

From: [Gallagher, Robert](#)
To: [Kagaoan, Gladys](#)
Subject: RE: Re: Trinity Health of New England request for additional information
Date: Tuesday, August 9, 2022 6:23:00 AM
Attachments: [image001.png](#)

Good Morning Dr. Kagaoan,

In your response you state "The contract with the specific language you requested will follow." When do you expect to be able to submit the contract signed by all parties?

Regards,

Robert L. Gallagher
Health Physicist
Medical & Licensing Assistance Branch
U.S. NRC, Region I
2100 Renaissance Blvd.
King of Prussia, PA 19406
(610) 337-5182 office
(610) 337-5269 fax



From: Kagaoan, Gladys <Gladys.Kagaoan@TrinityHealthOfNE.org>
Sent: Monday, August 08, 2022 3:36 PM
To: Gallagher, Robert <Robert.Gallagher@nrc.gov>
Subject: [External_Sender] Re: Trinity Health of New England request for additional information

August 8, 2022

RE: TRINITY HEALTH OF NEW ENGLAND MEDICAL GROUP
GHC NUCLEAR LABORATORY LICENSE AMENDMENT

License No: 06-30812-01
Docket No: 03035246
Control No: 631497

Dear Mr. Gallagher,

In response to your request for additional documentation, I am attaching herewith a schematic of our proposed additional cardiac nuclear imaging site in Canton, CT.

1a. Unit doses of radiopharmaceuticals used for purposes of myocardial imaging are ordered from and delivered by Cardinal Health, Inc on the day of the procedure. This is the same supplier used by our main laboratory located at 1000 Asylum Ave Suite 4300 Hartford, CT. Our laboratory will be using Tc-99m sestamibi, Tc-99m pyrophosphate, and, less frequently, Thallium-201. Doses are delivered in labelled, sealed, shielded containers, received only by our nuclear technologist per my designation, only on laboratory business hours, and kept in the locked Hot Lab following predetermined procedures and protocols. Receipt of all shipments of radionuclides will be recorded. Monitoring is performed as soon as practical after receipt of the package but no later than 3 hours after the package is received.

Barium and Cesium point sources, as well as a Cobalt sheet source used for initial calibration of a new Siemens Camera will be kept in a leaded cabinet for storage and decay. A picture of the leaded cabinet with specifications is attached herewith as well. This will be located in the southwest corner of the Hot Lab in the attached schematic (true north if following the compass on the architect's drawing).

1b. The leaded cabinet will allow for storage and decay-in-storage of both isotopes and waste in different containers and segregated by lead lined drawers within this cabinet.

A sharps container is placed behind an L block to house used needles and syringes. This L block is placed on top of the aforementioned lead lined cabinet. Before this container is disposed of with regular biohazard sharps, all surfaces of the container is monitored with a Geiger counter while in a low-level radiation area. This is cleared for disposal only when radiation levels are no longer distinguishable from background. If still distinguishable from background, this container will be kept in the aforementioned storage area/cabinet.

1c. Unit doses are handled by the nuclear technologist using aseptic technique and balanced with radiation protection practices. The technologist wears gloves, a lab coat, a finger badge dosimeter as well as a whole body dosimeter. Doses are prepared behind an L block that is placed on top of the lead lined cabinet. Radioactive isotopes are prepared in a lead syringe shield and transported to the stress laboratory in a lead pig. Patient's IV lock septum and vial septum of nonradioactive pharmaceuticals are wiped with alcohol prior to injection. Dose, location and time of injection are documented in the patient's electronic medical record, and separately on a log book located in the Nuclear Laboratory. Radiation safety practices using principle of time, shielding and distance is observed.

Knowledge, training and experience of the nuclear technologist is documented in a Procedures and Protocols Manual Ancillary volume. This includes yearly radiation safety course, as well as required CME logs.

1d/e. The nuclear laboratory area is outlined in yellow-green in the attached file. This area is isolated by lockable doors restricting access to non-radiation personnel. A sign bearing the radiation symbol and the words CAUTION or DANGER RADIOACTIVE MATERIAL and additional sign bearing the radiation symbol and the words CAUTION RADIATION AREA will be posted in all areas where it is

possible for an individual to receive a dose > 5 mrem in any 1 hour. Signage is printed in red on a yellow background as per standards.

In the attached floor plan, care has been taken to designate the location of the Hot Lab which has the highest potential area of radiation away from the rest of the office.

The wall to the left of the hot lab is an outer wall without significant pedestrian traffic. The side entrance to the office will be utilized to deliver unit doses in to the Hot Lab without need to traverse the rest of the main office.

Similarly, the wall at the bottom of the page is another outer wall without significant pedestrian traffic. There are locked doors preventing public access to this back walkway.

