SAINT PETER'S UNIVERSITY HOSPITAL
A MEMBER OF SAINT PETER'S HEALTHCARE SYSTEM

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New Brunswick, NJ 08903-0591
732-745-8600 • www.saintpetersuh.com

Br. 1

United States
Nuclear Regulatory Commission
Medical Licensing Assistant
475 Allendale Road
King of Prussia, PA 19406-1415

December 8, 2008

RE: Amendment of license 29-07566-01 03002502

Please amend this license as follows:

Add Sirtex Y-90 microspheres as a regulated use under 20 CFR 35.1000. This request was previously submitted as letter dated January 25, 2008 Control 141898. The authorized user will be Gopal Desai, M.D.

Add Erwin Ruff as an authorized medical physicist for 35.600 Remote afterloader unit. See Item 2 Attachments.

Please direct all questions to Mr. Robert J. Tokarz, Radiation Safety Officer. He can be contacted at 732-424-0909 and rtokarz@mac.com

Thank you for your attention to this matter.

Sincerely,

Anthony Costabile
Chief Operating Officer

RECEIVED
REGION 1
DEC 15 PM 12: 02

(Ref. 141898)

143106

Saint Peters University Hospital: 29-07566-01, Y-90 spheres.
ITEM 1

AUTHORIZATION FOR USE OF Yttrium-90 microspheres

December 8, 2008

Control 141898

This is a request to amend NRC license 29-07566-01 to include the use of Yttrium-90 microspheres.

Training and Experience

The authorized user for Y-90 microspheres (AU) must meet the training and experience requirements of 10 CFR 35.390 or 10 CFR 35.490. Additionally, the AU must have successfully completed training in the operation of the delivery system, safety procedures, and clinical use for each type of Y-90 microspheres for which authorization is sought. The additional Y-90 microsphere specific training and experience requirements were satisfied by satisfactory completion of a training program provided by the Y-90 microsphere manufacturer, Sirtex. Documentation is enclosed as "ATTACHMENT 1".

The clinical use experience included three supervised hands-on *in-vitro* simulated cases for the Sirtex Y-90 microsphere for which the individual is seeking AU status. *In-vitro* simulated cases demonstrated issues that are encountered during Y-90 microsphere administration procedures. Following the license amendment that names the individual as an AU for Y-90 microsphere use, the first three patient cases completed by the individual will be hands-on and supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which the individual is authorized.

Documentation for the above training and experience is submitted as ATTACHMENT 1. This documentation includes the in-vitro simulated cases and a commitment that each individual will complete the first three hands-on patient cases supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which authorization is sought. Additionally for pathway 2, we will submit documentation to the appropriate NRC Regional Office within 30 days of when these three patient cases have been completed.

In addition, we commit to provide training in the manufacturer's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training will be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

Leak Tests

Leak tests are not required for Y-90 microspheres based on the criteria in 10 CFR 35.67(f).

Saint Peters University Hospital: 29-07566-01, Y-90 spheres.
ITEM 1

License Commitments - Written Directives, Inventory, Patient Release, Labeling, & Medical Event Reporting

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

• 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.

• The written directive shall include the patient or human research subject's name and two separate entries:

1) Pre-administration: the date; the signature of the AU; the treatment site; the radionuclide (including the physical form [Y-90 microspheres]); the prescribed dose/activity; and, if appropriate for the type of microsphere used, identify the manufacturer and include the statement "or dose/activity delivered at stasis"; and

2) After administration but before the patient or human research subject leaves the post-procedural recovery area: the date; the signature of the AU; and the total dose/activity delivered to the treatment site. 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. Note: The post-administration entries into the written directive are not an amendment to the written directive; rather, these entries complete the written directive.

• The pre-administration 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). The post-implantation written directive will specify the dose(s)/activity(ies) delivered to the specified site(s) outside the primary treatment site due to shunting.

• Administration of Y-90 microspheres will be performed in accordance with the written directive. If the written directive is specified in dose (rad or Gray), the licensee should describe how the total dose to the treatment site, as well as the doses to other sites, would be determined before and upon completion of the administration, to confirm that the administration is performed in accordance with the written directive.

