McLAREN
REGIONAL MEDICAL CENTER

November 12, 2007

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
2443 ~~801~~ Warrenville Road
Lisle, Illinois 60532-4351

Dear Sir/Madam:
Please consider the following amendment to our License #21-04171-04, McLaren Regional Medical Center:

^{90}Y Administration in the form of SIR-micropheres for the treatment of non-liver cancer. The activity of the yttrium we need in facility is 6 GBq

To support the application for administrating SIR-microspheres, we have provided the following documentation:

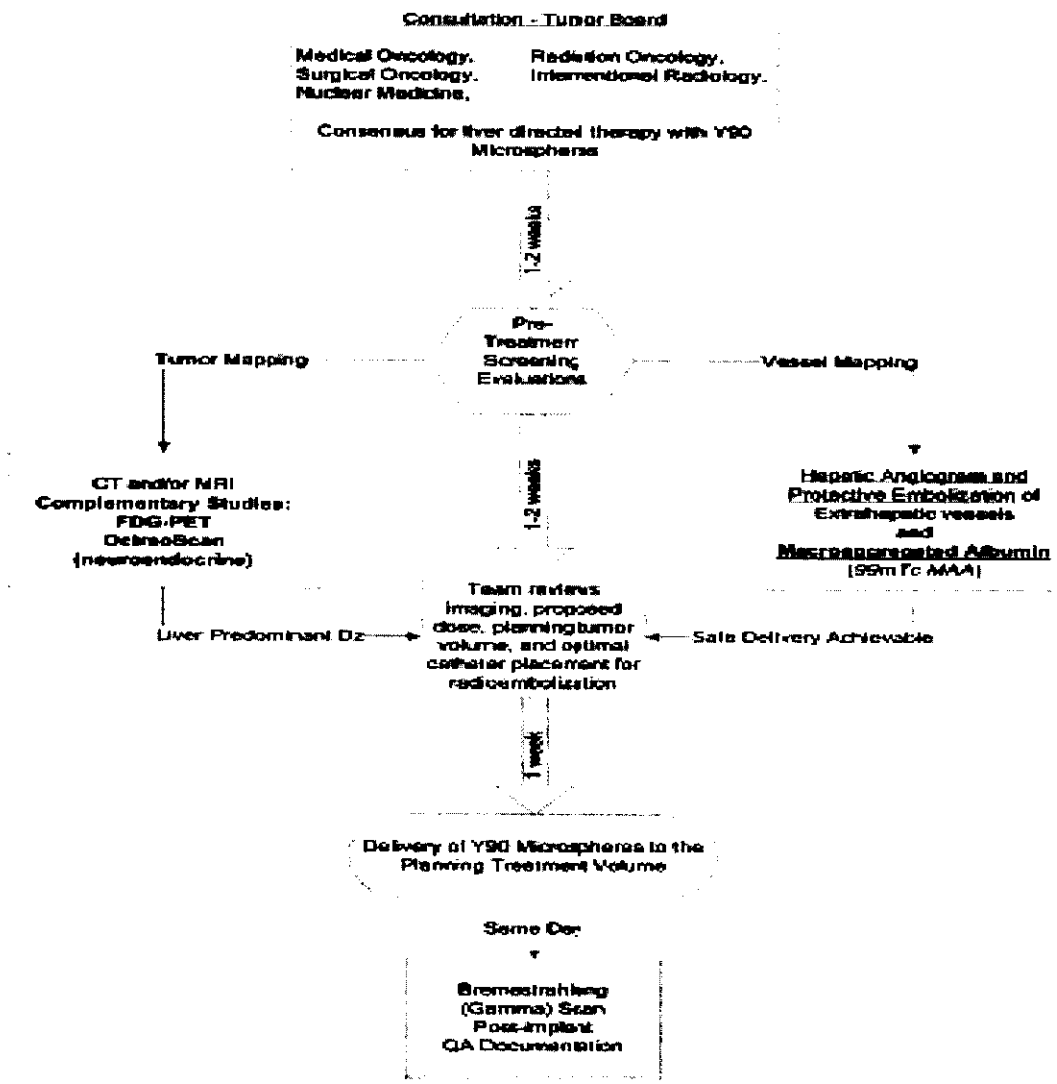
1) Overall SIR-microsphere administration procedure
2) Nuclear medicine procedure for the radionuclide
3) Written directive document
4) Angio suite preparation for administration of the yttrium-90 SIR-microsphere administration
5) Radiation survey of angio/interventional radiology suite after administration
6) Nursing procedure manual SIR-microsphere
7) Emergency procedure to deal with any spillage that may occur
8) Radiation survey of patient and rooms
9) Other relevant documents.

If you have any questions about any of the procedure, do not hesitate to contact Dr. Paul Mobit, Chief of Medical Physics for clarification on 810-342-3804

Brent Wheeler
V P Auxiliary/Support Services
810-342-4407
Cc: RSO

GREAT LAKES CANCER INSTITUTE McLAREN

Yttrium-90 / SIR-Microspheres Treatment Procedure



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

Patient name:_____ **Hospital Identifier**_____

Date _____

BSA_____ **Tumor Volume** _____

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

Supplies Needed:

2 filtered vent needles (PROVIDED BY SIRTEX)
1 5ml syringe
Syringe shield (PROVIDED BY SIRTEX)
1 siliconized needle to draw dose (PROVIDED BY SIRTEX)
Sterile Water for INJECTION – 5ml bottle
Tongs
Tweezers
Alcohol Wipes
Permanent Marker

