



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
475 ALLENDALE ROAD – SUITE 102
KING OF PRUSSIA, PA 19406-1415

June 28, 2024

Phillip Kohanski, M.D., Chief Radiologist
The William W. Backus Hospital
326 Washington Street
Norwich, Connecticut 06360

**SUBJECT: THE WILLIAM W. BACKUS HOSPITAL, REQUEST FOR ADDITIONAL
INFORMATION, MAIL CONTROL NO. 641171**

Dear Dr. Kohanski:

This is in reference to your letter dated May 24, 2024, requesting to amend NRC License No. 06-11734-02. In order to continue our review, we need the following additional information. Please be aware that all “Item”, “Section”, and “Appendix” references below are referring to NUREG-1556, Volume 9, Revision 3, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses” found at <https://www.nrc.gov/docs/ML1925/ML19256C219.pdf>.

1. Item 13, Certification - The NRC views a letter signed by a management representative as indication that management has reviewed the application and concurs in the statements and representations contained therein. Our records have Matthew Kaufman, Vice President of Operations, listed as the licensee’s senior management contact. The May 24, 2024, letter was signed by yourself, Dr. Kohanski.
 - a. Please confirm that Dr. Kohanski is authorized to make legally binding commitments on behalf of the licensee organization.

OR

- b. If Dr. Kohanski is not authorized to make legally binding commitments on behalf of the licensee organization, please have an individual authorized to make legally binding commitments on behalf of the licensee organization provide either of the following:
 - i. Confirm that you endorse the requests and statements submitted by Dr. Kohanski on behalf of your organization in the amendment request dated May 24, 2024.
 - OR
 - ii. State that you do not endorse the requests and statements submitted by Dr. Kohanski on behalf of your organization in the amendment request dated May 24, 2024, and request to withdraw the requests and statements.
2. Item 7, Authorized Users – You have requested the addition of Kyle Richards, M.D. as an Authorized User (AU) under 10 CFR 35.100 and 10 CFR 35.200. As your basis for

the addition, you referenced Dr. Richards being listed on License No. #00-0962 issued by the Commonwealth of Massachusetts Department of Public Health. However, Condition 9.B to License No. 00-0962 states that Dr. Richards was approved for "Any imaging and localization procedure permitted by 105 CMR 120.547, **except generators.**" Please note that this regulation under the Commonwealth of Massachusetts is the parallel to 10 CFR 35.200 under NRC regulations.

As detailed in 10 CFR 35.290, NRC requires AUs being added to licenses for uses under 10 CFR 35.200 be trained in "Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs." We do not grant AU status exempting the generator component. Therefore, please provide evidence of the supervised work experience eluting generator systems required in 10 CFR 35.290(c)(1)(ii)(G).

We will continue our review upon receipt of this information. Please reply to my attention at Jonathan.Pfingsten@nrc.gov.

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.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>. Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me at 610-337-5170 or via electronic mail at Jonathan.Pfingsten@nrc.gov.

Thank you for your cooperation.

Sincerely,

Jonathan Pfingsten, Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 06-11734-02
Docket No. 030-01287
Mail Control No. 641171

cc: Matthew Kaufman, Vice President of Operations

THE WILLIAM W. BACKUS HOSPITAL, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 641171 DATED JUNE 28, 2024

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SUNSI Review Complete: Jonathan Pfingsten

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