



THE QUEEN'S MEDICAL CENTER

1301 Punchbowl Street ▪ Honolulu, Hawaii 96813 ▪ Phone (808) 538-9011 ▪ FAX: (808) 547-4646

September 7, 2012

RECEIVED

SEP 17 2012

DNMS

USNRC Region IV
1600 E. Lamar Blvd
Arlington, TX 76011-4511

Docket: 030-14522
License: 53-16533-02

RE: Amendment Request to add new Y-90 SIR-Spheres Authorized User

Greetings:

Please amend The Queen's Medical Center radioactive materials license to add Shay J. Lee, M.D. as an Authorized User for therapeutic administration of SIR-Spheres microspheres. Dr. Shay J. Lee has completed microsphere-specific training provided by Sirtex Medical Ltd. for new users and is currently listed on our license as an AU for 35.300 use. Documentation for this microsphere-specific training is enclosed.

Please contact the RSO, Brian Oyadomari, at (808) 691-4884 or email at boyado@queens.org if any additional information is needed. Thank you.

Sincerely,

Darlena Chadwick
Vice President, Patient Care

Attached:

1. Training certification for Shay J. Lee, M.D.

PUBLIC

- Immediate Release
- Normal Release

NON-PUBLIC

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

Reviewer: RWC Date: 9-19-12

SI TeX

SIRTEX MEDICAL, INC.
300 Unicorn Park Drive
Woburn, MA 01801
Tel: 978 642 3000

July 11, 2012

Dr. Shay Lee, MD
Nuclear Medicine
The Queen's Medical Center
1301 Punchbowl Street
Honolulu, HI 96813

Dear Dr Lee:

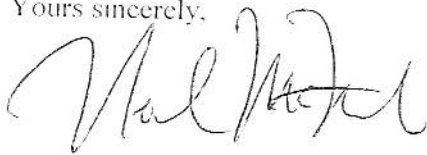
Re: SIR-Spheres® Microspheres Authorized User Training and Certification

This letter certifies that on 7/10/2012, 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 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 physical presence of a Sirtex proctor to attend your *in-vivo* cases.

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

Yours sincerely,



Neal McMahon
Regional Sales Manager

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



DATE
09/18/2012

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE

The Queen's Medical Center
ATTN: Brian Oyadomari
Radiation Safety Officer
1301 Punchbowl Street
Honolulu, Hawaii 96813

LICENSE NUMBER

53-16533-02

MAIL CONTROL NUMBER

579112

LICENSING AND/OR TECHNICAL REVIEWER

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This is to acknowledge the receipt of your:

LETTER and/or APPLICATION DATED: 09/07/2012

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 Boulevard
Arlington, TX 76011-4511
(817) 200-1103 or (817) 200-1140

9/18/12

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 02230
Status Code: Pending Amendment
Fee Category: 3E 7C
Exp. Date:
Fee Comments: CODE 23
Decom Fin Assur Req: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: QUEEN'S MEDICAL CENTER, THE
Received Date: 09/17/2012
Docket Number: 3014522
Mail Control Number: 579112
License Number: 53-16533-02
Action Type: Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: Carol L. Hice

Date: 9/18/12

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: _____