

Brl

June 14, 2010

Penny Lanzisera
Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region 1
Division of Nuclear Materials Safety
475 Allendale Road
King of Prussia, PA 19406-1415

RECEIVED
REG 1
2010 JUN 21 PM 12:31

RE: Bridgeport Hospital Amendment Request
License No. ~~06-10160-01~~ 06-01060-01
Docket Number 030-01247
Mail Control No. 144426

Dear Penny Lanzisera,

Per communications received on May 17, 2010 from Sirtex Medical Inc., (see enclosed) it was requested that activity per vial be listed preferentially as 189mCi as a maximum in addition to stating 132mCi per vial as a minimum as we had previously requested and were approved. Therefore, we would have a maximum of 378mCi at any time.

If you should have any questions please feel free to contact me at 203-384-3169.

Sincerely,



Michael R. Tatta
Director Imaging Services

Cc: Scott Williams, MD
Patrick Schmincke

attachment

573001
267 Grant Street
P.O. Box 5000
Bridgeport, CT 06610-0120
203.384.3000

NMSS/RGN1 MATERIALS-002



Sirtex Medical Inc.
16 Upton Drive, #2-4
Wilmington, MA 01887

Telephone: (888) 474-7839
Fax: (978) 229-9585
Web: www.sirtex.com

May 17, 2010

RE: Sirtex Delivery Changes

Dear SIR-Spheres® microspheres users and RSO's,

We would like to provide an update on our intent to change the delivery window of SIR-Spheres microspheres in order to meet customer requests and minimize shipping delays.

The licensing requirements have been sent out, via your Regional Sales Representatives, to the appropriate people within your hospital in order to begin the process of amending your license. We have been asked to additionally advise you that our maximum activity per vial as stated in our Sealed Source and Device Registry is 189 mCi. As previously stated, the minimum activity is 132 mCi per vial and the maximum activity that you should put on your license is 189 mCi.

Currently we are planning to "go live" with this change in July. However, this is dependent on hospitals amending their licenses to the higher activity so that the SIR-Spheres microspheres can be received the day prior to calibration instead of the day of calibration (treatment).

If you have not already sent in an amendment for your license, we request that you do so as soon as possible to minimize shipping delays. As we progress we will provide another update with the intended date for changeover.

Thank you for your time.

Regards,

Linda Teigland
Director of Operations US

You may require the following information in order to amend your license:

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

Sealed Source Model Designation: Sirtex Medical Limited
SIR-Spheres® microspheres Y001

Isotope: Yttrium-90

Required Activity: 4.89 GBq (132 mCi) per vial (minimum requirements)
7.00GBq (189 mCi) per vial (maximum)

Please contact your local representative if you need assistance or have any questions.