ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Providence Hospital **License No.:** 50-17838-01

Docket No.: 030-13426 **Mail Control No.:** 471091

Type of Action: Amend **Date of Requested Action:** 08-17-06

Reviewer Assigned: **ARM reviewer(s):** Torres

Response	Deficiencies Noted During Acceptance Review
	[ ] Open ended possession limits. Limit possession. Submit inventory. [ ] Submit copies of most recent leak test results. [ ] Add - delete IC license condition. Add IC paragraph in cover letter. [ ] Split license from cover letter. Add SUNSI marking to license. [ ] Ask the licensee if they have any type-amount of EPAct Material.

Reviewer's Initials: _____ **Date:** _____

☐Yes ☐No Unrestricted release Group 2 or >: Transfer memo to FCDB within 10 days.

☐Yes ☐No Decommissioning notification should be completed within 30 days.

☐Yes ☐No Termination request < 90 days from date of expiration

☑Yes ☐No Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)

☐Yes ☐No TAR needed to complete action.

Branch Chief's and/or Sr. HP's Initials: RTC **Date:** 8/29/06

SUNSI Screening according to RIS 2005-31

☐Yes ☑No **Non-Publicly Available, Sensitive** if any item below is checked

General guidance:

_____RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule
_____Exact location of RAM (whether = or > than Category 3 or not)
_____Design of structure and/or equipment (site specific)
_____Information on nearby facilities
_____Detailed design drawings and/or performance information
_____Emergency planning and/or fire protection systems

Specific guidance for medical, industrial and academic (above Category 3):

_____RAM quantities and inventory
_____Manufacturer's name and model number of sealed sources & devices
_____Site drawings with exact location of RAM, description of facility
_____RAM security program information (locks, alarms, etc.)
_____Emergency Plan specifics (routes to/from RAM, response to security events)
_____Vulnerability/security assessment/accident-safety analysis/risk assess
_____Mailing lists related to security response

Branch Chief's and/or Sr. HP's Initials: RTC **Date:** 8/29/06

Pre-Licensing Screening

Applicant Information: **Control No.** 471091

Name: Providence Hospital	Type of Request: Amend Program Code(s):
Location: AK	License No.: 50-17838-01 Docket No.: 030-13426

STEP 1–Radioactive Materials and Quantities Requested:

Instructions for Step 1: Complete Step 1 for all applications. If all your responses in Step 1 are "No" then do not complete Step 2 (Screening Criteria). Sign and date the completed step-sheet and add it as the sensitive and non-publicly available OAR in ADAMS. If a "yes" response is indicated for any item in Step 1, also complete Step 2. If the type of use is subject to a Security Order or the requirements for increased controls, complete Step 3 (Item A or Item B) without delay.		Yes or No
A.	The request is from a new applicant.	NO
B.	NUREG-1556, Volume 20, Section 4.9 indicates a licensing site visit is needed for the requested type of use, e.g., (1) Type A broad scope license, (2) panoramic irradiator containing > 10000 curies, (3) manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material, (4) radioactive waste brokers, (5) radioactive waste incinerators, (6) commercial nuclear laundries, and (7) any other application that in the judgement of the reviewer and cognizant supervisor involves complex technical issues, complex safety questions, or unprecedented issues that warrant a site visit.	NO
C.	The applicant requested certain radionuclides and quantities that equal or exceed the Risk Significant Quantity (TBq) values in the table, below, that have been "highlighted" by the reviewer	NO

Table of Risk Significant Quantities

(Category 2 Quantities, IAEA Safety Guide No. RS-G-1.9, Categorization of Radioactive Sources, August 2005)

Radionuclide	Risk Significant Quantity (TBq[1])	Risk Significant Quantity (Ci[1])	Radionuclide	Risk Significant Quantity (TBq[1])	Risk Significant Quantity (Ci[1])
Am-241	0.6	16	Pm-147	400	11,000
Am-241/Be	0.6	16	Pu-238	0.6	16
Cf-252	0.2	5.4	Pu-239/Be	0.6	16
Cm-244	0.5	14	Ra-226[2]	0.4	11
Co-60	0.3	8.1	Se-75	2	54
Cs-137	1	27	Sr-90 (Y-90)	10	270
Gd-153	10	270	Tm-170	200	5,400
Ir-192	0.8	22	Yb-169	3	81

[1] The primary values are TBq. The curie (Ci) values are for informational purposes only.

