

August 10th, 2009

Ms. Sandra Gabriel, Senior Health Physicist
U.S. NRC Region I
Nuclear Materials Section B
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Br-1

Re: License Amendment request for NRC Radioactive Materials License #: 47-09576-01
(St. Mary's Medical Center, locate in Huntington, West Virginia)

03003388

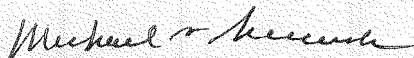
Dear Sandy:

We are currently authorized for SIR-Spheres yttrium-90 (Y-90) insoluble resin microspheres under 10 CFR 35.1000. As you may know, Sirtex will be increasing the minimum activity per vial of their SIR-Spheres Y-90 product. Therefore, we wish to correspondingly increase our possession limits for up to 207 mCi per vial with a maximum possession limit of 1000 mCi total.

For your reference, a copy of the product modification memo from Sirtex is attached.

We appreciate your consideration of this amendment request. If you have any questions regarding this request or should you need any further information, please do not hesitate to contact us.

Sincerely yours,



Michael G. Sellards
President and Chief Executive Officer



James T. Norweck, MS, DABR
Radiation Safety Officer
Cell: 304-710-0172
jnorweck@radiology-inc.com

Enclosures

144099
NRC/RONI MATERIALS-002



SIRTEX MEDICAL INC.
16 Upton Drive, Unit 2-4,
Wilmington, MA 01887 USA

Phone: +1 888 474 7839
Fax: +1 978 229 9585
Website: www.sirtex.com

MEMORANDUM

TO: ALL SIR-Spheres microspheres Users, RSO's
FROM: Linda Teigland
DATE: August 4, 2009
SUBJECT: License Amending Information

In order to use our product, you will need to amend your Radioactive Materials License which will require the following information:

Issuer: The Commonwealth of Massachusetts, Radiation Control program

License No: MA-1229-D-101-S

Distributor: Sirtex Wilmington LLC
16 Upton Drive., #2-4 Wilmington, MA 01887

Sealed Source Model Designation: Sirtex Medical Limited SIR-Spheres® microspheres

Isotope: Yttrium-90

Maximum Activity: 5.74 GBq (155 mCi) per vial (minimum requirements)

Sirtex Medical is preparing to launch a change to our SIR-Spheres microspheres product by this Fall. In order to be able to receive the improved product, we respectfully request that you urgently seek to amend your license to a minimum of 155 mCi per vial of SIR-Spheres microspheres. We will send you additional information as the date for the product improvement gets closer, but please submit the appropriate paperwork as soon as possible so that your facility will be able to receive the product. Once the product improvement is made, the old product will no longer be available. Without the proper documentation in place we will not be able to provide your physicians and patients with our product. Thank you in advance for your assistance with this matter.

This is to acknowledge the receipt of your letter application dated

8/10/09, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (47-09576-01) 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

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 144099.
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 (R1)
(6-96)

Sincerely,
Licensing Assistance Team Leader