1. **Dose Preparation**
   - ❑ Monitor preparation area pre dose preparation.
   - ❑ Wipe test outer carton.
   - ❑ Open and wipe test lead piglet.
   - ❑ Remove dose v-vial from the sterile pouch and use permanent marker to mark sides 180 degrees apart on metal of septum.
   - ❑ Wipe septum with alcohol swab.
   - ❑ Vent dose v-vial septum using venting needle inserted 1/8 inch from metal where mark is; do not scrape side of vial with needle. Place v-vial in the acrylic v-vial holder. Set aside the top of v-vial holder. Leave venting needle in vial.
   - ❑ Remove yellow lead piglet from shipping container.
   - ❑ Take piglet and invert for two minutes 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 wipe shipping vial containing SIR-Spheres.
   - ❑ Using tongs remove SIR-Spheres shipping vial from lead piglet. 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.
- ❑ Vent shipping vial. Leave venting needle in vial.
- ❑ Place 5ml syringe in acrylic syringe shield and attach needle (provided by Sirtex).
- ❑ 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.
- ❑ Stabilize v-vial with tongs when putting in dose.
- ❑ Dispense SIR-Spheres into the v-vial by puncturing 1/8 inch from the mark opposite from the vent needle. Again, take care not to scrape the side of the v-vial with the needle.
- ❑ If necessary, add sterile water to the dose v-vial to bring the fluid level to approximately 1/2 of the v-vial (3 mls).
- ❑ Wipe septum 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

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

Average_____

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: _____

GREAT LAKES CANCER INSTITUTE McLAREN

Guidelines for Yttrium-90 / SIR-Microspheres procurement, Dose Preparation and Post Procedure Dose Verification

Ordering and procuring :
Yttrium-90 SIR microsphere would be ordered based on the written directive of the authorized user. The receiving and handling will be performed by Nuclear Medicine based on current policy and procedures.

Patient name:_____ **Hospital Identifier**_____

Date _____

BSA_____ **Tumor Volume** _____

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

Supplies Needed:

2 filtered vent needles (PROVIDED BY SIRTEX)
1 5ml syringe
Syringe shield (PROVIDED BY SIRTEX)
1 siliconized needle to draw dose (PROVIDED BY SIRTEX)
Sterile Water for INJECTION – 5ml bottle
Tongs
Tweezers
Alcohol Wipes
Permanent Marker

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   - ❑ Monitor preparation area pre dose preparation.
   - ❑ Wipe test outer carton.
   - ❑ Open and wipe test lead piglet.
   - ❑ Remove dose v-vial from the sterile pouch and use permanent marker to mark sides 180 degrees apart on metal of septum.
   - ❑ Wipe septum with alcohol swab.

- ❑ Vent dose v-vial septum using venting needle inserted 1/8 inch from metal where mark is; do not scrape side of vial with needle. Place v-vial in the acrylic v-vial holder. Set aside the top of v-vial holder. Leave venting needle in vial.
- ❑ Remove yellow lead piglet from shipping container.
- ❑ Take piglet and invert for two minutes 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 wipe shipping vial containing SIR-Spheres.
- ❑ Using tongs remove SIR-Spheres shipping vial from lead piglet. 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.
- ❑ Vent shipping vial. Leave venting needle in vial.
- ❑ Place 5ml syringe in acrylic syringe shield and attach needle (provided by Sirtex).
- ❑ 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.
- ❑ Stabilize v-vial with tongs when putting in dose.
- ❑ Dispense SIR-Spheres into the v-vial by puncturing 1/8 inch from the mark opposite from the vent needle. Again, take care not to scrape the side of the v-vial with the needle.
- ❑ If necessary, add sterile water to the dose v-vial to bring the fluid level to approximately 1/2 of the v-vial (3 mls).
- ❑ Wipe septum 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

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Average_____

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:** _____

GREAT LAKES CANCER INSTITUTE McLAREN

SIR-Microspheres Protocol for Patient Eligibility

I. Indication: Sir-Spheres is indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intra-hepatic artery chemotherapy (IHAC) of FUDR (Floxuridine).

II. Insurance and pre-authorization

A. Have patient explore insurance and pre-authorization for the following
1. Appointment to radiation oncologist
2. PET scan
3. CT
4. Pet scan
5. Liver Spleen scan
6. MAAAP Study
7. All Interventional charges per Dr. _____
8. Treatment
9. Follow up Bremsstrahlung planar and SPECT image

III. Initial Evaluation

A. Refer patient to Dr. _____
B. Nuclear Medicine evaluation
1. Complete history sheet on computer
2. Screen for SIR-Spheres contraindications listed below:

Previous external beam radiation therapy to the liver

Ascites or clinical liver failure

Markedly abnormal synthetic and excretory liver function tests

Tumors amenable to surgical resection for cure

Greater than 20% lung shunting as determined by the nuclear medicine MAAAP scan

Pre-assessment angiogram or MAAAP demonstrates significant reflux of hepatic arterial blood to the stomach, pancreas or bowel

Disseminated or extra-hepatic disease

Has been treated with capecitabine within the previous 2 months

Any patient who will be treated with capecitabine any time following treatment with Sir-Spheres

Portal vein thrombosis.

Primary liver cancer:

- Not a FDA approved indication for using SIR-Spheres, however, this would be an off-label use of an approved radiopharmaceutical.