• The semi-annual physical inventory of microspheres aggregates (e.g. vials) will include:

1) the radionuclide and physical form; and

2) Unique identification of each vial in which the microspheres are contained; and

3) The total activity contained in each of the vial(s); and

4) The location(s) of the vial(s).

• Procedures should 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.

• The following additional guidance applies when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:

1) Label vials and vial radiation shields with radionuclide and form (e.g., Y-90 microspheres).

2) Label syringes and syringe radiation shields with the radionuclide, form, and therapeutic procedure (e.g., Y-90 microspheres, brachytherapy).

Saint Peters University Hospital: 29-07566-01, Y-90 spheres.
ITEM 1

• The licensee shall commit to report any event, except for an event that results from intervention of a patient or human research subject, in which:
1) 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
2) The administration of Y-90 microspheres results in a dose:
That differs from the prescribed dose, as documented in the pre-administration 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 pre-administration written directive, by 20 percent or more; or
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
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 pre-administration portion of the written directive
• Additionally, we will comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

SIRTEX MEDICAL, INC.
16 Upton Drive, #2-4
Wilmington, MA 01887
Tel: 978 642 3000

Ref: 104US03

December 5, 2008

Gopal Rao Desai, MD, DABR
Chairman, Department of Radiation Oncology
St. Peter's University Hospital
254 Easton Avenue
New Brunswick, NJ 08903

Dear Dr. Desai

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

This letter certifies that on December 5,2008, 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 September 2008 NRC guidance. This training included three (3) supervised hands-on *in-vitro* simulated set-up and delivery procedures that demonstrate possible issues encountered during the yttrium-90 microsphere administration.

Following the license amendment that names you as an AU for SIR-Spheres yttrium-90 microspheres use, Sirtex will arrange for the first three (3) *in-vivo* patient cases to be performed in the physical presence of a Sirtex proctor.

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

Yours sincerely,

Craig Lawrence
Regional Sales Manager

cc: Dr. Samuel Putnam, Sirtex Medical Director

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

Saint Peters University Hospital
ITEM 2

NRC FORM 313A (AMP) (10-2006) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.51]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized Medical Physicist
ERWIN RUFF

Requested Authorization(s) (check all that apply)
- ☐ 35.400 Ophthalmic use of strontium-90
- ☐ 35.600 Teletherapy unit(s)
- ☒ 35.600 Remote afterloader unit(s)
- ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

*Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☐ **1. Board Certification**

a. Provide a copy of the board certification.

b. Go to the table in 3.c. and describe training provider and dates of training for each type of use for which authorization is sought.

c. Skip to and complete Part II Preceptor Attestation.

☐ **2. Current Authorized Medical Physicist Seeking Additional Authorization for use(s) checked above**

a. Go to the table in section 3.c. to document training for new device.

b. Skip to and complete Part II Preceptor Attestation

☒ **3. Education, Training, and Experience for Proposed Authorized Medical Physicist**

a. Education: Document master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.

Degree	Major Field
M.S. 10/06	MEDICAL PHYSICS
College or University	
COLUMBIA UNIVERSITY NEW YORK CITY	

b. Supervised Full-Time Medical Physics Training and Work Experience in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

☒ Yes. Completed 1 year of full-time training in medical physics (for areas identified below) under the supervision of DAVID S. MARSDEN PH.D FACR who meets the requirements for an Authorized Medical Physicist.

AND

☒ Yes. Completed 1 year of full-time work experience in medical physics (for areas identified below) under the supervision of DAVID S. MARSDEN PH.D who meets the requirements for an Authorized Medical Physicist.

