## WEST VIRGINIA UNIVERSITY HOSPITALS

## September 18, 2007

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U.S. Nuclear Regulatory Commission Sandra Gabriel, Sr. Health Physicist Medical Branch, Region I 475 Allendale Road King of Prussia, PA 19406-1415

## Subject: License Amendment SIR-Spheres, Yttrium 90 Microspheres

## Re: West Virginia University Hospitals NRC License No. 47-23066-02, Docket 030-20233

Dear Ms. Gabriel,

West Virginia University Hospitals Inc, hereby requests an amendment to radioactive material license No. 47-23066-02 to include Y-90 as microspheres for use in the Model SIR-Spheres, Brachytherapy Device. Authorization is requested for 3.0 GBq (81 mCi) maximum activity per vial and for a 5 vial maximum possession limit of 15.0 GBq (405 mCi) provided by SIRTEX Medical Ltd in accordance with FDA requirements.

The requested activity and multiple activity holdings are required in brachytherapy afterloader for the anticipated administration into malignant hepatic tumors. The proposed changes to our radioactive material medical use program have been approved by the Radiological Safety Committee. We are seeking to begin the treatments in mid-October 2007.

- I. The Licensee shall assure that Authorized users shall meet the training and experience requirements of 10 CFR35.490 or 10 CFR 35.940 as well as the specific vendor training in the use of the microspheres and the microspheres delivery system.
- II. The Licensee shall assure that a written directive be palced according to the US NRC "Licensing Guidance - TheraSphere and SIRSpheres Yttrium-90 Microspheres".
- III. The Licensee shall implement all the Radiation Safety Procedures that apply to the use of Y-90 microspheres or delivery system.

We would appreciate it if you could expedite this process.

Sincerely yours,

Stephen Tancin Vice President

Nasser Razmianfi

Director and Radiation Safety Officer

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NMSS/RGN1 MATERIALS-002

Hospital Administration

Ruby Memorial Hospital West Virginia University Children's Hospital Jon Michael Moore Trauma Center Chestnut Ridge Hospital Medical Center Drive Morgantown WV 26506-8059 Phone: 304-598-4200