3. Physical: by Dr. _____
4. Laboratory:
   Liver function tests
   CBC
   CT/MRI of liver
   Chest x-ray
4. Patient education
5. Informed consent
6. Physician coordinate schedule
7. Assure patient has had recent PET within 30 days. If not, re order
8. Schedule the following
   a. Schedule PET if not performed within 30 days of the liver spleen scan. If not, contact referring physician to have him/her order or to get a verbal order for the PET scan. At the time of the telephone call, get the second order for the follow up PET. The recommended time for follow up PET scan is __ months. The PET is one of the tumor markers to follow.
   b. Liver-spleen scan
   c. Date for angiogram per Dr. _____
   d. MAAAP immediately after placement of the catheter
   e. Coordinate with Dr. _____

III. Liver Spleen Scan procedure

B. See standard liver spleen procedure per current Nuclear Medicine procedure

IV. MAAAP Procedure: Macroaggregated Albumin Arterial Perfusion Scintigraphy In combination with Sir-Spheres treatment

A. Patient Preparation

B. Radiopharmaceutical:
- Technetium-99m macroaggregated albumin (MAA)
- 3 mCi (with range of 1 to 4 mCi) administered via arterial catheter

C. Camera Setup:
- Low-energy
- High sensitivity, low resolution
- Parallel-hole collimator
- 140 keV with 20% window
- 700K to 1000K

D. Camera:
- Special Procedures Section
- Argus or Single headed e-cam.

E. Computer
- 64 x 64

F. Procedure:
- Obtain room background counts for 60 seconds with camera in the approximate position and direction in which the camera will be used for the patient at least for the anterior view.
- Obtain counts of syringe on camera face in the same position as above for 60 seconds.
- The interventional radiologist will label the indwelling catheter that should be injected.

A. Inject radiopharmaceutical under sterile conditions and with a slow flow rate. Rapid injection may result in streamline flow and even movement of the catheter tip.

B. Image liver for 60 seconds in anterior, right lateral, and posterior positions. Try to include edge of lower lung, stomach, and upper abdomen.

C. Image lung for 60 seconds in the anterior and posterior view.

D. Review all images with physician.

E. Analysis
- Obtain region of interest of both lungs on both anterior and posterior views.
- Calculate geometric mean.

L. Interpretation Notes:

- Looking for non-tumor activity including lung, stomach, bowel, and liver.
- Physician review uptake values for lung and review images before injection of Sir-Spheres.
- Need copies of CT and MRI at time of MAAAP.
- Dictation as usual
    a. Indication
    b. Radiopharmaceutical and dose
    c. Technical procedure
    d. Description including:
    e. Qualitative assessment of activity in tumor.
    f. Any qualitative assessment of activity outside tumor in other parts of liver
    g. Any qualitative assessment of activity outside liver in bowel, stomach or lung.
    . Quantitative value for lung "uptake."

SAMPLE REPORT FROM NUCLEAR MEDICINE PHYSICIST

Patient: Mrs. Sample Patient MR: 2089101

Date: 3/26/2003

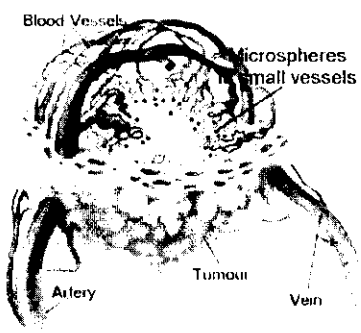
	Lt Lung	Rt Lung	Total Lung	Liver	Total Counts
C. Ant	4194	7120	11314	272293	315031
Post	**5330**	**5989**	**11319**	**123359**	**162600**

Pulmonary Shunting

Anterior	**3.6%**
Posterior	**7.0%**
Geometric Mean	**5.0%**

Based on standard gamma camera images of the Tc99m MAA the pulmonary shunting from the hepatic infusion is $\leq$5%, which meets the acceptable treatment guidelines shown below.

SIR-Spheres® are biocompatible radioactive micro-spheres that contain yttrium-90 and emit beta radiation. SIR-Spheres® are implanted using a syringe and travel via the blood stream, whereupon the spheres are targeted to the tumors within the liver. The SIR-Spheres® are trapped in the small blood vessels of the



tumor. It is not necessary to identify either the number or location of the tumors within the liver, as the SIR-Spheres® will target them regardless of where they are. Once targeted to the tumor, SIR-Spheres® irradiate it by a process known as Selective Internal Radiation Therapy (SIRT), leading to the destruction of the tumor, whilst most of the normal liver tissue remains relatively unaffected.

Contraindications

There are no data on the safety of SIR-Spheres® in pregnancy or children.

SIR-Spheres® are contraindicated in patient who have:

- had previous external beam radiation therapy to the liver
- ascites or are in clinical liver failure
- markedly abnormal synthetic and excretory liver function tests
- tumors amenable to surgical resection for cure
- **greater than 20% lung shunting (determined by the nuclear medicine break-through scan)**
- pre-assessment angiogram and MAA nuclear scan demonstrates significant reflux of hepatic arterial blood to the stomach, pancreas or bowel
- disseminated or extra-hepatic disease
- been treated with capecitabine within the previous 2 months, or who will be treated with capecitabine at any time following treatment with SIR-Spheres® .
- Portal thrombosis

. Interpretation:

- Adequate for Sir-Spheres treatment
- Inadequate for Sir-Spheres treatment

IV. Treatment

A. Pre treatment Coordination

- Place order by required Sirtex time (Eastern Standard time)
- Coordinate with Interventional Radiologist, Radiation Safety, and Radiation Oncologist.
- Obtain written informed consent
- Discharge per Dr. _____ is same day with no hospitalization required.
- Coordinate Post-Sir-Spheres Bremsstrahlung Imaging

B. H-2 blockers: Routinely receives H-2 blocking agents the day before implantation and for a period of one month post implementation.

