

**From:** Tripp, Lester  
**To:** [sbull@stamhealth.org](mailto:sbull@stamhealth.org)  
**Subject:** Request for Additional Information in Support of Amendment Request  
**Date:** Monday, March 31, 2014 1:12:00 PM  
**Attachments:** [NRC 313A\(AUS\).pdf](#)  
[nrc313a\(aud\).pdf](#)  
[nrc313a\(aut\).pdf](#)

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Licensee: Stamford Hospital  
License No. 06-06697-02  
Docket No. 03001265  
Control No. 582989  
Attn: Sarah Bull  
Radiation Safety Officer  
Date: March 31, 2014  
SUBJECT: STAMFORD HOSPITAL, REQUEST FOR ADDITIONAL INFORMATION  
CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 582989

Dear Ms. Bull:

This correspondence is in reference to your application dated January 17, 2014 requesting to amend Nuclear Regulatory Commission License No. 06-06697-02. In order to continue our review, we need the following additional information:

1. You have requested that Sean W. Dowling, M.D. be authorized for the use of Ir-192 permitted by 10 CFR 35.600 in an HDR unit. Due to changes in NRC regulations, the certification submitted for Dr. Dowling is not recognized by the NRC pursuant to 10 CFR Part 35. Beginning in June 2007, ABR certificate in Radiation Oncology is acceptable only if "AU eligible" appears above the ABR seal. Please see the following link for approved board certification:

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

10 CFR 35.57(b)(1) states, in part, that physicians identified as authorized user for the medical use of byproduct material on a Commission license before October 24, 2002, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subpart D. You have submitted documentation from Yale-New Haven Hospital (YNHH) that Dr. Dowling was an authorized user for all forms of brachytherapy, including high dose rate brachytherapy. 10 CFR 35.59 states, in part, that the training and experience specified in Subparts B and D must have been obtained within the 7 years preceding the date of this application or the individual must have related continuing education and training since the required training and experience was completed. We will need documentation of Dr. Dowling's continuing training and experience since he was listed as an authorized user under the Yale-New Haven Hospital (YNHH) Medical Broad Scope license in February 1992. NRC Form 313A (AUS) is attached to document continuing training and experience in the use of Ir-192 in HDR remote afterloading units. You may use this form to describe training and submit preceptor attestation provided by Memorial Sloane Kettering and others if applicable.

2. You have requested that Gregory D'Onofrio, M.D. be authorized for the use of licensed material permitted by 10 CFR 35.200. The board certification submitted for Dr. D'Onofrio is not recognized by the NRC pursuant to 10 CFR Part 35. Please see the following link for approved board certifications:

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

Please complete NRC Form 313(A) AUD (attached) for authorization to use license material permitted by 10 CFR 35.100 and 10 CFR 35.200 for documenting Dr. D'Onofrio's training and experience. Please start with Part I, 3.a, *Training and Experience for the Proposed Authorized User*, and then follow the directions accordingly. (You did submit Part II of NRC Form 313(A) AUD, signed by Harvey L. Hecht, M.D. However, you designated a board certification that is not recognized by the NRC in authorizing use of licensed material.

3. You have requested that Salvatore Carbonaro, M.D. be authorized for the use of licensed material permitted by 10 CFR 35.200. The certification submitted for Dr. Carbonaro is recognized by the NRC pursuant to 10 CFR Part 35. Please complete NRC Form 313(A) AUD (attached) for documenting Dr. Carbonaro's training and experience. You may use the *Board Certification Pathway* in Part I, Item 1, then skip to and complete Part II—*Preceptor Attestation* (which was partially completed and signed by Saira Aslam, M.D. from the National Naval Medical Center, Bethesda, Maryland).
4. You have requested that Brian Lazzara, M.D. be authorized for the use of licensed material permitted by 10 CFR 35.100, 35.200, 35.300, and 35.500. We are in receipt of Dr. Lazzara's board certification by The American Board of Radiology in Diagnostic Radiology. This certification will allow us to approve him for 10 CFR 35.100, 35.200, I-131 for diagnostic and therapeutic procedures. In order for us to amend your license as requested, please do the following:
  - a. Complete NRC Form 313(A) AUD (attached) for authorization to use license material permitted by 10 CFR 35.100 and 10 CFR 35.200; and
  - b. Complete NRC Form 313 (A) AUT (attached) for authorization to use licensed material permitted by 10 CFR 35.300 (limited to I-131).

You may use the *Board Certification Pathway* in Part I, Item 1, then skip to and complete Part II—*Preceptor Attestation*, for both forms. Please note that Joseph Mазzie, D.O. wrote a letter dated January 15, 2014, in support of Dr. Lazzara's training and experience and may be able to the requested forms.

5. You have requested that Howard Liu, M.D. be authorized for the use of licensed material permitted by 10 CFR 35.100, 35.200, and 35.300 (except for the treatment of thyroid carcinoma). We are in receipt of Dr. Liu's board certification by The American Board of Radiology in Diagnostic Radiology. In order for us to amend your license as requested, please do the following:
  - a. Complete NRC Form 313(A) AUD (attached) for authorization to use license

- material permitted by 10 CFR 35.100 and 10 CFR 35.200; and
- b. Complete NRC Form 313 (A) AUT (attached) for authorization to use licensed material permitted by 10 CFR 35.300 (limited to less than 33 millicuries of I-131. Please indicate less than or equal to 33 millicuries on Page 1 of NRC Form 313(A) AUT).

You may use the *Board Certification* Pathway in Part I, Item 1, then skip to and complete Part II—*Preceptor Attestation* for both forms.

6. You have requested that Josef R.S. Noga, M.D. be authorized for the use of licensed material permitted by 10 CFR 35.100, 35.200, and 35.300. We are in receipt of Dr. Noga's board certification by The American Board of Radiology in Diagnostic Radiology. However, it is illegible. Please send a clear copy. In order for us to amend your license as requested, please do the following:
  - a. Complete NRC Form 313(A) AUD (attached) for authorization to use license material permitted by 10 CFR 35.100 and 10 CFR 35.200; and
  - b. Complete NRC Form 313 (A) AUT (attached) for authorization to use licensed material permitted by 10 CFR 35.300. (limited to less than or equal to 33 millicuries of I-131. Please indicate that as less than or equal to 33 millicuries on Page 1 of NRC Form 313(A) AUT).

You may use the *Board Certification Pathway* in Part I, Item 1, then skip to and complete Part II—*Preceptor Attestation* for both forms.

7. From discussion with you concerning the facility diagrams submitted, it is our understanding that the only modifications made was the relocation of your Ventilation Room. On your diagram, please show the relocation of your Ventilation Room. If you are releasing the original Ventilation Room for unrestricted use, please send a copy of your close-out survey.
8. From our conversations with you, after the security of your HDR facility is finalized, we understand that you will resubmit the HDR unit request, and that you may send a request for the possession and use of Yttrium-90 microspheres.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://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).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 582989. If you have any technical questions regarding this deficiency letter, please call Lester Tripp at (610) 337-5358.

If we do not receive a reply from you within 15 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Lester Tripp  
Health Physicist  
Medical Branch  
Division of Nuclear Materials Safety