



West Virginia University

Radiation Safety Department

Fax Cover Sheet

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Date: 10/04/07	Number of Pages: 5 (Including Cover)
To: Ms. Penny Lanzisera Senior Health Physicist	From: Rhonda Stevens Administrative Secretary Senior
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MESSAGE:

Penny,
 Here is the request for additional information regarding request to add SIRspheres.
 Thank you for your help,
 Rhonda

141079

NMSS/RGN1 MATERIALS-002

**Request for additional information Regarding request to add
SIRspheres**

- 1) We confirm that we will follow all the requirements in 10 CFR part 35 for Brachytherapy sources and manual therapy
- 2) We confirm that "prescribed dose" means the total dose documented in the written directive and that the written directive will include
 - a) Before implantation :
 - i) The Treatment site
 - ii) The radionuclide chemical/physical form (Y-90 microspheres)
 - iii) Dose
 - b) After implantation before completion of the procedures
 - i) The Treatment site
 - ii) The radionuclide chemical/physical form (Y-90 microspheres)
 - iii) The Total Dose
- 3) We confirm if the authorized user uses the medical point of stasis to determine when to terminate implantation of the microspheres then it shall be included in the written directive before implantation, in this case the written directive shall include
 - a) Before implantation :
 - i) The Treatment site
 - ii) The radionuclide chemical/physical form (Y-90 microspheres)
 - iii) A Dose of either rad/gray (or rem/seivert) or the dose delivered at stasis
 - b) After implantation before completion of the procedures
 - i) The Treatment site
 - ii) The radionuclide chemical/physical form (Y-90 microspheres)
 - iii) The total Dose (*Note 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*)
- 4) We confirm that the written directive will,
 - i) Specify the maximum dose that would be acceptable for specified site outside the primary treatment site to which the microsphere could be shunted.(such as the lungs and gastrointestinal tract)
 - ii) Describe how to quantify the total dose to the treatment site as well as the total dose to others sites upon completion of the administered to confirm that the administration is accordance with written directive
- 5) The total dose to the treatment site as well as the total dose to other sites will be calculated using the Empiric Model to quantify the total dose prescribed. (*A copy of model procedure is attached*) and written directive procedures shall be developed, implemented and maintained to provide high confidence that the written directive is rigorously followed. The procedure shall provide assurance that the patient's identity

is verified before any administration of Y-90 microsphere and each administration is in accordance with the written directive.

- 6) The procedure for drawing and measuring the dosage prior to administration are:
 - a) Vial (call it V1) will be received from the vendor as a unit dose (mCi/ml).
 - b) Place V1 in the dose calibrator, and adjust the calibrator (calibrator factor/setting). That the calibrator reads the activity on the label. A specific desired volume is dispensed (based on the amount needed for the Treatment) via syringe,
 - c) The V1 will be measured again (activity remained) using the obtained calibration factor\setting, and then calculate the activity dispensed (shipped - remained).
 - d) The dispensed activity is then will be injected into the V-vial (not V1), the V-vial is placed in the dose calibrator (set the calibrator at the same setting previously used) and we read the response activity, Since the V -vial differ from V1, We now have a correction factor for the V-vial, that is the calculated dispensed activity/response activity).
 - e) Dose is administered; we measure the V-vial post administration, and then calculate the remained activity using the V-vial correction factor. The administered activity is then calculated,(activity dispensed – the calculated remained activity in the V-vial)

- 7) We confirm that the physical inventory for the microspheres shall be performed, it includes
 - I. The individual aggregates of the microsphere identifying the radioisotope,
 - II. The container the aggregate is in,
 - III. The total activity of the aggregate, and
 - IV. The location of the container

- 8) We confirm that patient release procedures shall be placed on the release of individual who has been administered Y-90 microspheres in accordance with 10 CFR 35.75

- 9) We confirm that when the Y-90 microspheres are placed in vials, syringes or radiation shields that are not labeled by the manufacturer, we will: (i) label the vials and the vials radiation shields with radioisotopes and form (i.e., Y-90 microspheres); and (ii) label syringes and syringes radiation shield with the radioisotopes, form, and therapeutic procedures (i.e., Y-90 microspheres, brachytherapy)

- 10) As an initially applicants for the medical use of SIRSpheres Y-90 microspheres, we also request authorization to allow future changes to our radiation a safety program provided all the conditions are met:
 - a) The revision is in compliance with the regulation
 - b) The revision is based upon NRC's current guidance for Therasphere and SIRSpheres Y-90 microspheres 35.1000 uses posted on the NRC web sites
 - c) The revision has been reviewed and approved by the licensee's radiation safety officer and licensee's management

Mail Control No. 141079

- 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; and
- f) The record will include a copy of the appropriate Web site guidance , the old proccdures , the new procedures, the effective date of the change , and the signature of the licensee management that reviewed and approved the change.