C. Empiric Dose: 81 mCi (3 GBq). Activity calibrated to 0900: hours Sydney time for Australia and Asia, and 18:00 USA Eastern Standard Time for the USA.

There are generally two acceptable methods in calculating the individual patient dose---the basic model and the BSA (Body Surface Area) model. The **basic model** accepts the safety margins of the dose known from the previously published clinical data and chooses the most safe and effective dose from it. The empirical model has been used in the pivotal clinical trial of the SIR-Spheres®.

The patient dose can be determined according to the following Table 1.

Table 1 – The Recommended Patient Dose

The % Involvement by the Tumor in the Liver	**Recommended Y-90 Dose***
> 50 %	**1.0 GBq**
25 % - 50 %	**2.5 GBq**
< 25 %	**2.0 GBq**

The **BSA model** is a variant of the empiric method and has been applied in clinical trials in which SIR-Spheres has been used in conjunction with systemic chemotherapy using 5-fluorouracil and leucovorin. The equation is:

$$\text{Activity of Sir-Spheres (GBq)} = (\text{BSA} - 0.2) + \frac{\%\ \text{tumor involvement}}{100}$$

- Body surface area is calculated from a weight/height chart.
- % Tumor involvement = $\frac{\text{volume of tumor}}{\text{volume of tumor + liver}} \times 100$

This method is recommended for patients having concurrent systemic chemotherapy or for particularly small patients. As with the basic model the percent lung shunt may necessitate a reduction in the amount to be administered.

CAUTION: **The recommended implanted activities are specific to SIR-Spheres®. They are not applicable and should not be extrapolated to other implanted Y-90 sources.**

- When there is 10 % or more lung shunting, the patient dose would be further reduced, according to the following table 2.

Table 2 – Dose Reduction Factors for Patients with Lung Shunting

% Lung Shunting	D. Reduction Factor
< 10 %	No reduction
10 % - 15 %	20 % reduction
15 % - 20 %	40 % reduction
> 20 %	No Treatment

Lung Shunt Calculation Procedure

- Inject 4 mCi (150MBq) of Tc-99m MAA into the hepatic artery via a port or catheter;
- Use a large FOV gamma camera, and obtain anterior and posterior images of the chest and abdomen (with 700k to 1 million counts on abdomen, and the same count on the chest);
- Take right lateral abdomen, using same count;
- Draw ROI around the whole liver and the whole lung and get the total counts for the lung and the liver;
- Calculate the % shunt using following formula:

% Shunt = (Lung Counts / Liver Counts + Lung Counts) x 100

Table 1 – Dose Reduction Recommendations

Per Cent Lung Shunting	**Activity of SIR-Spheres®**
< 10%	Deliver full amount of SIR-Spheres®
10% to 15%	Reduce amount of SIR-Spheres® by 20%
15% to 20%	Reduce amount of SIR-Spheres® by 40%
> 20 %	Do not give SIR-Spheres®

D. **Dose Preparation:** Dose to be drawn by _____

- As per User's Manual and training.

E. **Infusion:** Infusion under the supervision of Dr. _____.

- As per User's Manual and training.

V. Post therapy Bremsstrahlung scan of upper abdomen and lung

A. Radiopharmaceutical:
- None. The technologist will be imaging the Bremsstrahlung radiation from the ^{90}Ytrrium.

B. Camera Setup:
- High energy
- Parallel-hole collimator
- Window open from 170 keV up

C. Camera:
- Special Procedures Section
- Argus or Single headed e-cam.

D. Computer
- 64 x 64

E. Procedure:
- Image liver for 5 minutes in the anterior, right lateral, and posterior positions
- Image lung for 5 minutes in the anterior and posterior view.
- Review all images with physician.

F. Analysis
- None

B. Dictation

i. Indication: Verification of distribution of 90 Ytrrium Sir-Spheres

ii. Technical procedure: Images were obtained shortly after the therapeutic injection of 90 Ytrrium Sir-Spheres.

iii. Description including:
- Qualitative assessment of activity in tumor.
- Any qualitative assessment of activity outside tumor in other parts of liver
- Any qualitative assessment of activity outside liver in bowel, stomach or lung.

iv. Interpretation:
- Post therapy pattern of radioactivity confirms pre-treatment pattern, and/or
- Discordant pattern of radioactivity with . . . . .

VI. Dosimetry
- Total body 0.02 rad/mCi
- Gonads 0.02 rad/mCi
- Liver 0.02 rad/mCi

VII. Follow up

- **Serologic tests and clinical examination not less frequently than every two months after treatment or until such time as a decision has been made regarding the outcome of treatment.**

- **Reminder: B. H-2 blockers:** Routinely receive H-2 blocking agents the day before implantation and for a period of one month post implementation.

- Since the radiation oncologist is seeing the patient, billing the patient, he or she will follow the patient for complications.

Side effects:

- **Fever**: Virtually all patients develop a post-implant fever that starts immediately after implantation of Sir-Spheres and can last from a few days to a week. The fever is usually nocturnal and does not necessarily indicate sepsis but may be related to the embolic effect of the microspheres and the acute toxic effects of the tumor.

- **Acute pancreatitis ----** causes immediate severe abdominal pain. Verify by SPECT imaging of the abdomen (Yttrium-90 Bremsstrahlung image) and test for serum amylase.

