



Community
Health Network

Community Hospital East
1500 North Ritter Avenue
Indianapolis, IN 46219

April 27, 2007

Ms. Colleen Casey
USNRC
Region III
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352

Dear Ms. Casey:

In correspondence dated January 26, 2006 and May 23, 2006 pertaining to the amendment of Materials License 13-06009-01 to permit the use of MDS Nordion Therasphere yttrium-90 microspheres and Sirtex Medical SIR-sphere yttrium-90 microspheres we made the following commitments:

"IV. C. We commit that the approved authorized user will provide direct supervision that is, be physically present, and have authority for radiation safety.

D. We commit that the authorized user will be the only individual operating the device during patient treatment. "

These commitments were recommended in the Sirtex Y-90 MICROSPHERE GUIDE.

As these commitments are not required in the USNRC Microsphere Brachytherapy Sources and Devices Licensing Guidance document dated 2/25/2005, we would like to be released from them.


Justification for this request includes limiting the number of persons in the interventional radiology suite during the procedure and limiting the number of individuals who interact with the patient set-up and therasphere delivery system. The interventional radiologist places the catheter in the patient's hepatic artery and verifies location. The process is performed under sterile conditions. Authorized user delivery of the yttrium-90 microspheres consists in turning stop-cocks in the appropriate direction and flushing the microspheres through the catheter placed by the interventional radiologist. These steps would better be done by the interventional radiologist who is more familiar with the operation of the directional stopcocks, sterile procedure and the condition and anatomy of the patient's vasculature.

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Elimination of the commitments described above will reduce the number of people exposed to the Y-90 radiation and is not expected to compromise patient safety or outcome of the procedure. Reducing the number of different individuals touching the delivery system should reduce the possibility of a medical event through a spill or routing the dose into the waste vial.

Thank you for your guidance and assistance with gaining authorization to use this material.

Sincerely,

A handwritten signature in black ink, reading "Andrea D. Browne". The signature is fluid and cursive, with a long horizontal stroke at the end.

Andrea D. Browne, Ph.D.
Radiation Safety Officer



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