

**From:** [Abogunde, Maryann](mailto:Abogunde.Maryann)  
**To:** [mike.bohan@yale.edu](mailto:mike.bohan@yale.edu)  
**Subject:** NRC request for additional information - License Amendment for Bridgeport Hospital  
**Date:** Wednesday, August 07, 2013 1:08:00 PM

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Licensee: Bridgeport Hospital  
License No.: 06-01060-01  
Docket No.: 030-01247  
Control No.: 581063

Dear Mr. Bohan:

Please send a return e-mail to confirm that you received this message.

In order to continue our review of your amendment request dated May 30, 2013, we need the following additional information with regards to adding Terence W. Hughes, M.D., as an authorized user (AU) for Yttrium-90 SIR-Spheres use:

1. With regards to work experience under the supervision of an AU for Y-90 SIR-Spheres, the information provided in Item 3.b. of the NRC Form 313A (AUT) submitted appears to be incomplete. Please confirm that the training and experience received by the proposed AU, Terence W. Hughes, also involved:
  - a. Evaluation of each patient or human research subject for the dose/activity of Y-90 SIR-Spheres to be administered to each treatment site; and
  - b. Follow up and review of each patient's or human research subject's case history for Y-90 SIR-Spheres.
2. With regards to documentation of the 15 cases of clinical use of Y-90 SIR-Spheres provided in Item 3.c. of the NRC Form 313A (AUT), please confirm that the clinical use training also involved **hands-on operation of the delivery system** and **use of safety procedures** for Y-90 SIR-Spheres.

You may respond to my attention in writing by letter, email (if letter is scanned into a pdf format), or fax to 610-337-5269. Please reference Mail Control No. 581063 in your response.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Thank you for your assistance,

Maryann Abogunde  
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