV/0!	GBq
Body Surface Area Method	#DIV/0!	GBq
Eq. 3 activity	0.0	GBq
Liver Limited activity	#DIV/0!	GBq
Lung limited activty	#DIV/0!	GBq

Prescription

Selected Activity (GBq) = **GBq**
0.0 mCi

Dose reference date: **0-Jan-1900 @ 6 PM**

A planned dose of GBq will be delivered at 10 am on 00-Jan-1900

		Volume required for	
Activity (mCi)	**Activity (GBq)**	**Selected Activity**	**Date/Time**
92.3	3.4	0.0	00-Jan-1900 06:00
88.4	**3.3**	**0.0**	**00-Jan-1900 10:00**
84.7	3.1	0.0	00-Jan-1900 14:00
71.2	2.6	0.0	01-Jan-1900 06:00
68.2	2.5	0.0	01-Jan-1900 10:00
65.3	2.4	0.0	01-Jan-1900 14:00

Physicist: William Dezarn, Ph.D.

Physician: Andrew Kennedy, MD

Date Prepared _____

Guidelines for SIR-Spheres Dose Preparation and Post Procedure Dose Verification

Patient_____ **Hospital Identifier**_____

Date _____

BSA_____ **Tumor Volume** _____

Liver Volume_____ **Intended Dose** _____ **(mCi)**

Supplies Needed:

2 venting needles (25g 5/8" BD needle)
2 5ml syringes
1 20g 2 ¾ " spinal needle
**** STERILE WATER ****
Tongs
Tweezers
Alcohol Wipes
Permanent Ink Marker

1. Dose Preparation

- ❑ Monitor preparation area pre dose preparation.
- ❑ Swipe test outer carton and Type A shipping carton.
- ❑ Remove yellow lead piglet from shipping container. Swipe test piglet.
- ❑ Take piglet and invert several times vigorously to ensure re-suspension of SIR-Spheres in the shipping vial; repeat process as necessary prior to drawing the dose and prior to measuring residual activity.
- ❑ Remove piglet twist top and using tongs remove SIR-Spheres shipping vial from lead piglet. Swipe test shipping vial. Check that no SIR-Spheres are adhering to inner surface of shipping vial. Take note of calibration date on label and place vial in dose calibrator to obtain local reading.
- ❑ Record dose calibrator reading. Calculate from actual reading what the reading would be at the calibration time on the label. Check that the reading is within +/- 10% of 3.0 GBq (81mCi).
- ❑ Place piglet containing the shipping vial behind shield, pull back perforated aluminum cap with tweezers and wipe septum with alcohol swab.
- ❑ Remove dose v-vial from the sterile pouch and wipe septum with alcohol swab.
- ❑ Vent dose v-vial using venting needle (25 g 5/8" BD) inserted close to the outer edge of the bullseye of septum and place it in the acrylic v-vial holder. Set aside the top of v-vial holder. Leave venting needle in vial.
- ❑ Vent shipping vial. Leave venting needle in vial.

Guidelines for SIR-Spheres Dose Preparation and Post Procedure Dose Verification

- ❑ Place 5ml syringe in acrylic syringe shield and attach a spinal needle (use 2 3/4" and no less than 20 G).
- ❑ Using tongs, shake shipping vial to re-suspend SIR-Spheres; place back into piglet.
- ❑ Insert the shielded syringe needle into the shipping vial and withdraw the prescribed dose based upon volume. Draw the dose into syringe and prior to removing the syringe, draw in some air to allow any spheres trapped in the needle to be drawn up into the syringe. Withdraw syringe from the shipping vial.
- ❑ Using tongs, place the shipping vial into the dose calibrator and measure the residual in the shipping vial to determine the dose drawn. If not correct, adjust the dose as necessary by removing or adding to the shielded syringe from the shipping vial as described above.
- ❑ Dispense SIR-Spheres into the dose v-vial by puncturing the outer edge of the bullseye (diametrically opposite to the vent needle). It may be helpful to mark both sides on the aluminum rim of the v-vial where the septum was punctured to avoid repuncturing in the same place with the delivery set.
- ❑ If necessary, add sterile water to the dose v-vial to bring the fluid level to approximately 2/3 of the v-vial. The water should be added through the venting needle to minimize punctures.
- ❑ Re-measure v-vial with dose in the Capintec and record measurement
- ❑ Wipe septurn with alcohol swab, screw cap onto v-vial holder containing the dose vial, insert rubber plug into hole and transport to angiography suite.
- ❑ Set aside shipping vial and needles for disposal/decay.
- ❑ Monitor preparation area post dose preparation.