[2] The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC is in the process of amending its regulations for discrete sources of Ra-226.

Calculations of the Total Activity or the Unity Rule are attached to document whether or not the screening criteria in Step 2 were also completed to evaluate the application. **NOTE–If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s).**	Yes , No, or Not Applicable (NA)
Total Activity–multiple activities are requested for a single radionuclide and the sum of the activities equals or exceeds the quantity of concern for the radionuclide	—
Unity Rule--multiple radionuclides are requested and the sum of the ratios equals or exceeds unity, e.g.,[(total activity for radionuclide A) ÷ (risk significant quantity for radionuclide A)] + [(total activity for radionuclide B) ÷ (risk significant quantity for radionuclide B)] ≥ 1.0.	—

Signature and Date for Step 1:

RJTC 8/29/06

License Reviewer and Date

Providence | Alaska Medical Center

3200 Providence Drive
P.O. Box 196604
Anchorage, Alaska
99519-6604

Tel 907.562.2211

August 17, 2006

U. S. Nuclear Regulatory Commission
Attn: Nuclear Materials Licensing Branch
Region IV
611 Ryan Plaza, Suite 400
Arlington, TX 76011

RE: Amendment to Radioactive Material License 50-17838-01 030-13426

Dear Sir or Madam,

Please accept this letter as a request to add the SirTex Medical Inc's Sir-Spheres Yttrium-90 Microspheres brachytherapy device to our radioactive material license.

Attached please find the policies and procedures for this technique approved by the Radiation Safety Committee.

We would appreciate if **priority** could be given to this request as several very sick patients are waiting for this treatment. If you need additional information or have questions, please contact Ravi Rao or Yongli Ning at 907-261-3186.

Sincerely,

Al Parrish
Regional Vice President
& Chief Executive
Providence Health System Alaska Region

Attachments

PROVIDENCE ALASKA MEDICAL CENTER – DEPARTMENTAL POLICY

Radiation Oncology

Subject: Yttrium (Y-90) SIR-Spheres Procedures	**Number: PAMC 914.069-B** **Page: 1 of 13**	
Date Signed: **Approved by:** **Effective Date:** **Manager:** Judy Dieckhaus Ph.D **Radiation Safety Officer/ Medical Director:** MD **Radiation Safety Committee Chair:**	**Original Effective Date: 07/20/06** **Revision Date(s): 08/17/06** **Review Date:** ____ **Initialed by:** ____	**Review Date:** ____ **Initialed by:** ____
Policy Author: Ravindra Rao	**Review Date:** ____ **Initialed by:** ____	**Review Date:** ____ **Initialed by:** ____

I. PURPOSE/SCOPE:

To establish guidelines for pre-procedure, intra-procedure, post- procedure care and radiation safety precautions of patients undergoing Selective Internal Radiation Therapy (SIRT).

To provide radiation procedures for authorized persons to perform SIR-Spheres (Yttrium –90) administration.

II. POLICY:

In keeping with the philosophy and mission of the Providence Health system under the direction of the Radiation Safety Officer and the Radiation Safety Committee, all persons authorized to use radioactive materials will follow the guidelines established.

III. INDICATIONS FOR USE:

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).

IV. DEFINITIONS:

Radiation Safety Officer – Evidenced that the facility is licensed by the appropriate regulatory body demonstrated competence.

Medical Physicist – Documentation for all aspects handling SIR-Spheres.

Physician – Physicians to complete practical training. Physicians to identify potentially suitable patients to participate in a supervised implant.

V. PROCEDURE:

Supportive Data:

SIR-Spheres consists of micro spheres between 20-40~ (microns) in diameter. The microspheres contain yttrium-90. The upper size limit of the microspheres allows delivery to the tumors via the hepatic artery. The lower size limit prevents the microspheres passing from the arterial circulation through the tumor vasculature and into the venous circulation. The microspheres remain trapped within the vasculature of the tumors and deliver the radiation dose to the surrounding tissue. The microspheres do not degrade and remain permanently implanted. They are not retrievable unless the tumor is resected at a later stage. The activity of the microspheres, rather than their weight or volume, determines the number of microspheres delivered to any individual patient. The total radiation required by a patient is dependent on the extent of tumor tissue and is at the discretion of the Interventional Radiologist.

