

October 9, 2008

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Licensing Materials Section  
Nuclear Materials Branch  
U. S. Nuclear Regulatory Commission, Region 1  
475 Allendale Avenue  
King of Prussia, PA 19406-1415

Dear License Reviewer:

With regard to mail control number 142665 for our Radioactive Materials License No. 29-03382-01, we are committing to the following items below for our Sir-Spheres® amendment request:

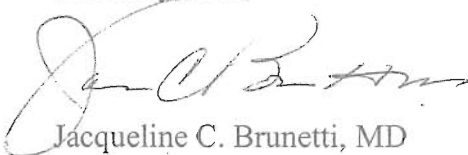
- (1) The authorized user, Dr. Rosenbluth, will complete his first three hands-on Sir-Spheres® cases supervised in the physical presence of a manufacturer representative.
- (2) We will submit documentation of completion of the three hands-on supervised cases to the NRC Region I office within 30 days of completion of the third case.
- (3) We will provide training in the manufacturer's procedures to all individuals involved in Y-90 microsphere use, commensurate with their duties. This training will be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.
- (4) We confirm that the facilities for dose preparation and administration will be the same as for our Therasphere® license.
- (5) We request incorporation into our license a change process for our TheraSphere® and Sir-Spheres® programs similar to 10 CFR 35.26. This will allow future changes to our program, without a license amendment, under the following conditions:
  - a) The revision is in compliance with the regulations; and
  - b) The revision is based upon NRC's current guidance for TheraSphere® and SIR-Spheres® Y-90 microspheres 35.1000 use posted on the NRC Web site; and
  - c) The revision has been reviewed and approved by our Radiation Safety Officer and management; and
  - d) The affected individuals will be instructed on the revised program before the change is implemented; and

e) We will retain a record of each change for five years; and

f) The record will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

If you have any questions regarding this application, please contact Allan Caggiano, Chief Medical Physicist at (201)-541-6369 (email: [caggiano@holyname.org](mailto:caggiano@holyname.org)).

Sincerely,



Jacqueline C. Brunetti, MD  
Radiation Safety Officer

JCB:md

cc: Michael Maron, President & CEO