

## Walt, GERALYN

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**From:** Gallagher, Robert  
**Sent:** Wednesday, June 22, 2016 2:20 PM  
**To:** mariosdabr@me.com  
**Cc:** Gallagher, Robert  
**Subject:** Request for Additional Information - Control No. 590794

License No. 52-21325-01  
Docket No. 03020510  
Control No. 590794

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

Mr. Rios Gerena,

This letter is in regards to the application dated April 4, 2016 requesting the addition of Javier Nazario, M.D. as an authorized user for Yttrium-90 (Y-90) microspheres, specifically SIR-Spheres®, to NRC License No. 52-21325-01 issued to Centro Medico del Turabo, Inc. d/b/a Hospital HIMA – San Pablo Bayamon. This will also add authorization for your facility to use Y-90 for manual brachytherapy use in the Sirtex Medical Limited SIR-Spheres. In order to continue our review more information is necessary.

1. You committed to providing training in your procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed and that this training would be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres. Please confirm that your Radiation Safety Officer will attend this training.
2. The application dated April 4, 2016 states that you intend on purchasing an Atomlab 500 dose calibrator to measure the Y-90 SIR-Spheres. Do you intend on using this new dose calibrator in your current Hot Lab and do you currently possess it?
3. Provide the manufacturer's name for the microspheres that you are requesting.
4. You committed to follow the manufacturer's procedures. Please confirm that you will follow the manufacturer's procedures for determining shunting to non-treatment sites prior to treatments.

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

Regards,

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