Patient Selection Criteria:

1. Resectability -determined by angioportal CT or MRI scan
2. Extent of disease in the liver -Tumor markers (CEA or aFP), LFTs
3. Presence and extent of extra-hepatic disease -CT scan of chest, abdomen, pelvis. Bone scan, CXR (most common sites are abdominal cavity, abdomen, clavicallymph nodes, lungs, bones)
4. Hepatic vascular anatomy -hepatic angiogram
5. Arteriovenous shunting -MAA nuclear medicine SPECT scan
6. Liver Function -LFTs, CT scan
7. Renal function -BUN, creatinine
8. General ability of the patient to tolerate implanted radiation

Relative and Absolute Contraindications: (* = Absolute)

SIR-Spheres should not be implanted into patients:

1. Who have had previous external beam radiation therapy to the liver.
2. Who are currently on or have been treated with Capecitabine within the previous two months.

***3.** Who have ascites or are in clinical liver failure. If pre-assessment demonstrates markedly abnormal synthetic and excretory liver function test.

4. Portal vein thrombosis precludes all forms of embolic therapy.

***5.** Degree of lung shunting -greater than 20% unacceptable. High dose of radiation will be shunted from the liver to the lung. If shunting could not be performed due to clinical or anatomical reasons then the procedure will be done only in case of patients that do not have a history of underlying liver disease or portal hypertension.

***6.** SIR-Spheres is contraindicated in patients with abnormal vascular anatomy that would result in significant reflux of hepatic arterial blood into stomach, bowel, pancreas or other abdominal organs.

7. Extra-hepatic disease: Its place in the management of patients with disseminated or extra-hepatic disease is questionable in the absence of an ancillary treatment regime for the distant disease.

***8.** Women of childbearing age should not be treated until absence of pregnancy is confirmed.

Pre-procedure:

Patient identified, armband placed, changed into gown.

1. Clear liquids – 4 hours prior to procedure
2. IV Hydration
3. Antiemetic
4. Blood work reviewed: CBC, LFTs, BUN, creatinine, PT, PTT, INR
5. History and Physical completed by radiologist
6. Informed consent obtained by radiologist
7. H2Blockers given if ordered
8. A full assessment of the patient will be done by the radiology nurse and documented on the Radiology Nursing Assessment Record. These include but are not limited to allergies, past surgeries, past medical history, pain assessment, current medications, and current therapies.
9. On the day of therapy, a urine test will be done and results obtained to confirm pregnancy on applicable patients.
10. Shunt study

Intra-procedure:

1. Patient placed supine on table. Pulses assessed in lower extremities.
2. Patient placed on monitor. BP, pulse, pulse ox, respirations, EKG. Nasal oxygen at 2L/minute, unless otherwise ordered, is initiated.
3. Groin site shaved and prepped with betadine. Sterile drape to site.
4. Upon receipt of orders from the radiologist, conscious sedation is started.
5. The dedicated nurse will administer drugs given during the procedure. He/She will conduct an ongoing assessment of the patient as per standard of practice (conscious sedation). Vital signs and level of consciousness will be documented every 5 minutes.
6. Patient's level of pain/discomfort will be closely monitored and documented. The radiologist will be kept informed regarding the patient's status.
7. Upon completion of procedure the catheter will be removed and continuous pressure will be applied to the site. During this period the nurse will continue to monitor patient and will reassess pulses.
8. Room clearance is generally the responsibility of the radiation safety officer or medical physicist. All staff should be checked, including soles of shoes, hands and body before leaving the room.
9. Patient may be removed from the room to recovery area upon confirmation with radiation safety officer.

Post-procedure:

Once the patient has received the implant, they effectively become the radiation source. The minimal penetration distance of the beta emissions in tissue means that patients pose a very small radiation risk to staff and other contacts. However some general precaution should be observed.

