



February 8, 2022

U.S. Nuclear Regulatory Commission
Nuclear Materials Licensing Section
Region III
2443 Warrenville Road
Lisle, IL 60532-4351

RE: U.S.NRC Radioactive Materials License No. 09-32781-03MD
Jubilant DraxImage, Inc., d/b/a Jubilant Radiopharma
2795 Universal Drive
Saginaw, MI 48603

Dear License Reviewer:

Please amend the above referenced radioactive material license to reflect the following modification:

1. Please amend line items 6 through 9 to authorize the receipt, preparation, storage, and distribution of Yttrium-90 impregnated resin microspheres, Sirtex Medical Limited SIR-Spheres Microspheres distributed by:

Sirtex Wilmington LLC 16 Upton Drive, Unit 2-4
Wilmington, MA 01887
Sealed Source and Device Registration Number: MA-1229-D-101-S
License Issuer: The Commonwealth of Massachusetts, Radiation Control Program

Jubilant Radiopharma requests a separate line item for Yttrium-90 impregnated resin microspheres (Sirtex Medical Limited SIR-Spheres Microspheres) with a 1 Ci possession limit. Unit doses will only be shipped to medical licensees authorized to receive SIR-Spheres, in agreement with their authorized limits.

Based on a review of our license commitments and a review of the Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance, April 20, 2021, Revision 10.2 we believe that our radiation safety program contains appropriate detection equipment and survey protocols. We are however, submitting alternative training & experience commitments which demonstrate Authorized User qualifications. We therefore confirm the following:

A Jubilant Pharma Company

OUR VALUES



Radiopharmacies Division

790 Township Line Road, Suite 325, Yardley, PA 19067

Telephone: (215) 550-2770

www.jubilantradiopharma.com

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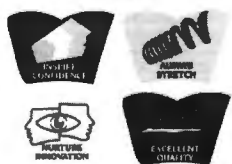


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- A. Authorized Nuclear Pharmacist will meet the training and work experience requirements per 10 CFR 35.2, 10 CFR 35.55, and 10 CFR 35.59.
- B. Additional training will be provided by the manufacturer (Sirtex) or an Authorized Nuclear Pharmacist who has been trained on Y-90 SIR-Spheres Microsphere for personnel manipulating doses to include:
 - 1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - 2. Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters and dose calibrators;
 - 3. Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to clients;
 - 4. Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures.
- C. Doses will only be prepared and labeled by an Authorized Nuclear Pharmacist.
- D. Authorized Nuclear Pharmacist will not be administering any doses.
- E. Distributed doses will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling, using, and storing sources.
- F. Doses will not be distributed beyond an expiration date as provided by the manufacturer.
- G. Only doses that have been prepared in accordance with manufacturer's instructions will be distributed.
- H. Dose calibrators used will be appropriately recalibrated to ensure accurate measurements according to manufacturer's instructions (i.e. geometry, window, etc.).
- I. Inventory, labeling and waste disposal of Yttrium-90 SIR-Spheres is provided as follows:
 - 1. Inventory: The Yttrium-90 SIR-Spheres are supplied by Sirtex in a single-dose 10mL vial which are prepared and dispensed to an authorized recipient. No inventory is maintained.
 - 2. Labeling: We confirm that vials, syringes and radiation shields will be labeled with radioactive device (i.e. SIR-Spheres) when the Yttrium-90 SIR-Spheres are not labeled by the manufacturer.

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3. Waste Disposal: In December 2007, Sirtex moved manufacturing of its SIR-Spheres microspheres from use of partial reactor-generated Yttrium to the use of 100% carrier free Yttrium-90 which has a specified purity of 99.99%. This means it is no longer possible to have the stray isotopes as previously reported. Since that date there have been no reports of the product containing any other isotope. (See Attached).

Please forward the amended radioactive materials license to Jubilant Draximage Inc. d/b/a Jubilant Radiopharma 790 Township Line Road, Suite 325, Yardley, PA 19067. Should you have specific questions about this amendment request, you may contact me at (407)-257-8998 or by email at craig.kinne@jubl.com.

Sincerely,

**Craig
Kinne**

Digitally signed
by Craig Kinne
Date:
2022.02.08
14:57:17 -05'00'

Craig S. Kinne, CHP, MHP
Jubilant DraxImage Inc. d/b/a Jubilant Radiopharma
Radiopharmacies Radiation Safety Officer
Mobile: (407) 257-8998
e-mail: craig.kinne@jubl.com

Attachment

cc: *Dr. Kaylene Evans, Pharm. D- Authorized Nuclear Pharmacist/Pharmacy Manager*
Dr. Robert Bjurstrom, Pharm. D. - Authorized Nuclear Pharmacist/RSO
Debra Rogers, MA - Paralegal, Licensing and Regulatory Coordinator
Jubilant Radiopharma Quality and Safety Department

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OUR VALUES



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SIRTEX MEDICAL LIMITED

ABN 35 078 166 122

Level 33, 101 Miller Street
North Sydney NSW 2060
Australia

PO Box 6244 North Sydney NSW 2059

Phone: 61 2 9964 8400
Fax: 61 2 9964 8410
Website: www.sirtex.com

SIR-SPHERES® MICROSPHERES PURITY

In December 2007, Sirtex moved manufacturing of its SIR-Spheres microspheres from use of partial reactor-generated Yttrium to the use of 100% carrier free Yttrium 90 which has a specified purity of 99.99%. This means it is no longer possible to have the stray isotopes as previously reported. Since that date there have been no reports of the product containing any other isotope.

This information covers all products manufactured at all locations, which are Sirtex Wilmington (USA), Sirtex Singapore and ANSTO ARI in Sydney, Australia.

A handwritten signature in black ink, appearing to read "Heather Winslade".

Heather Winslade
Global Head of Regulatory Affairs and Quality Assurance
September 13, 2011