CLINIC & HOSPITAL

November 27, 2012

Nuclear Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region IV
1600 E. Lamar Blvd.
Arlington, TX 76011-4511

Subject: License Amendment
NRC License No. 53-18126-01
Docket No. 030-14529

Dear License Reviewer:

We wish to amend our license to authorize the use of Y-90 SIR-Sphere microspheres with the Sirtex Medical SIR-Sphere Microsphere brachytherapy device. Information supporting this application is enclosed.

If you require any additional information please contact our Radiation Safety Consultant, Ronald Frick at 808-373-7009.

Sincerely,

Art Gladstone
Chief Operations Officer

Enclosures

PUBLIC
☐ Immediate Release
☑ Normal Release

NON-PUBLIC
☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other:_____

Reviewer: JNO Date: 12/11/12

November 27, 2012

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Sincerely,

Art Gladstone
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Enclosures

Item 6 Purpose

Byproduct Material	Chemical/Physical Form	Maximum Amount	Purpose
Material in § 35.1000 (Yttrium-90)	Sealed Source, Sirtex Medical Ltd. SIR-Spheres microspheres*	189 mCi per vial, 650 mCi total	Intravascular brachytherapy treatments of hepatic carcinoma

* NRC Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Sources No. MA-1229-D-101-S.

Item 7 Authorized Users

Authorized User	Authorized Use	Record of Training and Experience
James S. Sheperd, M.D.	Y-90 SIR-Spheres microspheres	Dr. Sheperd has received more than 80 hours of classroom and laboratory training, as documented in the enclosed preceptor statement from University of Florida. Dr. Sheperd has received training provided by Sirtex, which included three supervised hands-on in-vitro simulated cases that demonstrated possible issues encountered during the Yttrium-90 microsphere administration. Documentation of this training is enclosed. Following the license amendment that names Dr. Sheperd as an Authorized User for Y-90 microsphere use, the first three cases completed by Dr. Sheperd will be hands-on and supervised in the physical presence of a Sirtex representative. Documentation from Sirtex will be submitted to NRC Region IV office within 30 days of when these three patient cases have been satisfactorily completed.

Additional Information supporting use of Yttrium-90 SIR-Spheres

1. We will provide training to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed.

2. We will follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use, except where replaced by the following licensing commitments:

   a. For the purpose of written directives and medical event reporting requirements in the Y-90 microsphere guidance, "prescribed dose" means the total dose (rad or Gy). Alternatively, prescribed activity (mCi or GBq) may be used in lieu of prescribed dose.
   b. The written directive shall include the patient or human research subject's name; the date; the signature of an AU for Y-90 microspheres; the treatment site; the radionuclide (including the physical form [Y-90 microspheres]); the prescribed dose/activity; the manufacturer; and, if appropriate for the type of microsphere used, the statement "or dose/activity delivered at stasis."
   c. The written directive will specify the maximum dose(s)/activity(ies) that would be acceptable to the specified site(s) outside the primary treatment site due to shunting (e.g. lung and gastrointestinal tract).
   d. Administration of Y-90 microspheres will be performed in accordance with the written directive. If the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g. artery spasm or sudden change in blood pressure), the Authorized User will document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive will include the reason for not administering the intended dose/activity, the date, and the signature of an Authorized User for Y-90 microspheres.
   e. We will record the administered dose/activity delivered to the primary treatment site and to the other specified site(s). If the administration was terminated because of stasis, then the total dose/activity to the treatment site is the value of the total dose/activity administered when stasis occurred and the administration was terminated. The record will be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who made the assessment, the date, and the signature of an Authorized User for Y-90 microspheres, if terminated due to stasis.
   f. We will follow the manufacturer's procedures for calculating/documenting the dose to the treatment and other sites, preparing the dose for administration, and performing pre/post vial dose measurements.
   g. The semi-annual physical inventory of microsphere aggregates (e.g. vials) will include:
      i. the radionuclide and physical form; and

ii. unique identification of each vial in which the microspheres are contained; and
iii. the total activity contained in each of the vial(s); and
iv. the location(s) of the vial(s).

h. We will retain each semi-annual physical inventory record for three years.

i. We will develop procedures that describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research subject permits his/her release in accordance with 10 CFR 35.75.