1. With regard to body fluids and secretions:
    a. Dressings removed should be placed into a plastic bag, labeled as a radiation hazard and sent to the waste storage area in Cancer Therapy or Nuclear Medicine for storage and subsequent disposal.
    b. When changing catheter bags or drainage bags, gloves are to be worn.
    c. Urine may be discarded in the toilet using double flushing.
    d. Upon discharge the patient's sheets are monitored for radiation levels and disposed of per standard by radiation safety staff.

2. Visitors or children under **18** years of age shall not visit the patient while recovering at PAMC.
3. Visiting times shall be determined by the radiation safety staff.

4. Nursing care should be done from the left side of the patient to avoid the injection site.

Recovery:

1. Routine observations of pulse, blood pressure and respirations every 15 minutes until stable.
2. Groin incision should be observed for hematoma formation and bleeding when vital signs are checked.
3. Pulses assessed in lower extremity when vital signs checked.
4. Patient should be kept supine; the radiologist will determine the duration.
5. May receive normal nutrition and fluids as tolerated immediately after the procedure.
6. IV hydration will continue until patient is tolerating oral fluids.
7. Patient will be assessed for pain, nausea, vomiting, and fever. If treatment deemed necessary, follow physician's orders.
8. Discharge criteria include:
   a. Pain controlled with oral analgesic,
   b. Stable vital signs,
   c. Groin site stable,
   d. No bleeding noted,
   e. Tolerating oral nutrition.
9. The Interventional Radiologist or his approved designee will determine when patient is capable of discharge and will communicate this with the nurse.
10. Post Arteriogram Instructions and SIRT Instructions will be completed by the Interventional Radiologist or his approved designee and radiation oncologist respectively and signed. The orders will be reviewed with the patient and person accompanying patient, and signed. Any prescriptions will be given at this time.
11. Patient will be discharged in a wheelchair per current discharge / transport procedures.

Addendum:

Virtually all patients develop a post-operative fever that starts immediately after implantation of SIR-Spheres and can last from a few days to a week. Many patients will experience nausea that may last up to several weeks and this may occasionally be severe enough to require antiemetic mediation that should continue until the symptoms subside. Many patients experience abdominal pain immediately after administration of SIR-Spheres and may need pain relief with narcotic analgesia.

Serious complications may include acute pancreatitis, acute peptic ulceration. These will present immediately.
Delayed serious events can include radiation pneumonitis and radiation hepatitis.

Radiation Safety Procedure During Y-90 Microsphere Treatment

Applicability:
This procedure describes the activities to be performed starting from patient admission until release to ensure that an appropriate level of radiation safety is followed during treatments involving Yttrium-9O (Y -9O) microspheres and in compliance with the regulations. Also, that radioactive sources are handled in a safe manner in order to keep radiation doses received by radiation workers, visitors, and the public as low as reasonably achievable (ALARA).

SCOPE: This safety procedure applies to all Y -90 microsphere treatments.

PROCEDURE:

1. Training:

(a) Authorized users must meet the training and experience requirements of 10 CFR 35.490 as well as the specific vendor training in the use of the microspheres and the microsphere delivery system before involved in this procedure. Subsequent authorized users can be in-serviced by the current authorized user having undergone the specific vendor training.

(b) The Nuclear Medicine Technologist must receive the Vendor's training for drawing the appropriate dose per the written directive without causing any contamination.

(c) All personnel providing care for a patient receiving Y -90 microspheres implant therapy shall receive Radiation Safety Training, with refresher training provided at annual intervals.

(d) The Radiation Safety Training provided shall include:

- The size and appearance of the Y -90 microspheres brachytherapy sources.
- Safe handling, shielding instructions, and labeling of the radioactive materials.
- Procedures for patient access control.
- Procedures for visitor access control.

- Patient Release Criteria (10 CFR 35.75).
- Written Directive and Quality Management program
- Procedures for notification of the Radiation Safety Officer and Authorized User if the patient dies or encounters a medical emergency.
- The training and experience requirements for an Authorized User.

(e) Radiation Safety Officer shall maintain a record of training of these individuals, a description of the training (an outline), the date of training, and the name of the individual providing the training for three years following the date of training.

(f) Before releasing from inpatient care, the patient shall be provided with written radiation safety instructions that will help to minimize the radiation dose to other family members and the public as per the ALARA program and the requirements of 10 CFR Part 35.