- **Radiation Pneumonitis** ---- causes excessive nonproductive cough. Verify by X-ray evidence of pneumonitis.

- **Acute Gastritis** ---- causes abdominal pain. Verify by standard methods to diagnosis gastric ulceration.

- **Radiation Hepatitis** ---- causes unexplained progressive deterioration of liver function. Verify by transcutaneous core biopsy of the liver

- **Abdominal Pain**
- **Nausea**
- **Immediate severe pain**
- **Acute Peptic Ulceration**
- **Radiation Penumonitis**
- **Radiation Hepatitis**
- **Radiation pancreatitis**
- **Radiation Gastritis**

- Liver function tests and tumor markers not less than every four months.

GREAT LAKES CANCER INSTITUTE McLAREN

Yttrium-90 / SIR-Microspheres Written Directive

Patient Name:_____Date of Birth_____ Date:_____

Radiopharmaceutical: ^{90}**Y SIR SPHERES**

Route of Administration: **IV injection**

Prescribed Dosage:_____**mCi**

_____ _____
Signature of Authorized User Date

Confirmation of Patient's Identification
(At least two items below must be checked.)

	Patient was asked his name
	Patient was asked his address
	Patient was asked his social security number
	Name was checked on ID bracelet
	Patient was asked his date of birth

_____ _____
Signature of person confirming patient ID Date

	Great Lakes Cancer Institute McLaren Campus		Policy Title: Preparation of the Angio/International Radiology Suite for Y-90 SIR-microsphere administration
Cancer Center Section: ___ Physics / Nurses		Effective Date: Revised:	Author's Signature:
Policy Author: Paul Mobit, Ph.D. Chief Medical Physicist			Medical Director 's Signature:

1 Policy Objective: To specify the angio/interventional radiology suite for SIR-microspshere administration.

Room preparation:

1. The room will be prepared by the nursing staff. Disposable pads will cover the floor around the bed and the path to the bathroom, and the toilet is covered with plastic wrap.

2. Several **shoe covers** must left near the door to the room. Everybody entering the room must wear shoe cover which must be disposed of and left for radiation monitoring.

3. A "Caution Radioactive Material" sign should be posted on room door during treatment

4. Patient must be provided with disposable non-skid slippers.

5. Radiation Safety Guidelines are followed according to radiation safety protocols.

6. Personnel, who are not radiation safety competent, must not enter the room.

7. Patient may be up and around in the room but may not leave the room.

8. No pregnant staff/visitors may enter the room.

9. Visitors are allowed, children of the patient are allowed in the safe zones.

10. Linen and trash remains in the room until monitored by the Cancer Center Medical Physicist.

11. It is recommended the patient sit on the toilet seat which is protected by a plastic wrap and double flush after each use.

12. The suite must be monitor by cancer center physicist before being use for another patient.

GREAT LAKES CANCER INSTITUTE McLAREN

Yttrium-90 Essay for SIR microsphere Treatment

Patient Name:_____

Isotope: Y-90 **Lot Number:**_____

Equipment used:_____ **Equipment Setting:**_____

Activity Ordered_____**mCi and**

Assayed Activity:_____**mCi,**

Diff < 5%

Comments:

Medical Physicist:_____**Date:**_____

GREAT LAKES CANCER INSTITUTE McLAREN

Dealing with Radiation Emergency-Yttrium-90 SIR microsphere

Spreading of radiation beyond the spill area can easily occur by the movement of personnel involved in the spill or cleanup effort. Prevent spread by confining movement of personnel until they have been monitored and found free of contamination. A minor radiation spill is one that the laboratory staff is capable of handling safely without the assistance of safety and emergency personnel. All other radiation spills are considered major. Call the Radiation Safety Officer on 342 2210 to ensure proper procedures are being taken to clean up the spill.

Always Remember to "S.W.I.M."

- Stop the spill.
- Warn other personnel.
- Isolate the area.
- Minimize the exposure to radiation and contamination.

Minor Radiation Spill

- Confine the spill immediately.
- Alert people in immediate area of spill and keep non-essential personnel out of the area.
- Notify Radiation Safety Officer (810-342-2210). If he/she is unavailable call the cancer center at 810-342-3800
- Wear protective equipment, including safety goggles, disposable gloves, shoe covers, and long-sleeve lab coat.
- Place absorbent paper towels over liquid spill. Place towels dampened with water over spills of solid materials.
- Using forceps, place towels in plastic bag. Dispose in radiation waste container.
- Monitor area, hands, and shoes for contamination with an appropriate survey meter or method. Repeat cleanup until contamination is no longer detected.

Major Radiation Spill

- Attend to injured or contaminated persons and remove them from exposure.
- Alert people in the laboratory to leave the immediate area.
- Have potentially contaminated personnel stay in one area until they have been monitored and shown to be free of contamination.
- Notify Radiation Safety Officer 342 2210.
- Close doors and prevent entrance into affected area.

GREAT LAKES CANCER INSTITUTE McLAREN

Interventional Radiology suite survey and wipe test results after Yttrium-90 / SIR-Microspheres infusion

Patient Name:_____**Date:**_____**Radio nuclide: Y-90**

Background reading:____**uR/hr GM Model**_____**Calibrated**_____on_____

Area to be wiped	Trigger level mR/hr	GM survey meter Reading (mR/hr)	Wipe Test results
Bed (1)	0.1		
Pillow (2)	0.1		
Bed table (3)	0.1		
Toilet (4)	2.0		
Bedside Floor (5)	0.1		
Bedding and trash			-

Comments:_____

_____

GM survey must read below the trigger level of 2.0mR/hr and all wipe tests must read below 200 200dmp/100cm2 for the room to be release for general use. Radiation sign must be left on room door until the survey and wipe tests have been completed and signed.

