

From: [Nguyen, Janice](mailto:Nguyen_Janice)
To: joan.merton@midhosp.org
Subject: NRC Request for Information - Mail Control Number 577731
Date: Thursday, August 16, 2012 1:18:00 PM

Licensee: Middlesex Hospital
License Number: 06-00649-03
Docket Number: 030-01242
Mail Control Number: 577731

Dear Ms. Merton,

Could you please reply back to this email to confirm receipt?

This is in reference to your letters dated June 7 and 27, 2012, requesting to amend Nuclear Regulatory Commission License No. 06-00649-03.

In order to continue our review, we need the following additional information:

1. Please resubmit the NRC Form 313A (AUT) for Adam Abou-Elias, M.D. in its entirety. Specifically, the first half of page 4 had not been filled out and page 5 of the form had been omitted during the original submission. Please have the preceptor complete the top of page 4 and all of page 5, resign page 6, and then resubmit in full.
2. In regards to the addition of Nordion TheraSpheres, please make the following commitment in accordance with our Licensing Guidance – TheraSphere and SIR-Spheres Yttrium-90 Microspheres revised June 2012:

Administration of Y-90 microspheres must be performed in accordance with the written directive. If the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g. artery spasm or sudden change in blood pressure), the AU should document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive should include the reason for not administering the intended dose/activity, the date, and the signature of an AU for Y-90 microspheres.

3. Please submit a copy of Jeffrey Takahashi, M.D.'s subspecialty certificate in interventional radiology.
4. Please submit a copy of the course syllabus for the 8 hour TheraSphere training program conducted at Northwestern University on October 5, 2011.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits, see our toolkit index page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Please make sure that the response is signed by senior management. You may respond to my attention in writing by letter, email (if letter is scanned into a pdf format), or fax (610-

337-5269), referencing mail control number 577731.

If we do not receive a reply from you by August 31, 2012, we will assume that you do not wish to pursue your amendment. Please feel free to contact me with any questions you may have.

Please note that the office of the Region I USNRC Division of Nuclear Materials Safety has moved effective May 9, 2012. Our new address is:

U. S. Nuclear Regulatory Commission
Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

Thank you in advance for your help.

Jan Nguyen

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