2. Description of Duties:

(a) Interventional Radiologist:

- Prepares patient for dose delivery.
- Contacts other team members when patient is ready.
- Assembles microsphere delivery system.
- Ensures delivery system is correctly assembled.
- Assists in microsphere delivery.
- Delivers dose.
- Assists in disposal of delivery system.
- Sees patient in consultation and provides the patient with safety precautions

(b) Radiation Oncologist:

- Sees patient in consultation and provides the patient with safety precautions
- Ensures that a written directive is completed and signed.
- Ensures that the dose to be delivered is in accordance with that prescribed in the written directive.

(c) Medical Physicist

- If the prescription calls for a specific dose the Medical Physicist calculates the required activity based on the intended dose for specific patient.
- The Medical Physicist or his approved designee orders correct radioactive material dose from the manufacturer. The shipping address should be:

PAMC
Nuclear Medicine Department
3200 Providence Drive
Anchorage AK 99508

(d) Nuclear Medicine Technologist

- The dose will be drawn per the procedure listed below by a trained Nuclear Medicine Technologist in the Nuclear Medicine hot lab. Appropriate shielding and remote handling tools will be utilized. The prescribed dose will be dispensed into the "V" vial supplied, be in appropriate shielding and labeled with date, nuclide, patient name, and microspheres "Sir-spheres". This procedure will be overseen by the medical physicist for the first 10 patients to ensure correctness of the dose and to ensure the technologists comply with the written policy and procedure.
- All activity measurements should be conducted using fully dispersed or re-suspend SIR-Spheres to avoid inconsistencies associated with self-shielding due to geometry changes.
- All manipulations and handling of SIR-Spheres must be undertaken by a Physician or Physicist / trained staff.
- All handling of SIR-Spheres is undertaken using aseptic technique, standard radiation protection methods and equipment.
- The Interventional Radiologist in charge of the patient must determine the activity required by the patient.
- The activity of SIR-Spheres is calculated for the time of delivery into the patient using the decay table supplied with the device.
- The nuclear medicine technician or pharmacist should verify the activity of the shipped dose using the institution's radiation measuring equipment.
- Using aseptic technique, the required amount of SIR-Spheres is removed from the shipping container and delivered into the v-vial.
- The yttrium-90 activity in the v-vial should be confirmed and corrected if necessary.
- If required additional water for injection should be added to bring the volume in the v-vial to a minimum of 3ml.
- The v-vial is placed into the dedicated acrylic shield, the v-vial holder, designed for this purpose
- The v-vial holder containing the v-vial is transported to the patient treatment room.
- The NM Technologist assays the dose prior to delivery to the patient.

(e) Safety Assistant

- Before moving the brachytherapy sources from the source storage area, performs a survey to ensure that the sources are adequately shielded.

Transports sources to/from the patient's room with appropriate shielding for beta emitters in place (the manufacturer's shipping container) to keep the exposure to personnel ALARA. The dose will be transported to the Interventional suite in a plexiglass box on a cart. The "V" vial placed in the plexiglass delivery system setup will be located in an area convenient to the physician for dispensing the treatment on a small covered table. The sources must be under constant surveillance and control of either the NM Technologist or Radiation Safety Officer or designee all the time until delivered.

- The dose will be measured with an ion chamber on at least two sides of the plexiglass box, prior to being delivered, to determine the exposure for dose calculations.
- Monitors delivery system during dose delivery.
- Determines when maximum dose has been delivered.
- Performs final assay of remaining dose to determine amount delivered to patient.
- Keeps a log of the dose Received, Used, and Disposed.
- Receives package from the receiving dock when paged and processes. Checks for contamination and survey the package within three hours after it is received to make sure that the package received is in accordance with the regulatory requirements, verify that the dose received matches with the dose ordered and then deliver to Nuclear Medicine for storage. Sources shall be stored in the manufacturer's shipping container in a locked room (hot lab).
- Prepares the patient room to control contamination. The IR suite will be draped with disposable coverings to aid in clean up of possible contamination.
- The patient shall be briefed on radiation safety procedures for confinement to bed, visitor control, and other items, as appropriate by the radiation safety personnel before treatment.
- Ensures all team members attending to brachytherapy implant patients wear whole body radiation dosimeters when in the patient's room. All personnel who handle the implant sources must wear a ring dosimeter in addition to a whole body dosimeter. Nursing personnel will be given pocket dosimeters to monitor their exposure.
- Visitors shall maintain a distance of at least one meter from the patient and not be issued a dosimeter.
- Ensures proper shielding and material handling practices are followed.
- Ensures proper radiation monitoring equipment is available.
- Ensures disposal container is available.
- Performs surveys of hands, feet, and clothing of all individuals leaving the room.