j. When Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer, we will:
i. Label vials and vial radiation shields with radionuclide and form (e.g., Y-90 microspheres).
ii. Label syringes and syringe radiation shields with the radionuclide, form, and therapeutic procedure (e.g., Y-90 microspheres, brachytherapy).

k. We will report any event, except for an event that results from intervention of a patient or human research subject, in which:
i. the administration of byproduct material results in a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from the use of the wrong radionuclide; or
ii. the administration of Y-90 microspheres results in a dose
(1) that differs from the prescribed dose or the dose that would have resulted from the prescribed activity, as documented in the written directive, by more than 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue, and the total dose/activity administered differs from the prescribed dose/activity, as documented in the written directive, by 20 percent or more; or
(2) that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from an administration to the wrong individual or human research subject, via the wrong route, or by the wrong mode of treatment; or
(3) to an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and by 50 percent or more of the prescribed dose/activity expected to that site from the administration of Y-90 microspheres, if carried out as specified in the written directive.

l. We will comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

3. We request authorization to notify the NRC in the future that we have permitted an Authorized User to work at our facility without the need to request an additional license amendment, provided the following conditions are met:
a. the Authorized User satisfies the training and experience listed in NRC's

licensing guidance for Y-90 microspheres; and

b. the Authorized User is currently listed for the same type of Y-90 microsphere use on a Commission or Agreement State license, a permit issued by a Commission master material license, a permit issued by a Commission or Agreement State licensee of a broad scope, or a permit issued by a Commission master material license broad scope permittee; and

c. We provide NRC a copy of the license or permit on which the Authorized User was originally listed for the specific microsphere use; and

d. We provide documentation to NRC for each Authorized User of the above listed conditions no later than 30 days after the date that we allow the Authorized User to work as an Authorized User for the specific type of microsphere.

4. We request to incorporate into our license a change process which will allow some future changes to radiation safety programs. The following conditions will be met before any revisions to the radiation safety program:

a. the revision is in compliance with the regulations; and

b. the revision is based upon NRC's current guidance for SIR-Spheres® Y-90 microspheres 35.1000 use posted on the NRC Web site; and

c. the revision has been reviewed and approved by the Radiation Safety Officer and hospital management; and

d. the affected individuals are instructed on the revised program before the change is implemented; and

e. we will retain a record of each change for five years; and

f. 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 hospital management that reviewed and approved the change.

SIRTEX MEDICAL INC.
300 Unicorn Park Drive
Woburn, MA 01801
Tel: +1 (781) 721 3800
Fax: +1 (781) 721 3880

Ref: 104US07

November 2, 2012

James Sheperd, MD
Department of Radiology
Straub Hospital and Clinic
888 South King Street
Honolulu, HI 96813

Dear Dr. Sheperd:

Re: SIR-Spheres® Microspheres Authorized User Training and Certification

This letter certifies that on 11/02/2012, you successfully completed training in the operation of the delivery system, safety procedures and clinical use of SIR-Spheres yttrium-90 microspheres that are to be injected via the hepatic artery to treat patients with unresectable liver tumors in accordance with the June 2012 NRC guidance. This training included three (3) supervised hands-on *in-vitro* simulated set-up and delivery procedures as well as encompassing the following:

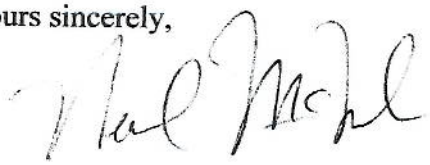
a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
b) Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters;
c) Evaluation of each patient for the dose/activity of Y-90 microspheres to be administered to each treatment site;
d) Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient;
e) Using administrative controls to prevent a medical event involving the use of byproduct material;
f) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures; and
g) Follow up and review of each patient's case history for Y-90 microspheres

Once your licence has been appropriately amended, Sirtex will arrange with you to have a proctor oversee your first three (3) patient treatments at a minimum, including being on site for each case.

® SIR-Spheres is a Registered Trademark of Sirtex SIR-Spheres Pty Ltd

Sirtex would like to thank you for your support in this process.

