

From: [Lanzisera, Penny](mailto:Lanzisera.Penny)
To: joan.merton@midhosp.org
Subject: Amendment request
Date: Friday, March 04, 2016 11:38:00 AM

L.N. 06-00649-03
D.N. 03001242
Mail Control 590132
Licensee: Middlesex Hospital

In order to continue our review of your amendment request dated January 21, 2016, we need the following additional information in accordance with the guidance for microsphere use found at <http://pbadupws.nrc.gov/docs/ML1535/ML15350A099.pdf>:

Dr. Bruce Kovalenko is currently listed on your NRC license for 35.100, 35.200, and I-131<33 millicuries. To support your request to add Therasphere use to Dr. Kovalenko's authorization, please submit:

1. subspecialty certification in interventional radiology by either the American Board of Radiology or the American Osteopathic Board of Radiology
2. 80 hours of classroom and laboratory training for byproduct material, including Y-90 microspheres, which may be concurrent with training received to support Board Certification in Diagnostic Radiology that includes:
 - a. Radiation physics and instrumentation;
 - b. Radiation protection;
 - c. Mathematics pertaining to the use and measurement of radioactivity; and
 - d. Radiation biology.
3. If Dr. Michael Soulen (sp?) is providing a preceptor attestation and provided training on Therasphere use to Dr. Kovalenko, please submit a copy of the permit issued by the University of Pennsylvania to the preceptor, Dr. Michael Soulen (sp??), approving him for Therasphere use. Alternatively, you may submit the first three patient cases completed by Dr. Kovalenko that were hands-on and supervised in the physical presence of a manufacturer representative for Theraspheres at a later date, as described below.

In addition, we understand that Dr. Kovalenko has completed 1 patient administration and will complete 2 additional patient cases. Please confirm that Dr. Kovalenko will complete the additional two hands-on patient cases supervised in the physical presence of a manufacturer representative and that you will submit documentation from the manufacturer to the NRC within 30 days of when all three patient cases have been satisfactorily completed.

Your reply must be an originally signed and dated letter. The letter may be scanned and submitted as a pdf document attached to an email; or it may be transmitted by facsimile to (610) 337-5269; or it may be sent by regular mail. If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your amendment request.

Finally, we understand that Dr. Takahashi is no longer at Middlesex Hospital and that he was your sole authorized user for Therasphere use. If you are unable to complete the submittal naming Dr. Kovalenko for this use within 30 days, please note that Dr. Takahashi along with the use for Theraspheres will be removed from your license.

Please respond by e-mail to acknowledge that you have received the e-mail request for additional information.

Thank you for your assistance,

Penny Lanzisera
Senior Health Physicist
US NRC Region I