



Mary Washington Hospital

MediCorp

1001 Sam Perry Boulevard
Fredericksburg, VA 22401
(540) 741-1100

NMSB1

16 January 2008

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pennsylvania
19406-1415

03008082

RE: NRC Material License 45-00935-02

Dear Sir or Madam:

2008 JAN 18 PM 12:19

RECEIVED
REGION I

Please amend the above referenced license to include Y-90 microspheres for use in the Model SIR-Spheres, Brachytherapy Device. SIR-Spheres microspheres consist of biocompatible microspheres containing yttrium-90 with a size between 20 and 60 microns in diameter. Yttrium-90 is a high-energy pure beta-emitting isotope with no primary gamma emission. The maximum energy of the beta particles is 2.27 MeV with a mean of 0.93 MeV. The maximum range of emissions in tissue is 11 mm with a mean of 2.5 mm. The half-life is 64.1 hours. In therapeutic use, requiring the isotope to decay to infinity, 94% of the radiation is delivered in 11 days. SIR-Spheres microspheres are a permanent implant.

Authorization is requested for 3.0 GBq (81 mCi) maximum activity per vial and for a 5 vial possession limit of 15 GBq (405 mCi) provided by SIRTex Medical Ltd in accordance with FDA requirements. The requested activity and multiple activity holdings are required for the anticipated administration into malignant hepatic tumors. Sir-Spheres will be used at 1001 Sam Perry Boulevard, Fredericksburg Virginia.

Please also amend our license to add 35,1000 for Dr. Neil Green as the Authorized User for the Y-90 SIR Spheres. Dr. Green will successfully complete supervised work experience including at least three cases for SIR-Spheres.

If you have any questions or if I may be of further assistance, please contact me at your convenience.

Sincerely,

Linda Prowett, BLS, CNMT, NCT
Radiation Safety Officer
540-741-1580

Marie Fredrick, RT(R), MJ, CRA
Vice President,
Ambulatory Services and Properties

141630

This is to acknowledge the receipt of your letter/application dated

1/16/2008, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 45-00935-02
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** 141630.
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