2. Pre-Procedure Dose Vial Measurements

- ❑ Ion Chamber Readings

ENSURE THAT THE DISTANCE THE READINGS ARE TAKEN IS NOTED SO THE DISTANCE WILL BE THE SAME FOR PRE AND POST PROCEDURE
(See attached template)

90° (mR/h)	180° (mR/h)	270° (mR/h)	360° (mR/h)

Average_____

Guidelines for SIR-Spheres Dose Preparation and Post Procedure Dose Verification

3. **Post-Procedure Dose Vial Measurements**

   ☐ Ion Chamber Readings

ENSURE THAT READINGS ARE TAKEN FROM THE SAME DISTANCE AS THE PRE-PROCEDURE READINGS WERE TAKEN

90° (mR/h)	180° (mR/h)	270° (mR/h)	360° (mR/h)

Average_____

4. **Percent Dose Delivered:** 1 - (Avg. Post/Avg. Pre) X 100 _____%

5. **Dose Delivered:** (Drawn Dose X % Dose Delivered) _____**mCi***

***If different from Prescribed Dose:** ___ **Yes** ___ **No**

Reason:

Date: _____

Signed: _____ **Signed:** _____

Title: _____ **Title:** _____

Dose Calibrator Calibration
(for use with Y-90 microspheres)

Inova Fairfax Hospital (IFH) possesses two Capintec dose calibrators (Models 7 and 15C). The information in this section pertains to these Capintec models. The Model 15C will be used as the primary calibration device.

IFH will use a dial setting of 775 with a multiplication factor of 70, or a dial setting of 48 with a multiplication factor of 10. These settings will give consistent readings for yttrium-90 sources between 1GBq and 3GBq over a range of volumes. These settings should be used initially and adjusted if necessary as a result of calibration activities. If the dial setting of 775 with a multiplication factor of 70 provides consistent and reliable measurements, it will be adopted as the standard.

The device will be measured in the Capintec and the activity measurements compared (allowing for decay). Adjustments to the settings will be made to bring the measurement from the Capintec to ±10% of the manufacturer-supplied measurement. An alternative is to apply a correction factor. These settings will then be the standard used for activity measurements of SIR-Spheres microspheres.

At regular intervals IFH will recheck that calibration remains accurate. This can be easily achieved by requesting a manufacturer activity measurement with a device.

To ensure that calibration is meaningful, the other factors that can influence the activity measurements must be as consistent as possible for each measurement made in the Capintec.

Potential areas of inaccuracy are:

- The activity measured
- The volume of the source
- The shape of the container holding the source
- The material of the container holding the source and
- Homogeneity of the suspension.

The accuracy of measurement may be dependent on the range of activity being measured. At the suggested settings, measurements up to 3GBq are generally linear and consistent. If alternative settings are used, linearity and consistency should be confirmed.

The volume of the source may alter the accuracy of measurement due to self-shielding that can occur with short penetration beta emissions. A slight inaccuracy occurs between measurements taken on a 3GBq device and a confirmatory measurement of residual activity after a patient dose is withdrawn from the vial. Ensuring the microspheres are fully suspended at the time of each measurement can minimize this. Allowing the microspheres to settle changes the effective volume of the source and contributes to unquantifiable self-shielding effects of water, air and the container.

The shape of the container should be consistent to minimize changes in the geometry of the source, and thus self-shielding effects. For this reason, the activity of the patient dose in the v-vial is confirmed by re-measuring the remaining activity in the shipping vial.

The container material also contributes to the activity measurement, as the penetration through plastic is substantially greater than through glass. A correction factor for the container is not generally necessary for glass containers. This potential inconsistency is removed if all measurements for SIR-Spheres microspheres are taken in the shipping vial.