THE GEORGE WASHINGTON UNIVERSITY HOSPITAL

UHS Universal Health

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August 31, 2010

Tara Weidner
Health Physicist
Medical Branch
Division of Nuclear Safety
U.S. Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

Subject: District Hospital Partners, L.P.
D/B/A The George Washington University Hospital
Request for Amendment to Material License

Reference: License No.: 08-30607-01
Docket No. 030-35424

Dear Ms. Weidner:

We wish to apply for an amendment to the District Hospital Partners, L.P. Material license.

On July 15, 2009, NRC approved our request to amend the Material License to include the use of yttrium-90 (Y-90) microspheres (TheraSpheres and SIR-Spheres) for the treatment of primary (hepatocellular) and secondary (metastatic) liver malignancies. Recently, SIRTEX MEDICAL INC., has made a change on SIR-Spheres microspheres maximum activity level from 4 GBq (108 mCi) to 7 GBq (189 mCi) for added flexibility in treatment timing (see Attachment- I & II). Please note that the SIR-Sphere dose administration protocol and dose calculation method remain the same.

Accordingly, we are requesting a further amendment to the Material License to increase SIR-Spheres Y-90 microspheres maximum activity per vial limit from 4 GBq (108 mCi) to 7 GBq (189 mCi). Our total possession limit for Y-90 SIR-Spheres may remain the same at 37 GBq (1 Ci) level.

900 23rd STREET, N.W. • WASHINGTON, DC 20037 • (202) 715-4000
www.gwhospital.com

573466

NMSS/RGN1 MATERIALS-002

A patient has been scheduled for the treatment with SIR-Sphere Y-90 microspheres during the 3rd and 4th week of September, 2010. In order to avoid delay in the treatment, while waiting for approval of our amendment request, SIRTEX agreed to supply us with 4 GBq(108 mCi) doses, as per our current license limit.

We are committed to fulfill our license conditions for the use of Y-90 microspheres.

If you have any questions, please contact Anisuzzaman Chowdhury, Ph.D. at 202-715-4959. He can be paged by dialing 202-715-4164.

Sincerely,

Kimberly D. Russo
Chief Operating Officer

Enclosure: 1. SIRTEX MEMORANDUM
2. SIR-SPHERES MICROSPHERES SHIPMENT INFORMATION SHEET.

AC083110

Attachment-I

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 12, 2010
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: 7 GBq (189 mCi) per vial

SIRTeX

SIR-SPHERES® MICROSPHERES

Shipment Information Sheet

Q: What is being changed?

A: Effective August 3, 2010, SIR-Spheres microspheres will ship to customers with the intent of the shipment being received a day prior to calibration date & time.

Q: When is the calibration date & time?

A: The specific day & time when the SIR-Spheres microspheres contained within the shipping vial have an activity level of 3GBq +/- 10% or 81mCi +/- 10%. Assuming there is no delay in receiving the shipment, the calibration date & time will be 6:00pm EST the day after shipment is received. Please see the pot label for calibration date & time information.

Q: Why is SIRTEX changing the shipment window of SIR-Spheres microspheres?

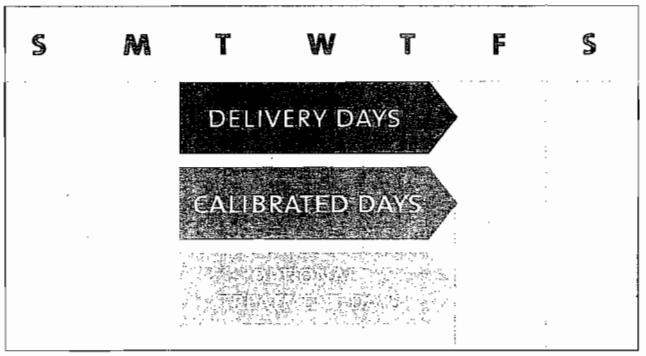
A: The intent of this change is to meet customer requests for added flexibility in treatment timing and to avoid potential issues caused by any shipping delays.

Q: How is the SIR-Spheres microspheres activity level measured before and after calibration date?

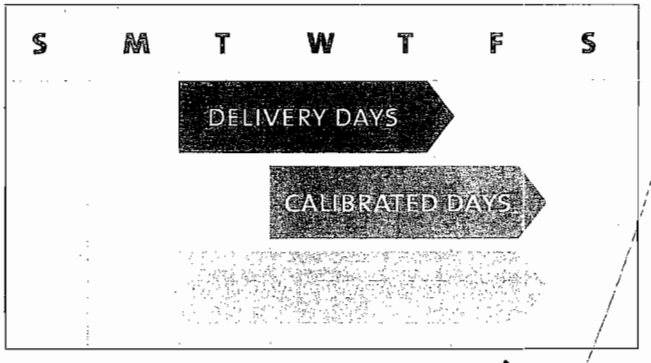
A: The Radioactive Decay Chart posted on the back of this document lists the SIR-Spheres microspheres activity level up to 36 hours before and 24 hours following calibration date & time.

Previous/New shipment examples and considerations:

Prior to August 3, 2010



August 3, 2010 and After



Notes

- *Delivery Days remain the same (if not affected by shipment delays).*
- *New Calibration Day is day after delivery*
  Tuesday delivery = Calibrated for Wednesday
  Wednesday delivery = Calibrated for Thursday
  Thursday delivery = Calibrated for Friday
- *Customer must still order dose **no later** than Tuesday the week prior for delivery.*

SIR-SPHERES IS A REGISTERED TRADEMARK OF SIRTEX SIR-SPHERES PTY LTD
SIRTEX MEDICAL INC. 16 WIGWAM DRIVE WILMINGTON, MA 01887 P: (888) 474-7839 | F: (978) 229-9585 WWW.SIRTEX.COM

This is to acknowledge the receipt of your letter/application dated 8/31/2010, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (08-30607-01)

[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

_____.

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** 573466.
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