Yours sincerely,



Neal McMahon
Regional Sales Manager

Cc: file

FLORIDA DEPARTMENT OF HEALTH

FLORIDA DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

PRECEPTOR/APPLICANT STATEMENT

Training and experience requirements for medical use of radioactive material are specified in Part VI, Subpart I of Chapter 64E-5, Florida Administrative Code (F.A.C.) (http://www.doh.state.fl.us/environment/radiation/). This document is to be completed by the applicant physician, the preceptor and designated individuals at the training medical institution such as Radiation Safety Committee Chairman or other Certifying Official. Use a separate document for each preceptor providing supervision of clinical training. Only clinical training received at a medical institution is acceptable.

INSTRUCTIONS:
Applicants with Radiological Specialty Board Certification or Accreditation for Graduate Medical Education Training in Nuclear Medicine needs to complete page 1 only.

OTHERWISE

An applicant wishing authorization only for diagnostic procedures needs to complete pages 1 – 4.
(Examples are imaging of the brain, liver, heart, lungs, etc, or thyroid uptake.)

An applicant wishing authorization only for therapy procedures needs to complete pages 2 and, 5 – 7.
(Example: treatment of thyroid cancer or hyperthyroidism, bone pain, or brachytherapy procedures to include permanent implants for treatment of prostate cancer, temporary implants for treatment of ovarian cancer, high dose rate remote afterloader devices (HDR) for treatment of ovarian caners or teletherapy sources.)

An applicant wishing authorization for **both** diagnostic and therapy procedures needs to complete pages 1 – 7.

NAME OF APPLICANT PHYSICIAN:	James (First)	Sheperd (Last)	S (MI)	☑ M.D. ☐ D.O.

RADIOLOGICAL SPECIALTY BOARD CERTIFICATION (Attach photocopy of certificate)	DATE OF CERTIFICATE
American Board of Nuclear Medicine – Nuclear Medicine	
American Board of Radiology – Diagnostic Radiology, Rad. Oncology, Radiology or Therapeutic Radiology	
American Osteopathic Board of Radiology – Diagnostic Radiology, Radiology or Radiation Oncology	
American Osteopathic Board of Nuclear Medicine – Nuclear Medicine	
British Fellow of the Faculty of Radiology or Royal College of Radiology – Radiotherapy	
Canadian Royal College of Physicians and Surgeons – Therapeutic Radiology	
An applicant with one of the above certifications is not required to complete this document if a copy of the board certificate applicable to the requested uses is provided. If the applicant has completed training in uses other than those covered by the board certification, then this document needs to be completed to show the additional training and experience	

– OR –

ACCREDITATION COUNCIL FOR GRADUATE MEDICAL EDUCATION (ACGME) TRAINING IN NUCLEAR MEDICINE
(Attach photocopies of provider certificates documenting completion of training. Some ACGME program numbers may be found using the search feature and reports tab at http://www.acgme.org/adspublic/)

Institution Name & AGME Provider Number	Affiliated Hospital & Address	Directors Name	Director's Phone # Director's Fax #	Dates of Training From – To
Univ of FL 4201121048	1600 SW Archer Rd Gainesville, FL 32610 Shands Hospital	Walt Drane	Phone: 265-0291 Fax 265-0279	7/1/06 – 6/30/10
			Phone: Fax	

– OR –

To knowingly make false statements to a public servant is a violation of section 837.06, Florida Statutes, and is punishable by fine or imprisonment.

PRECEPTOR/APPLICANT STATEMENT

An applicant physician who does not hold one of the above listed board certifications or who has not completed a 6-month ACGME-accredited program ***must*** submit documentation of didactic training and clinical experience. Complete the following didactic training table, and then complete the subsequent pages to document clinical experience. Include all required signatures.

INSTRUCTION IN BASIC RADIONUCLIDE HANDLING TECHNIQUES (DIDACTIC TRAINING)

(Attach photocopies of any other documents such as letters or certificates that demonstrate completion of didactic training)

