

**From:** [Gallagher, Robert](#)  
**To:** [ruth.shanley@wchn.org](mailto:ruth.shanley@wchn.org)  
**Subject:** Request for Additional Information - Control No. 591696  
**Date:** Tuesday, October 18, 2016 12:02:00 PM  
**Attachments:** [image001.png](#)

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Ruth Shanley  
Western Connecticut Health Network

RE: Danbury Hospital Request to Add Two Authorized Users for Yttrium-90 SIR-Spheres for Treatment of Liver Tumors

**PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL**

License No. 06-08544-01  
Docket No. 03001274  
Control No. 591696

Dear Ms. Shanley,

This is regarding your request to amend License Number 06-08544-01 to add authorization for use of Yttrium-90 SIR-Spheres for treatment of liver tumors to Todd Everett, M.D. and Joseph Santoro, M.D. In order for us to continue our review of your request additional information is necessary.

- A. Please submit documentation of training for both Todd Everett, M.D. and Joseph Santoro, M.D. which includes the following:
1. 80 hours of classroom and laboratory training for byproduct material, including Y-90 microspheres, which may be concurrent with training received to support their board certifications.
    - a. Radiation physics and instrumentation
    - b. Radiation protection
    - c. Mathematics pertaining to the use and measurement of radioactivity
    - d. Radiation biology
- B. The information submitted for Joseph Santoro, M.D. included a copy of his subspecialty certification in Vascular and Interventional Radiology by the American Board of Radiology dated November 7, 2005. 10 CFR 35.59 "Recentness of Training" requires the training to have been obtained within the 7 years preceding the date of the application or the individual must have had related continuing education and experience since the required training and experience was completed. Please submit documentation of related continuing education and experience Dr. Santoro completed within the past 7 years related to Vascular and Interventional Radiology.

You may find the guidance titled "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance" helpful in preparing your response. The document may be found at [www.nrc.gov/docs/ML1535/ML15350A099.pdf](http://www.nrc.gov/docs/ML1535/ML15350A099.pdf).

REC'D IN LAT 10/18/2016

We will continue our review upon receipt of the above requested information. Please contact Robert Gallagher at (610) 337-5182 with any questions.

Regards,

Robert L. Gallagher  
Health Physicist  
U.S. NRC, Region I  
2100 Renaissance Blvd.  
King of Prussia, PA 19406  
(610) 337-5182 office  
(610) 337-5269 fax

