September 4, 2014

License No. 06-06697-02
Docket No. 030-01265
Control No. 584317

Sara Bull
Chief Physicist and RSO
Stamford Hospital
P.O. Box 9317
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Stamford, CT 06904-9317

SUBJECT: STAMFORD HOSPITAL REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT OF LICENSE, CONTROL NO. 584317

Dear Ms. Bull:

This letter is in reference to your application dated January 17, 2014, in which you requested approval for possession and use of Ir-192 permitted by 10 CFR 35.600, and your letter dated May 12, 2014, in which you requested approval for the possession and use of Y-90 microspheres permitted by 10 CFR 35.1000, for 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 Dowling, M.D. be authorized to perform HDR procedures permitted by 10 CFR 35.600. You have submitted NRC Form 313A (AUS) and indicated that you have chosen the *Board Certification Pathway* for him to become an authorized user (AU) of iridium-192 permitted by 10 CFR 35.600. Also as stated on NRC Form 313A (AUS), additional information is needed if the board certification was completed more than 7 years ago and/or if the Board Certification is not accepted by the NRC. This additional information is specified in Item 3. ***Training and Experience for Proposed Authorized User.*** With regard to NRC Form 313A (AUS):

    a. Please completed **3.a.**
    b. Submit a completed section **3.d**. ***Supervised Work and Clinical Experience for 10 CFR 35.690*** signed by a supervising preceptor who is an authorized user for HDR.
    c. Also, the submitted **3.e**., the *Clinical Use of Device* Section indicates that the supervising individual was Harvey Hecht, M.D. for LDR experience under NRC License No. 06-06697-02. We need the supervising Preceptor to be an AU who is an authorized for iridium-192 permitted by 10 CFR 35.600 (HDR).

2. Part 2 of NRC Form 314A (AUS) ***Preceptor Attestation*** has five sections.
    a. The *attestation* to the training and experience for the proposed AU for 10 CFR 35.600 uses is in the second section.
    b. The *attestation* for 10 CFR 35.600 device training is in the third section.

c. The *attestation* of the individual's competency to function independently as an AU for the specific 10 CFR 35.600 devices requested by the applicant is in the fourth section.
d. The fifth and final section request specific information about the *preceptor's* authorization to use material authorized by 10 CFR 35.600 in HDR devices.

The preceptor for 10 CFR 35.600 proposed AU must fill out the second, third, fourth and fifth sections.

3. With regards to your proposed HDR facility;

    a. Please specify the location of your alarming radiation monitor on the facility diagram (e.g., will these be visible to someone who enters the room during source exposure). In addition, please confirm that back-up battery testing will be performed on treatment days before patient treatments;
    b. Please describe the warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for the HDR vault;
    c. Please identify any locations of penetration through shielded barriers (e.g., HVAC ducts or cable pass-through) surrounding the proposed HDR treatment room and describe the shielding of the penetrations;
    d. Please confirm the method used to secure the treatment room door and console keys whenever the unit is not in use or is unattended. Specifically, describe how and where the HDR keys will be secured; and
    e. Please confirm that the unit will not be operated in pulse mode.

4. 10 CFR 35.610 requires that licensees develop written safety procedures for emergency response for HDR units. The actions specified for emergency response should give primary consideration to minimizing exposure to patient and healthcare personnel while maximizing patient safety. Please submit a single document with written safety procedures that you will implement for emergency response to include:

    a. Step-by-step instructions/actions for responding to single and/or multiple equipment failures and the individual(s) responsible for implementing each action. Clearly specify which steps are to be taken under different scenarios (i.e., exposed source versus detached source);
    b. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
    c. The names and telephone numbers of authorized users, authorized medical physicists, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

Please confirm that a copy of these procedures will be posted at each HDR unit console.

5. 10 CFR 35.610 requires, in part that all device operators, authorized medical physicists, authorized users, and Radiation Safety Officer participate in drills of the emergency procedures, initially and at least annually. Please confirm that the emergency drills will performed as part of the initial and annual training and specify who will participate in them.

6. Please confirm that extremity monitors will be provided to individuals who may be called upon to respond to an emergency involving an unretracted or stuck HDR source.

7. Please provide your HDR periodic spot-checks procedures. 10 CFR 35.12(b)(2) requires that licensees submit procedures for periodic spot-checks for remote afterloader units required by 10 CFR 35.643. Please provide *detailed step-by-step* procedures that describe how you will perform each test below and the criteria for acceptable results:

    a. Electrical interlocks at remote afterloader unit room entrance;
    b. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
    c. Viewing and intercom systems ;
    d. Emergency response equipment;
    e. Radiation monitors used to indicate the source position;
    f. Timer accuracy;
    g. Clock (date and time) in the unit's computer; and
    h. Decayed source activity in the unit's computer.

    In addition, please confirm that if spot-check results indicate the malfunction of any system, you will lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

8. Please confirm that written directives for high dose rate (HDR) remote afterloaders will include the radionuclide, treatment site, dose per fraction, number of fractions, and total dose as required by 10 CFR 35.40(b)(5).

9. With regard to the proposed yttrium-90 microsphere use:

    a. Please confirm that you will submit documentation to NRC Region 1 within 30 days following completion of three hands-on clinical cases performed by the proposed AUs supervised in the presence of the manufacturer's representative.
    b. Please describe the location where yttrium-90 microspheres will be administered and describe areas located above, below, and adjacent to the location where yttrium-90 is used;

c. Please commit to manufacturer's procedure for assaying patient dosages;
d. Please confirm that if a 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 will document such changes in the written directive within 24 hours after the completion or termination or the administration. The modification to the written directive must include the reason for not administering the intended dose/activity, the date, and the signature of an AU for yttrium-90 microspheres;
e. Please confirm that the written directive shall include the patient or human research subjects name; the date; the signature of an AU for yttrium-90 microspheres; the treatment site; the radionuclide including physical form (yttrium-90 microspheres); the prescribed dose/activity; the manufacturer; and if appropriate for the type of microspheres used, the statement, "or dose/activity delivered at stasis";
f. Please confirm that the administration of yttrium-90 microspheres will be performed in accordance with the written directive;
g. If the administration is terminated due to stasis, please confirm that the record will be prepared within 24 hours after the completion or termination of the administration and will include the name of the individual who made the assessment, the date, and the signature of an AU for yttrium-90 microspheres, if terminated due to stasis; and
h. Confirm that you will follow the manufacturer's procedure for calculating/documenting the dose to the treatment and other sites, preparing the dose for administration, and performing pre/post vial dose measurements; or submit alternate methods.

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).

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. 584317. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5358.

In order to continue prompt review of your application, we request that you submit your response to this letter within 15 calendar days from the date of this letter.

Lester Tripp /RA/ 09/04/2014
Health Physicist
Medical Branch
Division of Nuclear Materials Safety