

# ROBERT WOOD JOHNSON

## UNIVERSITY HOSPITAL

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030-02525

### Fax Cover Sheet

Date: 2/15/07

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No. of Pages Including Cover Sheet: 5

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To: Penny Lanzisera

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Organization: NRC Department:

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Fax Number: 610-337 5269 Phone Number:

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From: Rao Department: Nuclear Medicine

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Fax Number: 732 418 8344 Phone Number: 732 937 8609

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Message:

Ms. Lanzisera,

Bob Tokarz has been talking to you about this request. Here is our response to the Items you mentioned in your e-mail. If you need any other information, please call me at 732-937 8609.

Thank you,  
*MDasika*  
Rao Dasika  
RSO

### CONFIDENTIAL

NMSS/IRGNI MATERIALS-002



**ROBERT WOOD JOHNSON**  
UNIVERSITY HOSPITAL

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February 15, 2007

Penny Lanzisera  
Senior Health Physicist, Medical Branch  
Division of Nuclear Material Safety  
Nuclear Regulatory Commission Region 1  
475 Allendale Road  
King of Prussia, PA 19406

Mail Control Number 140076

Subject: Request to Add Use of SIR-Spheres to NRC License under 10 CFR 35.1000

Dear Ms. Lanzisera,

1. *We confirm that for Y-90 microsphere treatments, "prescribed dose" will mean the total dose documented in the written directive.*

Prescribed dose will, in fact, mean total dose in the written directive.

2. *We confirm that the written directive for use of Y-90 microspheres will include:*  
(i) *before implantation: the treatment site, the radionuclide (including the chemical/physical form [Y-90 microspheres]), and dose; and (ii) after implantation but before completion of the procedure: the radionuclide (including the chemical/physical form [Y-90 microspheres]), treatment site, and the total dose.*

We will confirm that the written directive will include:

- Before implantation: treatment site  
radionuclide, in this case Y-90 microspheres  
dose
- After implantation but before completion of the of the procedure:  
radionuclide (Y-90)  
treatment site  
total dose

3. *If the medical end-point of stasis is used to determine when to terminate implantation of the microspheres, please confirm that this is included in the written directive before implantation. In addition, confirm that the written directive will include: (ii) before implantation: the treatment site, the radionuclide (including chemical/physical form [Y-*

90 microspheres]), and a dose of either XXX rad/Gray (or rem/Sieverts) or the dose delivered at stasis; and (ii) after implantation but before completion of the procedure: the radionuclide (including chemical/physical form [Y-90 microspheres]), the treatment site, and the total dose. If the implantation is terminated due to stasis, total dose will be the value of the total dose delivered when stasis occurred and the implant was terminated.

These conditions will be documented in the written directive.

4. We confirm that 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).

Technetium-99m macroaggregated albumin hepatic arterial perfusion scintigraphy and will be performed on each patient prior to treatment with Y-90 microspheres. Tc-99m MAA mimics the size of Y-90 microspheres, and it is assumed that the distribution of microspheres will be identical with that of Tc-99m MAA. Therefore, this scan will demonstrate where the microspheres could be potentially deposited.

If the scintigraphy demonstrates deposition to the GI tract that is not correctable with angiography, and the Y-90 microspheres cannot be delivered to the patient. Excessive shunting to the gastroduodenal artery, right gastric artery and other extrahepatic arteries should be low. Reflux of microspheres into the gastric circulation could result in severe ulceration, gastrointestinal bleeding, and pancreatitis. Excessive shunting to the lungs could result in radiation pneumonitis. A lung shunt fraction of less than 20% is acceptable. This translates to an acceptable dose of 15 Gy per treatment and 30 Gy cumulatively. The dose of administered Y-90 must be reduced to make lung doses safe. The following equation is employed to determine lung shunting:

$$\text{Lung shunt fraction} = \text{total lung counts} / (\text{total lung} + \text{liver counts})$$

5. We confirm that your procedures will describe how to quantify 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.

Triple phase CT provides the most reproducible imaging of the liver for tumor burden calculation. Because the treatment approach for Y-90 is most commonly lobar, proper imaging and volume calculation is essential for dosimetry purposes. This is used prior to administration of Y-90 microspheres to calculate the involved tumor burden and liver volume.