DIDACTIC TRAINING PROVIDER (include name, address, telephone number and radioactive material license number)	TOPICS (Required hours are for 64E-5.627 authorization: fewer hours are needed for 64E-5.626 or 64E-5.631 procedures)	TRAINING DATES FROM – TO:	TOTAL HOURS TRAINED
University of Florida 1600 SW Arch Rd Gainesville, FL 32610 352-265-0295 31-3	**Radiation Physics and Instrumentation** (15 hours required for 64E-5.626) (100 hours required for 64E-5.627) (25 hours required for 64E-5.630) (6 hours required for Sr-90 eye applicator) (110 hours required for 64E-5.632 and .634) (3 hours required for 64E-5.631)	7/1/06 – 6/30/10	100
as above	**Radiation Protection** (10 hours required for 64E-5.626) (30 hours required for 64E-5.627) (25 hours required for 64E-5.630) (6 hours required for Sr-90 eye applicator) (40 hours required for 64E-5.632 and .634) (2 hours required for 64E-5.631)	as above	30
as above	**Mathematics Pertaining to the Use and Measurement of Radioactivity** (5 hours required for 64E-5.626) (20 hours required for 64E-5.627) (10 hours required for 64E-5.630) (4 hours required for Sr-90 eye applicator) (25 hours required for 64E-5.632 and .634) (3 hours required for 64E-5.631)	as above	20
as above	**Radiopharmaceutical Chemistry** (5 hours required for 64E-5.626) (30 hours required for 64E-5.627) (No hours required for 64E-5.630) (No hours required for Sr-90 eye applicator) (No hours required for 64E-5.632 and .634) (No hours required for 64E-5.631)	as above	30
as above	**Radiation Biology** (5 hours required for 64E-5.626) (20 hours required for 64E-5.627) (20 hours required for 64E-5.630) (8 hours required for Sr-90 eye applicator) (25 hours required for 64E-5.632 and .634) (3 hours required for 64E-5.631)	as above	20
as above	**TOTAL Hours from above** (40hours required for 64E-5.626) (200 hours required for 64E-5.627) (80 hours required for 64E-5.630) (24 hours required for Sr-90 eye applicator) (200 hours required for 64E-5.632 and .634) (8 hours required for 64E-5.631)	as above	200

PRECEPTOR/APPLICANT STATEMENT

NAME OF APPLICANT PHYSICIAN:	First: James	Last: Shepard	MI: S	☑ M.D. ☐ D.O.

UPTAKE, DILUTION OR EXCRETION STUDIES (64E-5.626, F.A.C.)

CLINICAL TRAINING RECEIVED UNDER THE SUPERVISION OF AN AUTHORIZED USER AS SPECIFIED IN 64E-5.649(2)(b), F.A.C.	CLINICAL TRAINING HOURS
Mark each box as applicable: ☑ Examined patients and reviewed their case histories to determine their suitability for radionuclide diagnosis, including limitations or contraindications ☑ Selected the suitable radiopharmaceutical and calculated and measured the dosage ☑ Administered dosages to patients using syringe radiation shields ☑ Performed patient follow-up	1000 hr (Minimum of 20 hours)

IMAGING AND LOCALIZATION STUDIES (64E-5.627, F.A.C.)

Mark each box as applicable to indicate clinical experience:

RADIONUCLIDE	CARDIAC-ONLY/RENAL STUDIES
☒ Tl-201 and/or Tc-99m	Cardiac Imaging
☒ Xe-133 or Xe-127	Blood Flow Studies and Pulmonary Function Studies
☐ F-18	Cardiac Positron Emission Tomography (PET)
☒ Other: muGA	Other Cardiac Studies
☒ Other: Renal	Renal Studies
RADIONUCLIDE	**NON-CARDIAC STUDIES**
☒ F-18	Non-Cardiac Positron Emission Tomography (PET)
☒ Other:	Non-Cardiac Imaging and Localization
RADIONUCLIDE	**GENERATORS AND REAGENT KITS**
☒ Mo-99/Tc-99m Generator	Eluted Tc-99m from generator, assayed and tested the eluate for Mo-99 and alumina contamination as specified in 64E-5.650, F.A.C.
☐ Sr-82/Rb-82 Generator	Eluted Rb-82 from generator, assayed and tested the eluate for Sr-82 and tin contamination
☒ Tc-99m Reagent Kits	Processed reagent kits to prepare Tc-99m labeled radiopharmaceuticals
☐ Other:	

DIAGNOSTIC RADIOPHARMACEUTICAL CLINICAL TRAINING (64E-5.627, F.A.C.)