The wall to the right abuts the echocardiography room and the medical assistant touch down unit. The camera to be used in the Nuclear Imaging room is a Siemens C CAM that will not require lead shielding. A storage cabinet for consumables such as gowns/paper/electrodes abuts the Medical Assistant area, placing greater distance between the patient prep area (where injected patients wait) and the non-nuclear office personnel.

Per protocol, area surveys are performed daily or each day the laboratory is in use by the nuclear technologist and documented for my review.

2. The Hot Lab will be equipped with a Dose Calibrator, a well counter, 2 Geiger counters, L shield, lead pig and a leaded syringe box.

3. The contract with the specific language you requested will follow. Once available, I will send you a copy via PDF.

Please feel free to contact me with any additional requirements if needed.

Sincerely,

Gladys Kagaoan, MD

A PDF of a signed copy of this letter is attached labelled as NRC additional requirements Canton Site.

From: Gallagher, Robert <Robert.Gallagher@nrc.gov>

Sent: Monday, August 8, 2022 10:08 AM

To: Kagaoan, Gladys <Gladys.Kagaoan@TrinityHealthOfNE.org>

Subject: [External] RE: RE: RE: Trinity Health of New England request for additional information

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Trinity Health.

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Good Morning,

What is the status of the response to my request for additional information?

Regards,

Robert L. Gallagher
Health Physicist
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From: Kagaoan, Gladys <Gladys.Kagaoan@TrinityHealthOfNE.org>

Sent: Wednesday, August 03, 2022 10:29 AM

To: Gallagher, Robert <Robert.Gallagher@nrc.gov>

Subject: [External_Sender] RE: RE: Trinity Health of New England request for additional information

Our Legal Department has been engaged in getting the contract drawn up and signed by the Landlord with the specific language that your requested.
Once completed I will be sending you an entire packet.
Similarly, I will follow up today to get a sense of timing.
Thank you.

Gladys Kagaoan, MD

From: Gallagher, Robert <Robert.Gallagher@nrc.gov>

Sent: Wednesday, August 3, 2022 10:00 AM

To: Kagaoan, Gladys <Gladys.Kagaoan@TrinityHealthOfNE.org>

Subject: [External] FW: RE: Trinity Health of New England request for additional information

Importance: High

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Good Morning,

What is the status of your response to my request for additional information?

Robert L. Gallagher
Health Physicist
Medical & Licensing Assistance Branch
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2100 Renaissance Blvd.
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(610) 337-5182 office
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From: Kagaoan, Gladys <Gladys.Kagaoan@TrinityHealthOfNE.org>
Sent: Wednesday, July 13, 2022 3:46 PM
To: Gallagher, Robert <Robert.Gallagher@nrc.gov>
Subject: [External_Sender] RE: Trinity Health of New England request for additional information

Received.
Will send completed items to you as soon as possible.

Gladys Kagaoan, MD

From: Gallagher, Robert <Robert.Gallagher@nrc.gov>
Sent: Wednesday, July 13, 2022 3:30 PM
To: Kagaoan, Gladys <Gladys.Kagaoan@TrinityHealthOfNE.org>
Subject: [External] Trinity Health of New England request for additional information

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Docket No. 03035246
Control No. 631497

Dear Dr. Kagaoan;

This refers to your letter dated April 11, 2022. In order for us to continue our review please submit the following additional information:

1. On a detailed version of your facility diagram, please indicate the position of each of the areas described below and describe the type, dimensions, and thickness of shielding that you will use.
 - a. Storage of radiopharmaceuticals (refrigerated and nonrefrigerated).
 - b. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive 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.).
 - d. In addition, identify adjacent areas across the walls from use and storage locations 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.
 - e. In addition, identify adjacent areas across the walls from use and storage locations 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 (enclosed).
2. Please provide a list of the equipment used in the Hot Lab (dose calibrator, radiation detection instruments, etc.).
3. Your application appears to indicate that your location of use may be controlled by an entity other than yourself. If so, please provide documentation of a clear contractual agreement concerning access to your location of use for the purpose of decontamination or removal of licensed material from the location of use in the event of disharmony between you and the owner entity. This documentation should consist of signed certification from both parties.

We will continue our review upon receipt of this information. Your reply must be an originally signed and dated letter. The letter may be scanned and submitted as a pdf document attached to an email (preferred option); or it may be transmitted by facsimile to (610) 337-5269; or it may be sent by regular mail.

Please note that the Region I office is currently in the process of moving to 475 Allendale Road, King of Prussia, PA 19406, with the official move date to be determined. In the interim, if possible, please send all communications electronically to R1DRSSMail.Resource@nrc.gov with the mail control number referenced, or directly to me at Robert.gallagher@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.

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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) 337-5182 or via electronic mail at Robert.gallagher@nrc.gov.

Thank you for your cooperation.

Regards,

Robert L. Gallagher
Health Physicist
Medical & Licensing Assistance Branch
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