To: Michael J. Bohan
Radiation Safety Officer
From: Lester Tripp
NRC Region 1
Licensee: Bridgeport Hospital
License No. 06-01060-01
Docket No. 03001247
Control No. 585509
Re: License Renewal
Date: April 7, 2015

This correspondence is in reference to your letter dated December 1, 2014 requesting renewal of Nuclear Regulatory Commission License No. 06-01060-01. In order to continue our review, we need the following additional information:

1. Please confirm that Bridgeton Hospital has developed and will implement and maintain ***written*** procedures for the safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

2. Please provide a detailed description and facility diagram of the hot lab at Bridgeport Hospital Nuclear Medicine Department.

3. In your renewal application, you have requested to continue authorization for the possession and use of yttrium-90 SIR-spheres. Please follow the current guidance found in ***Microspheres Sources and Devices*** (Revised June 2012) at http://www.nrc.gov/materials/miau/med-use-toolkit.html and submit your radiation protection program for the safe use of yttrium-90 SIR-spheres. In doing so, please:

    a. Commit to the manufacturers' procedure for assaying dosages;

    b. Confirm that 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 will document such changes in the written directive within 24 hours after the completion or termination of 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;

    c. Confirm that the written directive shall include the patient or human research subject's name; the date; the signature of an AU for Y-90 microspheres; the treatment site; the radionuclide including physical form, (Y-90 microspheres); the prescribed dose/activity; the manufacturer; and if appropriate for the type of microsphere used, the statement, "or dose/activity delivered at stasis";

    d. Confirm that the administration of microspheres will be performed in accordance with the written directive;

    e. 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 for performing pre/post administration vial dose measurements; or submit alternate measurements.

4. 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 each 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 (except for low dose-rate remote afterloader facilities);

    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(s) 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.

5. Please confirm that your written HDR procedures include procedures for HDR source exchange.

6. You stated that console keys shall be removed from the unit and secured when the HDR unit is not in use or unattended. Please describe further how and where the console keys will be secured and by whom.

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. 585509. 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 30 calendar days from the date of this letter.

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