Completed 500 hours of work experience and 500 hours of clinical experience concurrently under the supervision of an authorized user at a medical institution, as specified in 64E-5.650(2)(b) and (c), F.A.C., including the following:

- ☒ Ordered, received and unpacked radioactive materials safely and performed the related radiation surveys
- ☒ Calibrated dose calibrators and diagnostic instruments and performed checks for proper operation of survey meters
- ☒ Calculated and prepared patient dosages and used administrative controls to prevent misadministration
- ☑ Used emergency procedures to contain spilled radioactive material and used proper decontamination procedures
- ☒ Eluted Tc-99m from generator systems, assaying and testing the elute for Mo-99 and alumina contamination, and processing the elute with reagent kits to prepare Tc-99m-labeled radiopharmaceuticals
- ☒ Examined patients and reviewed each case history to determine their suitability for radionuclide diagnosis, including limitations or contraindications
- ☒ Selected the suitable radiopharmaceutical and calculated and measured the dosages; administered dosages to patients and used syringe radiation shields; collaborated with the authorized user in the interpretation of radionuclide test results; patient follow-up

To knowingly make false statements to a public servant is a violation of section 837.06, Florida Statutes, and is punishable by fine or imprisonment.

PRECEPTOR/APPLICANT STATEMENT

SEALED SOURCES FOR DIAGNOSIS (64E-5.631, F.A.C.)

SOURCE AND DEVICE MANUFACTURER AND MODEL NUMBER	CLINICAL TRAINING/DEVICE SPECIFIC	TOTAL CLINICAL HOURS TRAINED
	☐ 2 hours of training in use of the device as specified in 64E-5.654(2)(c), F.A.C.	_____ (min. of 8 hrs.)

DIAGNOSTIC TRAINING VERIFICATION

Hours of specific training for diagnostic procedures must include both radiation safety and patient-related topics as specified in 64E-5.649 – 64E-5.654, F.A.C., as applicable. All information in Items 2 – 7 and 9 or 11 must be completed and legibly printed or typed. Items 9 and 10 may be completed by the radiation safety committee (RSC) chair. **– OR –**

Items 11 and 12 may be completed by a certifying official for the preceptoring medical institution. A certifying official is a corporate officer or other individual authorized to make legally binding statements for the institution. If training was performed at more than one institution, obtain a separate, completed statement from each.

1. Applicant Physician's Name (print):
James Sheperd
Phone: 352-256-5470 Extension:

2. Name and Address of Preceptoring Medical Institution:
University of Florida - Shands Hospital
1600 SW Archer Rd
Gainesville, FL 32601
Phone: 352-265-0291 Extension:

3. Name of Medical Director of Residency Program (print):
Lori Deitte
Phone: 352-265-0291 Extension:

4. Applicant Physician's Signature:
[signature]
Date: 2/11/10

5. Dates of Training:
From 7/1/06 To: 6/30/10

6. Total Number of Clinical Hours in Training: 1000

7. Preceptoring Medical Institution's Radioactive Materials License No.: 31-3

8. Preceptoring Physician's Name (print):
Walt Drane
Phone: 352-265-0291 Extension:

9. Preceptoring Physician's Signature:
[signature]
Date: 2/11/10

Florida requires documentation of clinical training from the RSC of the preceptoring medical institution. The signature of the RSC chair or a certifying official for the medical institution may be used to satisfy this requirement. A certifying official refers to a corporate officer or other individual authorized to make legally binding statements for the institution.

10. Name of Preceptoring Institution's RSC Chair (print):
Walt Drane
Phone: 352-265-0291 Extension:

11. Radiation Safety Committee Chair's Signature:
[signature]
Date: 2/11/10

- OR -

12. Name of Medical Institution's Certifying Official (print):
Phone: Extension:

13. Certifying Official's Signature:
Date:

To knowingly make false statements to a public servant is a violation of section 837.06, Florida Statutes, and is punishable by fine or imprisonment.

PRECEPTOR/APPLICANT STATEMENT

NAME OF APPLICANT PHYSICIAN:	James (First)	Shepard (Last)	S (MI)	☒ M.D. ☐ D.O.

THERAPEUTIC RADIOPHARMACEUTICAL CLINICAL TRAINING (64E-5.630, F.A.C.)

(training and experience as specified in 64E-5.651, F.A.C.)

