



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

June 21, 2024

Deborah Bitsoli, President
Trinity Health of New England Medical Group
300 Hebron Avenue, Suite 213
Glastonbury, CT 06033

SUBJECT: TRINITY HEALTH OF NEW ENGLAND MEDICAL GROUP, REQUEST FOR
ADDITIONAL INFORMATION, MAIL CONTROL NO. 640656

Dear Deborah Bitsoli:

This is in reference to your letter dated April 28, 2024, requesting to amend NRC License No. 06-30814. In order to continue our review, we need the following additional information:

1. When submitting future license amendments, please have the document signed by a management representative rather than a Nuclear Medicine Technologist. 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.

In your response letter, please have senior management confirm that they have reviewed and agree with all statements made in letter dated April 28, 2024.

2. Authorized User (AU) – Please provide the following:
 - a. In your amendment letter, you included a document dated February 16, 2021, from the Certification Board of Nuclear Cardiology (CBNC) indicating that Dr. Aileen Ingal was recertified in Nuclear Cardiology on January 1, 2012. However, for an individual qualifying as an AU because of a recognized board certification, the NRC requires a copy of the board certification issued by a specialty board whose certification process has been recognized by 10 CFR Part 35, Subparts D and/or E, as applicable to the use(s) requested. For a CBNC certificate to be recognized by the NRC, the wording "for Physicians Residing in the United States" must appear on the certificate. More information regarding NRC specialty board certificate recognition can be found on the NRC public website at <https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html#35290>. Please submit a copy of Dr. Ingal's original CBNC board certificate so that we can determine if it is accepted by the NRC. If the original board certificate is not accepted, please skip to Item 3. If the board certificate is accepted, you may stop after Item 2.b.
 - b. Since Dr. Ingal's documented experience occurred from 2008 to 2011, it is greater than 7 years old. Please submit documentation to show related continuing training and experience as indicated in 10 CFR 35.59. This experience (e.g., CME credits) should be applicable to diagnostic nuclear

medicine and received during the last seven years.

3. If the original board certificate is not accepted by the NRC, please submit the following:
 - a. Resubmit Form 313A (AUD) with a written attestation, signed by a preceptor physician AU to confirm that the training and experience attached in your application have been satisfactorily completed and the individual is able to independently fulfill the radiation safety-related duties as an AU for the requested medical use. Please note that preceptor does not have to be the same individual that provided the initial training. It can be anyone who is authorized for the same material and has independently verified the person's training and experience to become an authorized user.
 - b. Please provide a statement signed by Aileen Ingall that they alone completed all on-line modules and coursework that were presented for their structured educational program through Nuclear Education Online as part of the University of Arkansas for Medical Sciences and the University of New Mexico Health Science Center. Alternatively, you can provide information from Nuclear Education Online that indicates how they verify that the person who signed up for the program is the one that actually completed the program. Please also provide documentation of laboratory training in addition to the on-line/classroom training.
 - c. Since Dr. Ingall's documented experience occurred from 2008 to 2011, it is greater than 7 years old. Please submit documentation to show related continuing training and experience as indicated in 10 CFR 35.59. This experience should be applicable to diagnostic nuclear medicine and received during the last seven years.

Please Note: Additional information can be found in NUREG-1556, Volume 9, Revision 3, Section 8.7.2, "Authorized Users (AUs)." This document can be found on the NRC's public website at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html>.

We will continue our review upon receipt of this information. Please reply to my attention at hiba.ahmed@nrc.gov referencing *Mail Control No.* 640656

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 and Procedure," 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 610-337-5283 or via electronic mail at hiba.ahmed@nrc.gov.

Thank you for your cooperation.

Sincerely,

Hiba Ahmed, Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 06-30814-01
Docket No. 030-36256
Mail Control No. 640656

cc: Joseph B. Sappington M.D., Radiation Safety Officer
Jennifer Bonczek, Nuclear Medicine Technologist

TRINITY HEALTH OF NEW ENGLAND MEDICAL GROUP, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 640656 DATED JUNE 21, 2024

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SUNSI Review Complete: Hiba Ahmed

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