From: Gaskins, Farrah
Sent: Tuesday, July 17, 2018 10:45 AM
To: pkohanski@wwbh.org
Subject: Request for additional information for License No. 06-11734-02

PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION.

Licensee: The William W. Backus Hospital
License No.: 06-11734-02
Docket No.: 030-01287
Control No.: 609094

Dear Dr. Kohanski:

This is in reference to the letter dated June 4, 2018, requesting to amend Nuclear Regulatory Commission License No. 06-11734-02.

You requested that Dr. Richard Gessman be approved as an Authorized User (AU) for materials authorized by 10 CFR 35.100, 35.200, and 35.300, using the board certification pathway. Please note that per the NRC website https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html, we currently do not recognize Dr. Gessman's board certification.

In order to be recognized for 10 CFR 35.100, 35.200, and the oral administration of Iodine-131, the board certification must meet the following requirements: American Board of Radiology (ABR) certification process from June 2011 to July 2012 for the **Diagnostic Radiology** certificates issued with the words "AU eligible" appearing above the ABR seal; and from July 2012 forward for the **Diagnostic Radiology** certificates issued with the words "AU eligible" appearing above the ABR seal. Additionally, the certificates issued in July 2012 forward will initially be recognized for 4 years from the date of issuance and after the 4-year period, the ABR web site needs to be checked to ensure that the individual is still certified. The ABR monitors the certification status of its diplomates and posts this information on its **web site** for all individuals including those certified after 2012.

In order to be recognized for the parenteral administration of any beta emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required, the board certification must meet the following requirements: American Board of Radiology (ABR) certification process from June 2007 to May 2012 for the **Radiation Oncology** specialty with the words "AU eligible" appearing above the ABR seal and from May 2012 to present for **Radiation Oncology** specialty with the words "AU eligible" appearing above the ABR seal. Additionally, the certificates issued from May 2012 forward will initially be recognized for 4 years from the date of issuance and after the 4-year period, the ABR web site needs to be checked to ensure that the individual is still certified. The ABR monitors the certification status of its diplomates and posts this information on its **web site** for all individuals including those certified after 2012.

In order to continue our review, we need the following additional information:

1. If Dr. Gessman has a previous board certification that indicates "AU eligible," please submit this and make sure the effective date is displayed. Otherwise, Dr. Gessman will need to qualify under the training and experience pathway (rather than the board certification pathway).

2. You requested that Dr. Richard Gessman be approved as an Authorized User (AU) for materials authorized by 10 CFR 35.100 and 10 CFR 35.200. Please submit NRC Form 313A (AUD), or

equivalent, to demonstrate training and experience for these authorizations. If Dr. Gessman's board certificate does not indicate "AU eligible," please fill the form out using the training and experience pathway.

3. You have requested approval for "parenteral administration of any other radionuclide requiring a written directive" for Dr. Gessman. Please note that the other than administration of any beta emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required, the NRC is not aware of any approved use of "parenteral administration of any other radionuclide requiring a written directive" and therefore cannot approve new requests for this authorization. In addition, although the current license is authorized for materials use in accordance with 10 CFR 35.300, there are currently no AU's listed on your license with the aforementioned authorization, therefore you are not able to request this authorization for Dr. Gessman or sign as a preceptor for this authorization.

4. With respect to the NRC Form 313A (AUT) that you submitted, if you plan to demonstrate training and experience in lieu of board certification, you will need to submit a new form. Please note the training and experience pathway must be used to demonstrate qualification for the parenteral administration of any beta emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required (unless board certification pathway indicates subspecialty in Radiation Oncology), which requires 700 hours, including 200 hours of classroom and laboratory training.

5. If you are continuing with the board certification pathway to demonstrate training an experience for the oral administration of sodium iodide Iodine-131, in addition to resubmitting the certificate, you will need to resubmit the form and address the following:

    a. Please note that you have checked the box to request for authorization of 35.300 "Parenteral administration of any other radionuclide for which a written directive is required." NRC is not aware of any approved use of "parenteral administration of any other radionuclide requiring a written directive" and therefore cannot approve new requests for this authorization. In addition any other sections of the form where that option is checked must be removed.

    b. Please complete all sections of Part II (Preceptor Attestation).

    c. The fifth Section of Part II of the Form you have checked , as the preceptor, that you have met the requirements for 35.390 and have also checked "Parenteral administration of any other radionuclide for which a written directive is required". You are not authorized for this use and may not act as a preceptor to another doctor. Also see comment in 3.

    d. Training and experience must have been obtained within the last seven years in accordance with 10 CFR 35.59. Although there are a number of cases listed for administration of Iodine 131 greater than 33mCi, some cases are greater than seven years. Please demonstrate that Dr. Gessman has been supervised for three cases of administration of sodium iodide Iodine-131 greater than 33mCi.

We will continue our review upon receipt of the requested information. You may respond to my attention in writing by letter, email (if letter is signed by senior management and scanned into a pdf format), or fax (610-337-5269), referencing mail control number 609094. If you have any questions regarding this request for additional information please call me at (610) 337-5143.

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).

Kind regards,

Farrah C. Gaskins

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