Mark each box as applicable to indicate clinical experience:

RADIONUCLIDE	CONDITIONS TREATED	NO. OF CASES REQUIRED	NO. OF CASES PERFORMED
P-32 (colloidal) or Au-198 (colloidal)	Intracavitary Treatment of Malignant Effusions	3	0
I-131	Treatment of Cardiac Dysfunction or Hyperthyroidism	10	6
I-131	Treatment of Thyroid Carcinoma	3	5
I-131, P-32 (soluble), Sr-89, Sm-153 or Y-90	Systemic Therapy Treatments	3	
Other:	Symptomatic Goiter I-131		1

OPHTHALMIC USE OF STRONTIUM 90 CLINICAL TRAINING (64E-5.632, F.A.C.)

(Training and experience shall be as specified in 64E-5.653, F.A.C.)

RADIONUCLIDE	CONDITIONS TREATED	NO. OF CASES REQUIRED	NO. OF CASES PERFORMED
Sr-90	Treatment of Eye Disease	5	0

Mark each box as applicable:

☐ Received clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, including the use of strontium 90 for the ophthalmic treatment of 5 individuals, including each of the following as indicated.

- ☐ Examination of each individual to be treated
- ☐ Calculation of the dose to be administered
- ☐ Administration of the dose
- ☐ Follow-up and review of each individual's case history

THERAPEUTIC BRACHYTHERAPY CLINICAL TRAINING (64E-5.632, F.A.C.)

(Training and experience as specified in section 64E-5.652, F.A.C.)

RADIONUCLIDE	CONDITIONS DIAGNOSED OR TREATED
☐ Cs-137	Interstitial Treatment
☐ Co-60	Interstitial, Topical or Intracavitary Treatments
☐ Rn-222	Interstitial Treatment
☐ Ir-192	Interstitial Treatment
☐ Pd-103	Interstitial Treatment
☐ I-125	Interstitial Treatment
☐ Ir-192	Use of High Dose Rate Remote Afterloaders
☐ Au-198	Interstitial, Intracavitary or Topical Treatments
☐ Cs-137 or Ra-226	Interstitial, Intracavitary or Topical Treatments
☐ Other:	

PRECEPTOR/APPLICANT STATEMENT

THERAPEUTIC BRACHYTHERAPY CLINICAL TRAINING (64E-5.632, F.A.C.)
(continued)

Mark each box as applicable:

- ☐ Completed 500 hours of work experience under the supervision of an authorized user at a medical institution including the following:
  - ☐ Ordered, received, and unpacked radioactive materials safely and performed the related radiation surveys
  - ☐ Checked survey meters for proper operation
  - ☐ Prepared, implanted and removed sealed sources
  - ☐ Used administrative controls to prevent the misadministration of radioactive material
  - ☐ Used emergency procedures to control radioactive material
- ☐ Completed 3 years of supervised clinical experience including one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution, including the following:
  - ☐ Examined individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications
  - ☐ Selected the proper brachytherapy source, dose, and method of administration
  - ☐ Calculated the dose
  - ☐ Conducted post-administration follow-up and review of case histories in collaboration with the authorized user

TELETHERAPY CLINICAL TRAINING (64E-5.634, F.A.C.)
(Training and experience as specified in 64E-5.655, F.A.C.)

	RADIONUCLIDE	CONDITION TREATED
☐	Co-60	

Mark each box as applicable:

- ☐ Completed 500 hours of work experience under the supervision of an authorized user at a medical institution including each of the following as indicated.
  - ☐ Review of the full calibration measurements and periodic spot checks
  - ☐ Preparing treatment plans and calculating treatment times
  - ☐ Using administrative controls to prevent misadministrations
  - ☐ Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unity or console
  - ☐ Checking and using survey meters
- ☐ Completed 3 years of supervised clinical experience including 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution, including the following:
  - ☐ Examining individuals and reviewing each case history to determine their suitability for teletherapy treatment, and any limitations or contraindications
  - ☐ Selecting the proper dose and how it is to be administered
  - ☐ Calculating the teletherapy doses and collaborating with the authorized user in the review of the patient's progress and consideration of the need to modify originally prescribed doses as warranted by the patient's reaction to radiation
  - ☐ Post-administration follow-up and review of case histories

PRECEPTOR/APPLICANT STATEMENT

THERAPEUTIC TRAINING VERIFICATION

Hours of specific training for therapeutic procedures must include both radiation safety and patient-related topics as specified in 64E-5.651 – 64E-5.655, F.A.C., as applicable. All information in Items 2 – 7 and 9 or 11 must be completed and legibly printed or typed. Items 9 and 10 may be completed by the radiation safety committee (RSC) chair. **– OR –**

Items 11 and 12 may be completed by a certifying official for the medical institution. (A certifying official is a corporate officer or other individual authorized to make legally binding statements for the institution.). If training was performed at more than one institution, obtain a separate, completed statement from each.