Description of items left for storage in Nuclear Medicine

1. _____ (_____mR/hr)
2. _____ (_____mR/hr)
3. _____ (_____mR/hr)
4. _____ (_____mR/hr)

Other Comments:_____

Medical Physicist:_____**Floor RN:**_____ **Date**_____**Time:**_____

GREAT LAKES CANCER INSTITUTE McLAREN

Room 1110 (South Tower) survey and wipe test after patient has been released following Yttrium-90 / SIR-Microspheres treatment

Patient Name:_____Date:_____Radio nuclide: Y-90

Background reading:____uR/hr GM Model_____Calibrated_____on_____

Exposure rate at 1 m from patient_____mR/hr.

Patient can be released if exposure rate is less than 2mR/hr

Area to be wiped	Trigger level mR/hr	GM survey meter Reading (mR/hr)	Wipe Test results
Bed (1)	0.1		
Pillow (2)	0.1		
Table (3)	0.1		
Bed table (4)	0.1		
Phone (5)	2.0		
TV remote Control (6)	2.0		
Toilet (7)	2.0		
Bath (8)	2.0		
Sink (9)	2.0		
Bedside Floor (10)	0.1		
Entrance Floor (11)	0.1		
Chair (12)	1.0		
Bedding and trash			-

Comments:_____

GM survey must read below the trigger level of 2.0mR/hr and all wipe tests must read below 200 200dmp/100cm2 for the room to be release for general use. Radiation sign must be left on room door until the survey and wipe tests have been completed and signed.

Description of items left for storage in Nuclear Medicine

1. _____ (_____mR/hr)
2. _____ (_____mR/hr)
3. _____ (_____mR/hr)

Other Comments:_____

Medical Physicist:_____Floor RN:_____ Date_____Time:_____

GREAT LAKES CANCER INSTITUTE McLAREN

HOME GUIDELINES FOR PATIENTS RECEIVING ^{90}Y SIR SPHERES

A therapeutic amount of radioactive ^{90}Y has been administered into your liver. The external radiation level around you is very low due to the large amount of attenuation (or shielding) of the beta radiation provided by your body; however, you will have a small amount of radiation that is detectable near your liver over the next few days. Because the amount of radioactive material dissipates in a relatively short period of time, the precautions outlined below need only be followed for the first 3 days following your treatment:

1. Maintain an appropriate distance, approximately arms length, from others except for brief periods. This precaution is most important when you are around children and/or pregnant women.

2. If you are incontinent, wear latex or rubber gloves when handling items that have come into contact with urine. You should wash undergarments, linens, and any other items separately from other non-contaminated items. Disposable undergarments (i.e., "Depends") may be placed in your regular trash receptacle.

3. If you have to see a physician or go to the Emergency Room within the 3 days following your treatment, notify them of your ^{90}Y treatment and that there is a small amount of radioactive material in your liver. Treatment should not be delayed based on the small amount of radioactivity in your liver. If there are any questions, medical personnel should call or page:

    - Dr. H E Gayar: 810-342-3800_____
    - Dr. J.Nettleton 810-342-3800_____

4. You may wish to carry these instructions with you (e.g., fold and place in your wallet or purse) for the first 3 days following your treatment. After that time, these instructions may be discarded.

Once three days post-treatment have passed, no radiation safety precautions are necessary.

FOR ADDITIONAL INFORMATION OR EMERGENCY ASSISTANCE, CONTACT:

Nuclear Medicine-McLaren – (810) 342-2210
Interventional Radiology-McLaren 810-342-2209
Radiation Safety Officer: Dr. Christopher J Colin (beeper 389-0834) or Nuclear Medicine: 22210
Medical Physicists: Paul Mobit, Art Ewald, V K Sharma: 810-342-3800

GREAT LAKES CANCER INSTITUTE McLAREN

Yttrium-90 / SIR-Microspheres Patient/Significant Other Education

Patient's Name_____ **Date of education**_____**by**_____

Instruction	Reviewed with patient/ significant other	Agreed
1. Sleep in a separate bed (at least 6 feet from anyone else). The sleeping partner spends at least 35% of waking hours (6 hours) from the patient during the time precautions are in affect.		
2. Do not take a long trip (4 hours or more) sitting near others (e.g. car, train, airplane, bus)		
3. Stay at least 6 feet from children and pregnant women. All efforts should be maintained to completely avoid contact with children younger than 18 and pregnant women.		
4. Minimize time spent near others and delay return to work.		
5. Keep at least 6 feet from others whenever possible.		
6. Discontinue breastfeeding permanently; breastfeeding should not be reinitiated.		
7. When taking shorter trips, sit as from as possible from others.		
8. Menstruating women should use tampons that can be flushed down the toilet. If this option is not possible, dispose of tampons in a separate plastic trash bag and store in your home for ten days then you may dispose of that trash in the usual manner.		
9. Do not let others use your bathroom.		
10. Sit while urinating and flush the toilet three times with the lid down.		
11. Wash hands often, including after each toilet use, and shower daily.		
12. Drink plenty of liquids.		
13. Use separate towels, washcloths and toothbrush from the rest of the household members.		
14. Use separate dishes and utensils for 1 week and wash separately.		
15. Hold clothing and linen (sheets and towels) for 1 week before laundering and launder separately from the rest of the household's laundry.		
16. Avoid using disposable items (i.e. paper and plastic utensils and dinnerware) that cannot be flushed down the toilet.		
17. Inform your physician or other healthcare provider of your treatment.		