In the event patients have to be admitted the following procedures shall be followed:

- The "Caution Radioactive Material" form for Permanent Implant shall be completed and attached to the patient's chart.
- The door to the patient's room shall be posted with "Caution, Radioactive Material".
- Instructions for nurses shall be posted on the patient's door.
- Signs reminding housekeeping not to enter the room and not to remove trash or linen shall be posted.
- Pregnant nursing personnel shall not be assigned to the care of a radioactive patient.
- A special duty nurse should not be assigned to care for a radioactive patient without the approval of the Radiation Safety Officer.
- Pregnant women and minors shall not be allowed to visit patients.
- Performs exposure rate (mrem/hr) measurement following the brachytherapy procedure at bedside, at one meter from bedside, in the visitors' safe area, at the doorway, and in the surrounding areas. The exposure rates in adjacent uncontrolled areas must conform to the federal regulations. Radiation safety staff shall keep a record of this and any other necessary information for at least three years.
- Assists in identification and collection of radioactive waste.
- Releases the patient per NRC regulations.
- Surveys room for contamination following patient release and completely decontaminate the contaminated areas room before releasing the room to be used by other non-radiation patients.
- Collects and labels all radioactive waste and recovers packaging from source transport.
- Returns waste to designated waste disposal area or storage area for decay in storage.

3. Radiation Safety During Dose Delivery:

- All individuals entering the treatment room will be wearing protective equipment as needed, including scrubs, or disposable gown, hair net, face mask, gloves, shoe covers, and lead aprons during fluoroscopy.
- All personnel participating in dose delivery shall wear personnel dosimeters.
- No smoking, eating, or drinking shall be permitted in radioactive material handling areas.

4. Radiation Monitoring Instruments

- An ion chamber shall be used to perform monitoring during dose delivery and for patient release.
- A Geiger Mueller detector shall be used for monitoring of contamination on equipment and personnel. Care must be taken to compensate for interference from background radiation near the patient following dose delivery.
- Pocket dosimeter.

5. Emergency Procedures

In case of a patient's death or medical emergency following the dose delivery, the Radiation Safety Officer (RSO), referring physician and the Authorized User shall be notified immediately. In case of emergency surgery, all radiation safety precautions will be followed, including wearing of film and ring badges and steps will be taken to prevent accidental squirting of patient body fluid onto the eyes, ears, nose and mouth of the surgical staff and uncovered portions of their bodies.

In case of emergency contact:

Radiologist:

Phone: _____ Pager: _____

Authorized User:

Phone: _____ Pager: _____

RSO:

Phone: _____ Pager: _____

6. Spill Procedures

(a) Minor Spills

- Notify all individuals in the area that a spill has occurred.
- Prevent the spread of contamination by covering the spill with an absorbent material and controlling the movement of potentially contaminated individuals.
- Clean up the spill using protective clothing and absorbent material.
- Survey the area and affected individuals with an appropriate contamination-monitoring instrument.
- Report the spill to the RSO immediately.

(b) Major Spills

- Evacuate the area. Ensure all individuals leaving the area are monitored for contamination.
- Prevent the spread of contamination by covering the spill with an absorbent material and controlling the movement of potentially contaminated individuals.
- Shield the radiation source, if possible without significantly spreading the contamination of increasing individual doses.

- Secure the room to prevent entry.
- Perform personnel decontamination as necessary.
- All contaminated items will be bagged and stored for decay.
- Notify the RSO immediately.

7. Records and Reports

Records:

Radiation safety records associated with delivery of Y –90 microsphere therapy may include:

- Records of material ordering and receiving, delivery and disposal
- Personnel training
- Dose assay and delivery
- Area and personnel surveys, and spill recovery.
- Patient instructions

Radiation safety survey records, policies and procedures for Y –90 microsphere treatment shall be maintained by the Radiation Safety Officer.

