From:	Gallaghar, Robert
To:	jricci@wwbh.org
Cc:	ltimkin@wwbh.org; Nguyen, Janice; Gallaghar, Robert
Subject:	Request for Additional Information for Backus Hospital (Mail Control No. 581527)
Date:	Monday, November 25, 2013 3:06:00 PM

REQUEST FOR ADDITIONAL INFORMATION PLEASE CONFIRM RECEIPT BY RETURN EMAIL

Docket No. 03001287
License No. 06-11734-02
Control No. 581527

Lester Timkin
Vice President of Clinical Operations
The William W. Backus Hospital
326 Washington St.
Norwich, CT 06360

SUBJECT: THE WILLIAM W. BACKUS HOSPITAL, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 581527

Dear Mr. Timkin:

This is in reference to your application dated July 17, 2013, requesting to renew Nuclear Regulatory Commission License No. 06-11734-02. In order to continue our review, we need the following additional information:

1. You are currently licensed to possess and use radioactive materials permitted by 10 CFR 35.100, 35.200, 35.300, 35.400, and 35.500. Your submitted application to renew your license requests authorization to possess and use radioactive materials permitted by 10 CFR 35.100, 35.200, and 35.300. Please confirm that you no longer require authorization to possess and use radioactive materials permitted by 10 CFR 35.400 and 35.500. Note that this change will affect those individual authorized users listed in Condition 12 of your license for 10 CFR 35.400 (Meena Savur Moran, M.D. will be removed from the license) and 35.500.

2. Please submit documentation of the proper disposal of all sealed sources possessed and used by 10 CFR 35.400 and 35.500. Please also submit final leak test and inventory documentation for all Gadolinium-153 sealed sources permitted by 10 CFR 35.500.

3. You are currently licensed to possess and use radioactive materials permitted by 10 CFR 35.200 which now includes positron emitting tomography (PET) radiopharmaceuticals. Please confirm that you will not be performing PET studies. Alternatively, you may request this authorization and submit facility diagrams, including installed shielding and a list of safety equipment specific to 511 keV.

4. On a detailed version of your facility diagram, please indicate the position of each of

the areas described below (a-d) and describe the type, dimensions, and thickness of shielding that you will use.

a. Storage of radiopharmaceuticals (refrigerated and non-refrigerated).
b. Storage of radioactive waste. If this area is not located within your main department, describe how you will secure the material.
c. Preparation and dispensing of radiopharmaceuticals (e.g., lead glass L-block, etc.).

In addition, identify areas adjacent areas across the walls from, and above and below, use and storage areas and show that adequate steps have been taken to assure that radiation levels in unrestricted areas will not result in doses to individual members of the public in excess of those specified in 10 CFR 20.1301. Please indicate what rooms are restricted or unrestricted areas as defined in 10 CFR 20.1003.

5. Please provide a description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys.

6. Please confirm that you will develop, implement and maintain written procedures for the safe use of unsealed byproduct materials that meet the requirements of 10 CFR 20.1101 and 20.1301.

7. Please confirm that all patients treated under 10 CFR 35.300 will be outpatients releasable pursuant to 10 CFR 35.75. Alternatively, you may submit diagrams of shielded patient rooms used for inpatients.

8. Please confirm that there are no changes in authorized users.

9. Please provide the manufacturer and model number for any sealed sources that do not meet the criteria in 10 CFR 35.65 (e.g. greater than 30 millicuries).

10. Please confirm the following statement: “We reserve the right to upgrade our survey instruments as necessary as long as they adequate to measure the type and level of radiation for which they are used.”

11. Please confirm the following statement: “Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under ‘Criteria’ in NUREG-1556, Vol. 9, Rev. 1, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.’”

12. Please confirm that you are not releasing any areas that were specific to the use of 10 CFR 35.400 (i.e. hot lab, preparation area, etc.). Alternatively, please submit closeout surveys of these areas so that they may be removed from your license and released for unrestricted use.

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. 581527. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5272.

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.

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.

Sincerely,

Robert L. Gallaghar
Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
James Ricci, Radiation Safety Officer