Please be advised of the potential risk of toxic effects on the male and female gonads (testicles,-sperm and ovaries-eggs) following the SIR-sphere therapeutic regimen. You are advised that these effects are immediate and last during treatment and for 12 months following the administration of the treatment. In the event a pregnancy occurs during this period of time, you should be apprised of the potential hazard to the fetus.

I understand the above mentioned safety instructions and guidelines explained to me and I am willing and able to follow them in order to minimize exposure to others:

Patient/Guardian_____ Date_____

Nurse_____ Date_____

Authorized user or
The radiation safety officer or his/her designee_____ Date_____

The original of this teaching tool goes in the chart; a copy goes to the patient, Medical Oncologist and Interventional Radiologist's chart.

GREAT LAKES CANCER INSTITUTE McLAREN

^{90}Y Dose Administration Sheet

SIR-Spheres

Patient's Name:_____ **Date:**_____

Package Receipt: **Bkg**: _____ **Outer Pkg Wipe:**_____**Pig Wipe:** _____

Bucket Wipe: _____ **Vial Wipe:** _____

Calibrated @ _____**hours at** _____**mCi** **($A_t = A_o e^{(0.01083\ hr^{-1} / \_\_\_ hrs)}$)**

1. **Sir-Sphere Only (1 GBq = 27 mCi)**

   A. Shipping Vial Initial Measured Activity(cal setting #50 x 10) (mCi):_____ Time: _____

   B. Volume of Activity (ml):_____ C. Concentration (A ÷B) (mCi/ml):_____

   D. Dose to be administered per written directive (mCi):_____

   F. Volume to Draw Up (D ÷ C) (ml):_____

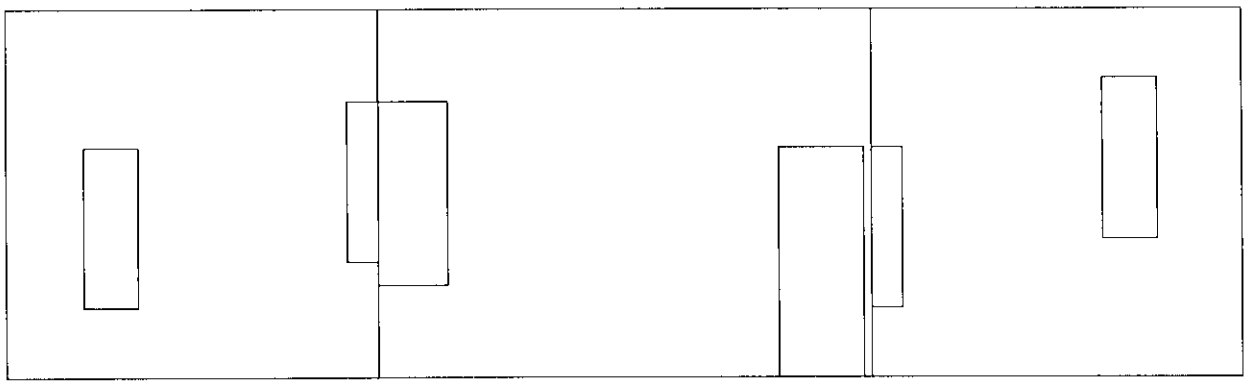
   E. Target Vial Reading (A-D) (mCi) _____ 20% Vial range _____ to _____

   G. Shipping Vial Residual Activity (mCi):_____ Time: _____

   H. Syringe Activity (A – G)(mCi):_____ 20% Dose range _____ to _____

   I. Syringe Dose within 20% of Written Directive Dose? ☐ Yes ☐ No (If "No", redraw the dose)

II. Sir-Sphere Survey of Individuals and Area



☐ No contamination found in area or Readings (mR/hr or cpm – see room layout above)

☐ No contamination found on individuals
or:

Name	Contamination Location	Measurement (cpm)

III. Sir-Sphere Measurements

GM Readings Instrument/Model/Serial:_____

A. Initial Dose Vial Measurement (taken at 3 inches) @ _____(Time)

90° (mR/h)	180° (mR/h)	270° (mR/h)	360° (mR/h)	**Avg. Waste (mR/h)**

B. Waste Measurements (taken at 3 inches) @ _____(Time)

90° (mR/h)	180° (mR/h)	270° (mR/h)	360° (mR/h)	**Avg. Waste (mR/h)**

C. Average Initial Measurement Decayed: (Avg. Initial)$e^{-(0.693/64h)(t)}$ = _____ mR/h

D. Percent Dose Delivered: 1 - (Avg. Waste/Avg. Initial Measurement Decayed) X 100 _____%

E. Decayed Dose: (Original Activity)$e^{-(0.693/64h)(t)}$ = _____ mCi

F. Dose Administered: (Decayed Dose X % Dose Delivered) _____mCi

G. Does dose administered differ from the prescribed dose by more than 20% : ☐ Yes* ☐ No

If "Yes", the reason:_____

Comments:_____

Name: _____ Title: _____

Patient Survey (mR/hr) @ 1 foot:_____ @ 1 M:_____

Instrument Model/Serial:_____

Name: _____ Title: _____

IR Room #:_____

☐ Survey of individuals and room measurements were background or

Survey (mR/hr)

_____

_____

_____

Surveyed By:_____

Instrument Mod/Ser:_____

Patient Holding Room:_____

☐ Survey of room was background or

Survey (mR/hr)

_____

_____

_____

Surveyed By:_____

Instrument Mod/Ser:_____

	Great Lakes Cancer Institute McLaren Campus	Policy Title: SIR-Sphere Procedure manual for clinical staff
Cancer Center Section: ___ Physics / Nurses	Effective Date: Revised:	Author's Signature:
Policy Author: Paul Mobit, Ph.D. Chief Medical Physicist		Medical Director 's Signature:

1 Policy Objective: To specify the clinical and support staff's responsibility for the care of an adult patient receiving SIR-Sphere Brachytherapy for treatment of liver cancer.