Reports:

Certain reports may be required if a Y-90 microsphere delivery results in a spill, or medical event.

All required reports shall be prepared and submitted in accordance with the regulations.

8. Immediate Post-Implant Care:

The patient may be moved from the treatment room into a recovery room. This is particularly the case for the transfemoral implant, as angiography suites are heavily utilized. If the implant is via an implanted catheter, and takes place in a routine room, the patient can remain in the room.

If any dressings, such as those over the port or the transfemoral wound need attendance, staff should wear gloves as a matter of routine. It may be advantageous to wear double gloves. Any dressings removed should be placed into a plastic bag, labeled as a radiation hazard and sent to the radiation facility for storage and subsequent disposal.

Once procedure is complete the following is true for three days:

- Clean up spilled urine
- Wash hands thoroughly after using toilet
- No pregnant visitors
- Sleep alone
- Keep a distance of 3 feet from others

- Do not allow children or pets to sit on your lap

The following is true for one week:

- Use condoms for sexual relations

The following is true for 27 Days:

- In the event of a medical emergency or death, a family member or guardian should notify the attending medical staff or funeral director of the date and type of radioactive material treatment

End of Policy

References:

Ho S, Lau WY, Leung TWT, Johnson p~ Internal radiation therapy for patients with primary or metastatic liver cancer. Cancer 1998; 83(9): *1894-1907*

Stubbs RS, Cannan RJ, Mitchell A, Alwan MH. An initial experience with selective internal radiation therapy(SIRT) for non-resectable colorectal liver metastases. G.L Cancer 1999;3(2):135-143

Gray BN, Burton MA, Kelleher DK, Anderson ~ Selective Internal Radiation thera[py for treatment of liver metastases:measurement of response rate. Journal of Surgical Oncology 1989; 42:192-196

Code of Federal Regulations 10: Part 35. Radiation Safety Manual.
Regulatory Guide 8.39, "Release of Patients Administered with Radioactive Materials" and Part 35.75..

NO POUCH NEEDED.
See back for peel and stick application instructions.

RECIPIENT: PEEL HERE

FedEx Express *US Airbill*

FedEx Tracking Number 8489 4511 4267

Form ID No. 0215

Recipient's Copy

1 From This portion can be removed for Recipient's records.

Date 17 August 06 FedEx Tracking Number 848945114267

Sender's Name Ravi Rao Phone

Company

Address

City State ZIP Dept./Floor/Suite/Room

RECEIVED AUG 21 2006 DNMS

2 Your Internal Billing Reference

3 To

Recipient's Name Nuclear Materials Licensing Branch Phone

Company U.S. Nuclear Regulatory Commission

Recipient's Address Region IV

We cannot deliver to P.O. boxes or P.O. ZIP codes. Dept./Floor/Suite/Room

Address 611 Ryan Plaza Ste 400

To request a package be held at a specific FedEx location, print FedEx address here.

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8489 4511 4267

4a Express Package Service *Packages up to 150 lbs.* * To most locations

- [X] FedEx Priority Overnight — Next business morning*
- [ ] FedEx Standard Overnight — Next business afternoon*
- [ ] FedEx First Overnight — Earliest next business morning delivery to select locations*
- [ ] FedEx 2Day — Second business day*
- [ ] FedEx Express Saver — Third business day*

FedEx Envelope rate not available. Minimum charge: One-pound rate

4b Express Freight Service *Packages over 150 lbs.* ** To most locations

- [ ] FedEx 1Day Freight* — Next business day**
- [ ] FedEx 2Day Freight — Second business day**
- [ ] FedEx 3Day Freight — Third business day**

* Call for Confirmation:

5 Packaging * Declared value limit $500

- [X] FedEx Envelope*
- [ ] FedEx Pak* — Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak
- [ ] FedEx Box
- [ ] FedEx Tube
- [ ] Other

6 Special Handling Include FedEx address in Section 3.

- [ ] **SATURDAY Delivery** — Available ONLY for FedEx Priority Overnight, FedEx 2Day, FedEx 1Day Freight, and FedEx 2Day Freight to select ZIP codes
- [ ] **HOLD Weekday at FedEx Location** — Not available for FedEx First Overnight
- [ ] **HOLD Saturday at FedEx Location** — Available ONLY for FedEx Priority Overnight and FedEx 2Day to select locations

Does this shipment contain dangerous goods? One box must be checked.