LOBAR Prescribed Y-90 SirSphere Total Activity Dose Calculations

(Note: Enter Data in Yellow Fields. Results will be displayed in Green Fields) Last Revision to this spreadsheet: May 14, 2007

Patient: _____ Date: _____
 Hospital Number: _____ Rad Onc Number: _____
 % Lung Shunting = 11.80% Physician: _____
 Patient Height (ft) = 5.25 Patient Weight (lbs) = 158.0
 RT Lobe Tumor Vol (cc) = 20.10 RT Lobe NORMAL Liver Vol (cc) = 1461.1
 LT Lobe Tumor Vol (cc) = 6.20 LT Lobe NORMAL Liver Vol (cc) = 555.9
 MID Lobe Tumor Vol (cc) = 0.00 MID Lobe NORMAL Liver Vol (cc) = 0.0
 All Lobes Tumor Vol (cc) = 26.30 All Lobes Normal Liver Vol (cc) = 2017.0
 Entire Liver Volume = All Tumor Volumes + All Lobes Volumes (cc) = 2043.3
 % Tumor Involvement in Entire Liver (as calculated from AITV/ [AITV+AINLV]) = 1.3%
 % Tumor Involvement in Right Liver (as calculated from RTTV/ [RTTV+RTNLV]) = 1.4%
 % Tumor Involvement in Left Liver (as calculated from LfTV/ [LfTV+LdNLV]) = 1.1%
 % Tumor Involvement in Middle Liver (as calculated from MidTV/ [MidTV+MidNLV]) = #DIV/0! No MID Lobe

Using the Table 1 Dose

(Model applied in clinical trials when SirSphere were used in conjunction w/ hepatic perfusion chemo with FUOR)

SirTex's TABLE 1:

% Tumor Involvement Whole Liver	Y-90 Dose (mCi)	Y-90 Dose (GBq)
%T1 > 60%	87	3
25% <= %T1 < 50%	87.8	2.5
%T1 < 25%	54	2

Note: Rad hepatic avoided when normal liver dose is kept below 25 Gy.

From Table 1: Patient Y-90 Total Activity Dose w/o Lung Shunt Modification Factor (mCi) = 54.0 mCi

SirTex's TABLE 2:

% Lung Shunting %LS	Dose Modification Factor
%LS < 10%	100% (no reduction)
10% <= %LS < 15%	80%
15% <= %LS < 20%	60%
%LS > 20%	0% (no treatment)

Dose Modification Factor = 80%

Recommended Y-90 Activity (GBq) = 1.60
 Recommended Y-90 Activity (mCi) = 43.20
 Y-90 SirSphere Activity going to Entire Liver (GBq) = 1.41
 Y-90 SirSphere Activity going to Lungs (GBq) = 0.19
 Equation 3 from SirTex Medical Training Manual:
 Tissue Radiation Dose (Gy) = 49670 * (Y-90 Activity in Tissue in GBq / Mass of tissue in g)
 Calculated Average Entire Liver Dose (Gy) = 33 Assuming a Unit Vol.
 Calculated Average Lung Dose (Gy) = 9 8:1 Tumor/Liver Activity
 Estimated Average Tumor Dose (Gy) = 166 Density Ratio

Recommended Y-90 Activity (GBq) = 1.16
 Recommended Y-90 Activity (mCi) = 31.29
 Y-90 SirSphere Activity going to Right Liver (GBq) = 1.02
 Y-90 SirSphere Activity going to Lungs (GBq) = 0.14
 Equation 3 from SirTex Medical Training Manual:
 Tissue Radiation Dose (Gy) = 49670 * (Y-90 Activity in Tissue in GBq / Mass of tissue in g)
 Calculated Average RT Liver Dose (Gy) = 33 Assuming a Unit Vol.
 Calculated Average Lung Dose (Gy) = 7 8:1 Tumor/Liver Activity
 Estimated Average RT Lobe Tumor Dose (Gy) = 166 Density Ratio

Recommended Y-90 Activity (GBq) = 0.44
 Recommended Y-90 Activity (mCi) = 11.91
 Y-90 SirSphere Activity going to Left Liver (GBq) = 0.39
 Y-90 SirSphere Activity going to Lungs (GBq) = 0.05
 Equation 3 from SirTex Medical Training Manual:
 Tissue Radiation Dose (Gy) = 49670 * (Y-90 Activity in Tissue in GBq / Mass of tissue in g)
 Calculated Average LT Liver Dose (Gy) = 33 Assuming a Unit Vol.
 Calculated Average Lung Dose (Gy) = 3 8:1 Tumor/Liver Activity
 Estimated Average LT Lobe Tumor Dose (Gy) = 167 Density Ratio

Recommended Y-90 Activity (GBq) = 0.00
 Recommended Y-90 Activity (mCi) = 0.00
 Y-90 SirSphere Activity going to Middle Liver (GBq) = 0.00
 Y-90 SirSphere Activity going to Lungs (GBq) = 0.00
 Equation 3 from SirTex Medical Training Manual:
 Tissue Radiation Dose (Gy) = 49670 * (Y-90 Activity in Tissue in GBq / Mass of tissue in g)
 Calculated Average MID Liver Dose (Gy) = #DIV/0! Assuming a Unit Vol.
 Calculated Average Lung Dose (Gy) = 0 8:1 Tumor/Liver Activity
 Estimated Average MID Lobe Tumor Dose (Gy) = #DIV/0! Density Ratio