UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

June 3, 2014

Docket No. 03001247 License No. 06-01060-01
Control No. 582703

Michael Tatta
Director, Imaging, Laboratory and Radiation Oncology
Bridgeport Hospital
267 Grant Street
Bridgeport, CT 06610-1020

SUBJECT: BRIDGEPORT HOSPITAL, LICENSE RENEWAL, CONTROL NO. 582703

Dear Mr. Tatta:

This correspondence refers to your request for renewal of your NRC license. Enclosed with this letter is the six-month renewal of NRC License No. 06-01060-01. In your letter dated December 9, 2013, you informed us that you needed an additional 30 days past the December 31, 2013, expiration date to submit a complete renewal application. On April 25, 2014, you submitted a partial application for renewal. As we discussed during a telephone conversation on May 27, 2014, the six-month renewal is issued in order for us to allow you enough time to respond to our request for additional information.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

In order to continue our review of your renewal request, we need the following additional information:

1. Regarding the Ra-226 contamination on the lead brachytherapy safe and L- block, please describe your plans and timeframe for decontamination and disposal of this material.

2. From our conversation with Mike Bohan, your Radiation Safety Officer, on May 27, 2014, it is our understanding that the Cs-137 brachytherapy sources possessed by Bridgeport Hospital were transferred to Yale-New Haven Hospital. We further understand that you do not have any radioactive materials permitted by 10 CFR 35.400, and you wish to delete authorization for material permitted by 10 CFR 35.400. Please submit the confirmation of transfer from Yale-New Haven Hospital and the last leak test records for these brachytherapy sources (Cs-137) that support removal from your license.

3. Please describe wipe test counters currently possessed at each facility where radioactive material is possessed and used.

4. Please specify if PET radiopharmaceuticals are used at any of your locations. If so, please submit shielding calculations for all areas in which PET radiopharmaceuticals are used (e.g., quiet rooms, hot lab, scan rooms, etc.).

5. Please confirm that you are requesting continuation for the authorization for possession and use of radioactive material permitted by 10 CFR 31.11 for in vitro studies. If you no longer require this material, please provide disposal and decontamination records of areas where this material was used. In addition, describe the radioisotopes used since initially licensed for in vitro studies.

6. Please specify what areas are located above and below areas of use and storage at the following locations:

    a. Nuclear Medicine Hot Lab at Bridgeport Hospital;

    b. Trumbull Radiation Oncology-Trumbull

    c. Cardiac Specialists-Fairfield

    d. Cardiac Specialists-Trumbull

    e. Cardiac Specialists-Danbury

    f. Cardiac Specialists-Milford

7. Please provide your HDR periodic spot-check 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.

8. For HDR emergency procedures, please:

    a. Describe the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

b. Confirm that your posted procedures include 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.

9. 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.

10. Please describe the methods 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.

11. 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 Brachytherapy 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 addition, please:

    a. Describe the location where yttrium-90 microspheres will be administered and all areas located above, below, and adjacent to this location.
    b. For authorized users initially completing only in vivo cases, provide a commitment that each individual will complete at least the first three hands-on patient cases supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which authorization is sought. In addition, confirm that you will submit documentation from the manufacturer to the appropriate NRC Regional Office within 30 days of when these three patient cases have been satisfactorily completed.
    c. Commit to provide training in your procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

We will continue our review of your application upon receipt of this information. Please reply to my attention at the Region 1 Office and refer to Mail Control No. 582703. If you have any technical questions regarding this deficiency letter, please call Lester Tripp 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 correspondence.

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).

Thank you for your cooperation.

Sincerely,

Original signed by Penny Lanzisera

Penny Lanzisera
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 88

cc:
Michael J. Bohan, Radiation Safety Officer

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