1. Applicant Physician's Name (print): James S. Sheperd Phone: Extension:	4. Applicant Physician's Signature: Date: 2/11/10
2. Name and Address of Preceptoring Medical Institution: University of Florida - Shands Hospital 1600 SW Archer Rd Gainesville, FL 32610 Phone: 352-265-0291 Extension:	5. Dates of Training: From: 7/1/06 To: 6/30/10 6. Total Number of Clinical Hours in Training: ~~1000~~ Incl. dx & clinical NRS 7. Preceptoring Medical Institution's Radioactive Materials License No.: 31-3 8. Preceptoring Physician's Name (print): Walt Drane MD Phone: 352-265-0291 Extension:
3. Name of Medical Director of Residency Program (print): Lori Deitte Phone: Extension:	9. Preceptoring Physician's Signature: Date: 2/11/10

Florida requires documentation of clinical training from the RSC of the preceptoring medical institution. The signature of the RSC chair or a certifying official for the medical institution may be used to satisfy this requirement. A certifying official refers to a corporate officer or other individual authorized to make legally binding statements for the institution.

10. Name of Preceptoring Institution's RSC Chair (print): Walt Drane Phone: 352-265-0291 Extension:	11. Radiation Safety Committee Chair's Signature: Date: 2/11/10

- OR -

12. Name of Medical Institution's Certifying Official (print): Phone: Extension:	13. Certifying Official's Signature: Date:

To knowingly make false statements to a public servant is a violation of section 837.06, Florida Statutes, and is punishable by fine or imprisonment.

4/03 Edition

Murnahan, Colleen

From: Ronald Frick [rfrick@gammacorp.com]
Sent: Friday, November 30, 2012 9:22 PM
To: Murnahan, Colleen
Cc: Hill, Carol
Subject: Straub Clinic & Hospital amendment request
Attachments: NRC amendment request Y90 Sirspheres.pdf

Colleen,
I have attached an amendment request from Straub Clinic & Hospital to add authorization for Y-90 SIR-Sphere microspheres.
Please contact me if you need additional information.
Thank you,
Ron Frick
Gamma Corporation
rfrick@gammacorp.com

Hill, Carol

579527

NRC FORM 532
(1-2012)

U. S. NUCLEAR REGULATORY COMMISSION

DATE

12/05/2012

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE	LICENSE NUMBER
Straub Clinic & Hospital, Dept of Nuclear Medicine ATTN: Art Gladstone, Chief Operations Officer 888 South King Street Honolulu, HI 96813	53-18126-01
	MAIL CONTROL NUMBER 579527
	LICENSING AND/OR TECHNICAL REVIEWER cmurnahan CM

This is to acknowledge the receipt of your:

☑ LETTER and/or ☐ APPLICATION DATED: 11/27/2012

The initial processing, which included an administrative review, has been performed.

☑ AMENDMENT ☐ TERMINATION ☐ NEW LICENSE ☐ RENEWAL

☑ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please fill out NRC Form 531, located at the following link:

http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf

Send the completed NRC Form 531, by facsimile, to the following number: (301) 415-5387

A copy of your action has been emailed to our License Fee and Accounts Receivable Branch, in our Headquarters office in Rockville, MD. You will be contacted separately if there is a fee issue involved.

Your application has been assigned the above listed **MAIL CONTROL NUMBER.** When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region IV
U. S. Nuclear Regulatory Commission
DNMS/NMSB - B
1600 E. Lamar Blvd.
Arlington, TX 76011-4511
(817) 200-1103 or (817) 200-1140

NRC FORM 532
(1-2012)

e-mailed to licensee 12-6-12

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 02120
Status Code: Pending Amendment
Fee Category: 7C
Exp. Date: 05/31/2015
Fee Comments:
Decom Fin Assur Reqd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee:	STRAUB CLINIC & HOSPITAL
Received Date:	11/30/2012
Docket Number:	3014529
Mail Control Number:	579527
License Number:	53-18126-01
Action Type:	Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: Colleen Murnahan

Date: 12-03-12

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: _____