



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

May 26, 2023

Joseph B. Sappington, M.D.,
Radiation Safety Officer
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. 634934**

Dear Dr. Sappington:

This is in reference to your application dated March 14, 2023, requesting to renew NRC License No. 06-30814-01. The items below reference NUREG-1556, Volume 9, Revision 3, which can be found online at: <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html>. In order to continue our review, we need the following additional information:

1. Consistent with NUREG-1556, Volume 9, Revision 3, Section 8.9.1 “Facility Diagram,” please address the items below:
 - a. Your application dated March 14, 2023, under Item 8.15, included a description of a “Prep Room” as a location for the administration of radiopharmaceuticals. The provided facility diagrams (Attachment 9-a1, 9-a2, 9-b1, and 9-b2) did not identify a room as a “Prep Room.” Please clarify if this room appears under a different name or if this room was not included on the provided facility diagrams (and if so, please provide supplemental facility diagrams to address this room consistent with the description in the subject section of NUREG-1556, Volume 9, Revision 3).
 - b. Your application dated March 14, 2023, in Attachment 9-a2 and 9-b2, included “Exam Room 1,” which was identified in your application under Item 8.15 as a location for the administration of radiopharmaceuticals. This room was truncated on the provided diagrams. Please revise the facility diagrams associated with Attachment 9-a2 and 9-b2 to ensure this room is included in its entirety.
 - c. Your application dated March 14, 2023, in Attachment 9-a2 and 9-b2, included a “Stress Testing” room. This room and its associated equipment is commonly used for the administration of radiopharmaceuticals during cardiac stress tests. However, this was not a room identified in Item 8.15 of your application as a location for the administration of radiopharmaceuticals. Please clarify if you intend to administer radiopharmaceuticals to patients in this room.

- d. In order to better understand the context of your facilities relative to one-another and the areas associated with other unlicensed operations in the vicinity, please provide a wider view (e.g. an overall floor schematic) of your operations relative to the remainder of the floor.
2. Consistent with NUREG-1556, Volume 9, Revision 3, Section 8.9.3 "Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material" please either:

Commit to the following:

"For measurement of alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator, identify specialized measurement equipment and the nationally recognized standard used to calibrate the instrument or provide a copy of the manufacturer's instructions to calibrate the instrument."

OR

Commit to only using unit dosages made by a manufacturer or preparer licensed under 10 CFR 32.72, and that you will rely on the provider's dose label for the measurement of the dosage and decay-correct the dosage to the time of administration.

OR

Commit to not using alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator.

3. Your management contact appears to be different from what the NRC has on file. Please provide contact information (nominally phone and email contacts) for Deborah Bitsoli, President, and the management representative who signed your renewal application.

We will continue our review upon receipt of this information. Please reply to my attention at:

R1DNMSMail.Resource@nrc.gov

Reference – Jason vonEhr

Mail Control No. 634934

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) 337-5256 or via electronic mail at Jason.vonEhr@nrc.gov.

Thank you for your cooperation.

Sincerely,

Jason vonEhr, Senior 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. 634934

cc:

Jennifer Bonczek, CNMT
Deborah Bitsoli, President

TRINITY HEALTH OF NEW ENGLAND MEDICAL GROUP, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 634934 DATED MAY 26, 2023

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DATE	05/26/2023						

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