2. General Information: SIR-Sphere™ is a system designed to deliver internal radiation therapy to patients with malignant non resectable liver tumors. It maximizes the benefits of internal radiotherapy while minimizing disadvantages. The SIR-Sphere enables the radiation oncologist to provide direct internal radiation to the tumor bed. The duration of treatment is about 11 days, depending on the desired radiation dose. The patient may stay in the hospital for a few days. The procedure may also be done as an out-patient procedure

3. Potential Advantages:

The source of radiation is placed in the area most likely to contain remaining cancer cells.

4. Room preparation:

4.1 All patient undergoing SIR-Sphere treatment are to be admitted into room 1110 (11th floor, South Tower)

4.2 The room will be prepared by the 11th floor nursing staff. Disposable pads will cover the floor around the bed and the path to the bathroom, and the toilet is covered with plastic wrap.

4.3 Several **shoe covers** must left near the door to the room. Everybody entering the room must wear shoe cover which must be disposed of and left for radiation monitoring.

4.4 A "Caution Radioactive Material" sign should be posted on room door during treatment

4.5 A brief description of the SIR-Sphere procedure and emergency contact numbers for the RSO, Medical Physicists and Radiation Oncologist should also be posted on the patient room door.

4.6 Medical Physicist from the Cancer Center must draw lines on the floor beyond which visitors can go beyond in order to limit their radiation exposure.

5.0 Nursing Guidlines

5.1 Assess surgical incision site.

5.2 Assess pain and administer pain medication as needed and reassess for relief from pain at regular intervals.

5.3 Incorporate patient and employee safety throughout the procedure

5.4 Provide patient with disposable non-skid slippers.

5.5 Offer assistance with ADL's.

5.6 Offer psychosocial support to minimize social isolation

5.7 Family and friends are allowed to visit.

5.8 Radiation Safety Guidelines are followed according to radiation safety protocols.

5.9 Direct patient care is to be provided by nursing staff with annual competency in radiation safety. Those providing care must wear radiation dosimetry badges.

5.10 Personnel, who are not radiation safety competent, must not enter the room.

5.11 Patient may be up and around in the room but may not leave the room.

5.12 Use of disposable food trays and equipment such as BP cuff is **not** necessary.

Radiation Safety Guidelines:

6.1 No pregnant staff/visitors may enter the room.

6.2 Visitors are allowed, children of the patient are allowed in the safe zones.

6.3 Shoe covers should be worn by all entering the room if they will be stepping on the covered area of the floor.

6.4 Family and visitors must not use the patient's bathroom.

6.5 No sharing of food is allowed.

6.6 No lead shields are needed or used.

6.7 The safe zone is generally defined as maintaining a distance of 3 feet or greater from the catheter site despite the location of the patient within the room. The highest potential for exposure is on the same side as the catheter and within 3-6 feet of the skull. Beyond that area, the room is considered a safe zone.

6.8 Approach the patient from the opposite side of the catheter site.

6.9 Food trays should be delivered to the outside of the room.

6.10 Linen and trash remains in the room until monitored by the Cancer Center Medical Physicist.

6.11 It is recommended the patient sit on the toilet seat which is protected by a plastic wrap and double flush after each use.

McLaren Regional Medical Center

Department of Radiation Oncology

SIR-Sphere Therapy:

General Instructions (must be posted on the on room's door)

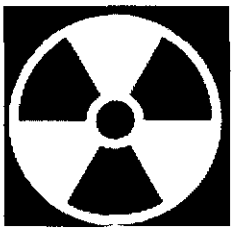
Patient Name's initial:_____Date_____

The patient named above is undergoing Radiation Therapy with Y-90 radiosolution. Treatment started at _____on the _____ and will end on _____ at _____. For the duration of the treatment, the following should be observed:

- **All staff caring for the patient must wear a radiation badge**
- **Nursing care should be administered normally but no trash or bedding or any other items should be taken out of the room until it is monitored by a Physicist**
- **Visits should be limited to 8 hours per day and visitors must not go beyond the marks on the floor**
- **No person younger than 18 years old is allowed in the room**
- **No Pregnant staff or family member should enter the room**
- **Any person entering the room should wear shoe covers and take them out as soon as they leave the room.**
- **The Patient and the room would be monitored daily by a Physicist from the Great Lakes Cancer Institute-McLaren.**
- **The room cannot be re-occupied until survey by the Medical Physicist**

In case of an emergency contact:

Dr. Nettleton (beeper 389-1528) or Dr. Gayar (beeper 389-1063): Radiation Oncologists
RSO: Dr. Blake Berman (beeper 389-1444) or Nuclear Medicine: 22210
Medical Physicists: (Dr. Paul Mobit 389-1867), Art Ewald 389-1320, VK Sharma 342-3800



U.S. NUCLEAR REGULATORY COMMISSION

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