The calculation incorporates the body surface area and estimate of tumor burden:

$$\text{SIR-spheres: A (GBq)} = \text{body surface area (m}^2\text{)} - 0.2 + (\% \text{ tumor involvement}/100)$$

$$\text{Body surface area} = 0.20247 \times \text{height}^{0.725} \text{ (m)} \times \text{weight}^{0.425} \text{ (kg)}$$

Another method of verifying dose accuracy after using the above equation is to use the following table:

Tumor Involvement in Liver (%)	Recommended Activity (GBq)
> 50	3.0
25-50	2.5
< 25	2.0

The above calculations are used to determine a dose pre-administration. Monitoring of the Y-90 microsphere infusion will be performed with use of an ionization chamber, with a minimum detection of 1 mrem/h, placed adjacent to the SIR-spheres kit. Keeping the ionization chamber at a fixed distance from the vial and measuring baseline pre-infusion dose can provide a live assessment of percentage infused. The dose reading should decrease as the infusion percentage increases. Following the administration of the Y-90 microspheres, measurements will be made with a portable ion chamber to determine remaining dose in (vial, gloves/gowns/shoe covers, inlet and outlet catheters, and towels beneath the delivery device). The residual activity from these components can be determined. The following formula is used to determine actual dose (Gy) delivered to the target liver after injection:

$$\text{Dose (Gy)} = 50 [(\text{measured activity (GBq)} \times (1 - \text{LSF}) \times (1 - \text{R})) / \text{liver mass (kg)}]$$

Where LSF is the fraction of injected radioactivity localizing in the lungs, as measured by the Tc-99m MAA scintigraphy, and R is the fraction of injected radioactivity remaining in the dose vial, outlet catheter, and catheter as measured by the ionization chamber

6. Our 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.

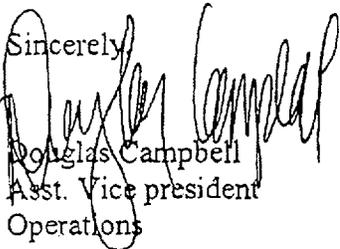
7. According to Table 1. Of Nuclear Regulator Guide 8.39, the exposure due to Y-90 to the public is minimum, hence no criteria for discharge is set. However, instructions related to general radiation safety will be given to the patient such as hydration, good hygiene, etc.

8. The dose of Y-90 microspheres will be measured with a dose calibrator. Upon completion of the administration the spent vial of Y-90 microspheres will be measured for residual activity. The difference between the two will be the activity delivered to the patient. The procedure is as follows:

- a) The background and zero checks will be done for the dose calibrator.
- b) Constancy and accuracy checks will be done.
- c) After proper shaking, the vial containing Y-90 microspheres from the manufacturer will be placed in the dose calibrator. The dial will be set (turned) such that it reads the same activity (corrected for decay) noted on the vial. This setting will be posted clearly on the dose calibrator for future measurements.

- d) The patient dose will be measured before and after administration to determine actual dose administered.
9. When the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer, we will label vials and vial radiation shields with the radioisotope and form. In addition, we will label syringe and syringe radiation shields with the radioisotope, and form, and therapeutic procedures (for example, Y 90 microspheres, brachytherapy).
10. When making future changes to the radiation safety program regarding SIR-spheres Y-90 microspheres
- e) the revision will be in compliance with the regulations;
  - f) the revision will be based upon NRC's current guidance for SIA-spheres Y-90 microspheres 35.1000 use posted on the NRC website;
  - g) the revision will be reviewed and approved by the licensee's radiation safety officer and licensee's management;
  - h) the affected individuals will be instructed on the revised program before the change is implemented;
  - i) the licensee will retain a record of each change for 5 years;
  - j) 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 you need any further information, please contact Rao Dasika at 732 937 8609.

Sincerely,  
  
Douglas Campbell  
Asst. Vice president  
Operations