- [X] No
- [ ] Yes — As per attached Shipper's Declaration
- [ ] Yes — Shipper's Declaration not required
- [ ] Dry Ice — Dry Ice, 9, UN 1845 ____ x ____ kg
- [ ] Cargo Aircraft Only

Dangerous goods (including Dry Ice) cannot be shipped in FedEx packaging.

7 Payment *Bill to:* Enter FedEx Acct. No. or Credit Card No. below. Obtain Recip Acct. No.

- [X] Sender — Acct. No. in Section 1 will be billed.
- [ ] Recipient
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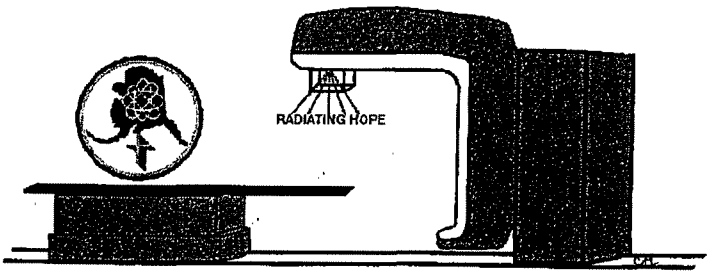
Providence Cancer Therapy Center

Providence Alaska Medical Center



3200 Providence Drive Anchorage, AK 99508 (907) 261-3186 FAX (907)261-3665

To: Roberto Torres, NRC **From:** Yongli Ning

Fax: 817-860-8188 **Pages:** 2 (including this page)

Date 8/24/06

Re: Commit to Licensing Guide

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

• **Comments:**

Roberto,

Please see the letter of commitment to Licensing Guidance.

Thanks you very much, for your help.

Yongli

8/24/06

471091

Providence | Alaska Medical Center

3200 PROVIDENCE DRIVE
P.O. BOX 196604
ANCHORAGE, ALASKA
99519-6604

Tel 907 562-2211

August 24, 2006

Roberto J. Torres
Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region IV
Division of Nuclear Materials Safety
Nuclear Materials Licensing Branch
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011

Dear Roberto,

Subject: Commitments for licensing Sir-Spheres (Yttrium-90 Microspheres)

In compliance with the NRC guidance for licensing Sir-Spheres (Yttrium-90 Microspheres) regimen to its Radioactive Material License 50-17838-01, Providence Alaska Medical Center commits to follow the conditions addressed in the Microsphere Brachytherapy Sources and Devices, Licensing Guidance – TheraSphere and SIRSphere Yttrium-90 Microspheres that is posted in the NRC website:

http://www.nrc.gov/materials/miau/med-use-toolkit/microsphere.html

If you need additional details/clarification, please do not hesitate to call Yongli Ning, or Ravindra Rao, Medical Physicists at 907-261-3186.

Sincerely,

L. Rodney Cook, MD
Radiation Safety Officer
Providence Alaska Medical Center
3200 Providence Drive
P.O.Box 196604
Anchorage, Alaska 99519-6604

Tel: (907)261-3186
Fax: (907)261-3665
Email: RLCook@provak.org

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Radiation Safety Officer
Providence Alaska Medical Center
3200 Providence Drive
P.O.Box 196604
Anchorage, Alaska 99519-6604

Tel: (907)261-3186
Fax: (907)261-3665
Email: RLCook@provak.org

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02120
Status Code: 0
Fee Category: 7C 2B
Exp. Date: 20150331
Fee Comments: CODE 21
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: PROVIDENCE HOSPITAL
   Received Date: 20060821
   Docket No: 3013426
   Control No.: 471091
   License No.: 50-17838-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: _____
   Check No.: /

3. COMMENTS

Signed Colleen Murnahan
Date 8-24-06

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:
   Amendment _____
   Renewal _____
   License _____

3. OTHER _____
   _____

Signed _____
Date _____