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

June 12, 2024

Evelyn Patino-Ortiz, MHSA
Administrator
P.O. Box 602727
Bayamon, PR 00960-6037

SUBJECT: C.T. RADIOLOGY COMPLEX & MRI INSTITUTE, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 639126

Dear Evelyn Patino-Ortiz:

This is in reference to your application dated January 31, 2024, requesting to renew NRC License No. 52-14931-01. 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. In order to continue our review, we need the following additional information:

1. In your application package, it is not clear what the name on the license should be and if a change of control has taken place. The name currently on the license is C.T. Radiology Complex & MRI Institute. The name on the application dated January 31, 2024, is C.T. Radiology Complex L.L.C and a note is saying that the license will be under an ownership or legal entity of Bayamon Imaging and Interventional Institute, L.L.C. There seems to be a missing attachment that was indicated in association with the corporation or legal entity name. Please provide this missing attachment and verify if there has been a change of control. Please also provide the correct name for the license.
    a. Note that if a change of control has taken place, there are associated documents that must be submitted. Please see NUREG-1556, Volume 15, Revision 1 for further guidance.

2. The mailing address in Section 2 provided on the NRC Form 313 is P.O. Box 602727 while the license has P.O. Box 2727. Please verify the correct P.O. Box for the license.

3. The address in Section 3 of NRC Form 313 is 1815 Carr 2, CT Radiology Bldg, Bayamon, PR 00959-7279. The license and previous inspections have the physical location at Edificio Santa Rita, State Road #2, KM 11.7, Bayamon, Puerto Rico, 00959. Please verify if the licensed location of use has been moved or if the address change was from a postal service change.
    a. *If your physical location for the licensed material has been moved*, please provide the necessary closeout survey documentation for the old location. Further guidance can be found in NUREG-1757, Volume 1, Revision 2. Please also submit new shielding calculations and new facility diagrams for this new location related to Section 8.9.1, "Facility Diagrams" (see below).

4. Addressing the diagram labeled “CT-PET Shielding Recommendation Revised,” additional information should be provided to allow NRC license reviewers to independently verify shielding calculations, per Section 8.9.1, “Facility Diagrams.”
    i. Drawings should be to scale, and the scale used should be indicated. The direction of north should be indicated.
    ii. Principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas *above, beside, and below* therapy treatment rooms and Positron Emission Tomography (PET).
    iii. Doors should be indicated, and specify which doors are access controlled (i.e., locked).
    iv. Shielding calculations for PET facilities. Include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe). The calculations should include the workload assumptions used.
    v. For PET, radiopharmaceutical, and sealed-source therapies, provide a description of surrounding areas, including the occupancy factors, and indicate whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003. For calculations of the maximum exposure in any given hour, an occupancy factor will not be used.
    vi. There should also be a statement of what was actually installed at the facility as shielding for confirmation.

5. For the current diagram that shows the nuclear medicine department, additional information is required. Please submit new facility diagrams in accordance with Section 8.9.1, “Facility Diagrams.” Specifically:
    i. Drawings should be to scale, and the scale used should be indicated. The direction of north should be indicated.
    ii. Location, room numbers, and principal use of each room, including patient treatment rooms or area where byproduct material is prepared, used, and stored (e.g., stress labs, camera rooms, hot lab, etc.)
    iii. Doors should be indicated, and specify which doors are access controlled (i.e., locked).

6. In Item 5 of your application, you requested the use of iodine-131 permitted by 10 CFR 35.300. This is a change from your current license, where you were authorized for any byproduct material permitted by 10 CFR 35.300. Please confirm if this change in radioactive material and use is correct.

7. In accordance with Section 8.9.2, “Radiation Monitoring Instruments,” please provide a description of the instrumentation (e.g., gamma counter, solid-state detector, portable or stationary count-rate meter, portable or stationary dose-rate or exposure-rate meter, single or multichannel analyzer, liquid scintillation counter (LSC), proportional counter) that will be used to perform required surveys. The response should include information such as the quantity of Ludlum 14C, probe information, and more information for the “DWTC gamma counter.”

8. In accordance with Section 8.9.3, “Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material,” please provide the model number

for Biodex Atomlab Dose Calibrator with well chamber described in the application.

9. In accordance with Section 8.9.5, “Other Equipment and Facilities”, there is a response required for PET radionuclide use and radiopharmaceutical therapy programs.
    a. In the application, you committed to using PET isotopes and to having a PET room, please describe if there is additional equipment for PET uses (e.g., specialty shielding for 511 keV).
    b. Also, if you will be using the volatile form of I-131, please verify the use of a fume hood. If you will not be using the volatile form of I-131, please confirm that you will only be using capsules.

10. The telephone number ending in 7248 was provided in NRC Form 313 Section 4 for David Rhoe’s contact information. In our web-based licensing system, there is a phone number ending in 9271. Please advise if we should update the contact information in our system and if the number ending in 7248 is a personal number, as personal information needs to be noted.

11. Please confirm that you do not have any sealed sources that do not meet the requirements of 10 CFR 35.65.

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

R1DRSSMail.Resource@nrc.gov
Reference – Kelli Trotter
Mail Control No. 639126

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 form 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) 337-5370 or via electronic mail at Kelli.Trotter@nrc.gov.

Thank you for your cooperation.

Sincerely,

Kelli R. Trotter

Digitally signed by Kelli R. Trotter
Date: 2024.06.12 09:36:08 -04'00'

Kelli Trotter, Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 52-14931-01
Docket No. 030-08264
Mail Control No. 639126

cc: David Rhoe, RSO

C.T. RADIOLOGY COMPLEX & MRI INSTITUTE, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 639126 DATED JUNE 12, 2024

DOCUMENT NAME: https://usnrc.sharepoint.com/teams/RegionIDRSSLicensing/Shared Documents/Licensing Actions/MLAB Pending Actions/639126- CT Radiology/L52-14931-01.639126.RAI.docx

SUNSI Review Complete: Kelli Trotter

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