Saint Peters University Hospital
ITEM 2

NRC FORM 313A (AMP) U.S. NUCLEAR REGULATORY COMMISSION
(10-2006)

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. **Education, Training, and Experience for Proposed Authorized Medical Physicist** (continued)

b. Supervised Full-Time Medical Physics Training and Work Experience (continued)

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Description of Training/ Experience	Location of Training/License or Permit Number of Training Facility/Medical Devices Used+	Dates of Training*	Dates of Work Experience*
Medical Physics	WHITE PLAINS HOSPITAL WHITE PLAINS NEW YORK NYS RML # 1059	10/06 To PRESENT	10/06 To PRESENT
Performing sealed source leak tests and inventories			
Performing decay corrections			
Performing full calibration and periodic spot checks of external beam treatment unit(s)			
Performing full calibration and periodic spot checks of stereotactic radiosurgery unit(s)			
Performing full calibration and periodic spot checks of remote afterloading unit(s)			
Conducting radiation surveys around external beam treatment unit(s), sterotactic radiosurgery unit(s), remote after loading unit(s)			

Supervising Individual**
DAVID S. MARSDEN PH.D FACR

License/Permit Number listing supervising individual as an authorized Medical Physicist
NYS RML 1059

for the following types of use:

☒ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

\+ Training and work experience must be conducted in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

* 1 year of Full-time medical physics training and 1 year of full time work experience cannot be concurrent.

** If the supervising medical physicist is not an authorized medical physicist, the licensee must submit evidence that the supervising medical physicist meets the training and experience requirements in 10 CFR 35.51 and 35.59 for the types of use for which the individual is seeking authorization.

Saint Peters University Hospital
ITEM 2

NRC FORM 313A (AMP) U.S. NUCLEAR REGULATORY COMMISSION
(10-2006)

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. **Education, Training, and Experience for Proposed Authorized Medical Physicist** (continued)

c. Describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Hands-on device operation	White Plains Hospital	N/A	N/A
Safety procedures for the device use	↓	↓	↓
Clinical use of the device	↓	↓	↓
Treatment planning system operation	↓	↓	↓

Supervising Individual
If training is provided by Supervising Medical Pysicist, (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)
David J Marsden Ph.D FACR

License/Permit Number listing supervising individual as an authorized Medical Physicist
NYS # 1059

for the following types of use:

☒ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

If Applicable:

Authorization Sought	Device	Training Provided By	Dates of Training
35.400 Ophthalmic Use of strontium-90			

d. Skip to and complete Part II Preceptor Attestation.

Saint Peters University Hospital
ITEM 2

NRC FORM 313A (AMP) U.S. NUCLEAR REGULATORY COMMISSION
(10-2006)

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section
Check one of the following:

1. Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized Medical Physicist

10 CFR 35.51(a)(1) and (a)(2).

OR

2. Education, Training, and Experience

☒ I attest that ERWIN RUFF has satisfactorily completed the 1-year of full-time
Name of Proposed Authorized Medical Physicist

training in medical physics and an additional year of full-time work experience as required by 10 CFR 35.51(b)(1).

AND

Second Section
Complete the following:

☒ I attest that ERWIN RUFF has training for the types of use for which authorization
Name of Proposed Authorized Medical Physicist

is sought that include hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

AND

Third Section
Complete the following:

☒ I attest that ERWIN RUFF has achieved a level of competency sufficient to
Name of Proposed Authorized Medical Physicist

function independently as an Authorized Medical Physicist for the following:

☐ 35.400 Ophthalmic use of strontium-90 ☐ 35.600 Teletherapy unit(s)
☒ 35.600 Remote afterloader unit(s) ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

AND

Fourth Section
Complete the following for preceptor attestation and signature:

☒ I meet the requirements in 10 CFR 35.51, or equivalent Agreement State requirements for Authorized Medical Physicist for the following:

☐ 35.400 Ophthalmic use of strontium-90 ☐ 35.600 Teletherapy unit(s)
☒ 35.600 Remote afterloader unit(s) ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

Name of Preceptor	Signature	Telephone Number	Date
FACR DAVID S. MARSDEN Ph.D	David S Marsden	9738385079	11/30/08

License/Permit Number/Facility Name
WHITE PLAINS HOSPITAL, NYS RML 1059

This is to acknowledge the receipt of your letter/application dated

12/8/08, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (29-07566-01)

[X] There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

[ ] Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 143106.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader