UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

March 10, 2023

Howard W. Salmon, Ph.D.
Radiation Safety Officer
Franciscan Health: Indianapolis, Mooresville, and Carmel
8111 S. Emerson Ave.
Indianapolis, IN 46237

Dear Dr. Salmon:

This letter is regarding the request dated March 8, 2023, signed by Terri S. Ruff, MBA, MHA, Chief Operating Officer, to amend your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-02128-03.

The U.S. NRC's guidance document for your type of license, which I refer to below as "the guidance," is NUREG-1556, Volume 9, Rev. 3, dated September 2019, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses." This guidance is available on the U.S. NRC website at:
https://www.nrc.gov/docs/ML1925/ML19256C219.pdf

Upon review of your request, I identified the following areas requiring additional or clarifying information:

1. Section 8.9.1, "Facility Diagram," of the guidance, identifies that the request should demonstrate that the limits specified in Title 10 of the *Code of Federal Regulations* (10 CFR) §20.1301(a) will not be exceeded and describe how access will be controlled.

   Upon review of the shielding evaluation included with your request, I determined that individual members of the public could encounter radiation levels on the exterior areas of the PET/CT Imaging Suite that would result in a radiation dose exceeding 2 millirem in any one hour and 100 millirem in a year.

   Further, your request does not describe how access to the PET/CT Imaging Suite will be controlled (e.g., locking doors).

   Therefore, identify the means that will be used to limit exposure to individual members of the public. You may consider adding shielding to the barrier in question, with corresponding modification of the facility description if necessary.

   In addition, please describe measures used to control access to the restricted areas.

   AAPM Task Group 108, "PET and PET/CT Shielding Requirements," provides guidance on how to design a PET facility and perform associated shielding calculations. The document also provides guidance on appropriate safety equipment to use.

2. Section 8.9.5, “Other Equipment and Facilities,” of the guidance states that the request should describe the equipment and facilities available for safe use and storage of licensed material.

   Your request does not describe the safety equipment available for safely handling and storing PET radionuclides.

   Provide a list of available monitoring and handling equipment that will be available at the proposed PET facility, including specialized equipment for handling and storing PET radionuclides (e.g., tungsten syringe shields and a PET-grade L-block).

3. 10 CFR §20.1101(b) identifies that the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

   Upon review of the request, I identified that radiation dose rates in the PET/CT Control Room exceed 2 millirem in any one hour. To ensure compliance with the regulatory requirement, you should employ procedures and engineering controls to limit the occupational doses to your radiation workers.

   Please describe the applicable measures that you will use to limit radiation exposures to your radiation workers.

4. 10 CFR §20.1902 identifies that the licensee must post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words, “CAUTION, RADIATION AREA.”

   A radiation area is an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 5 millirem in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

   Your e-mail accompanying the amendment request referred to the possible construction of a fence or other barrier to restrict access to the radiation area on the exterior of the PET/CT Imaging Room.

   If a fence is constructed at the boundary of the radiation area, you should post the required caution signage along the fence to alert personnel performing building maintenance or groundskeeping along the fenced location of the radiation hazard. Further, you should develop an administrative procedure to require notification and clearance from the Radiation Safety Officer before maintenance activities are performed within the fenced area.

   If applicable, please confirm that the required caution signage will be posted and provide a copy of the administrative procedure requiring notification and clearance from the Radiation Safety Officer before maintenance activities are performed on the exterior of the PET/CT Imaging Room.

In accordance with 10 CFR §2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

To continue review of your request, please submit your response to this letter within 15 calendar days from the date of this letter. In your response, please refer to the license, docket, and control number specified below. I will assume that you do not wish to further pursue this licensing action if I do not receive a reply within the specified timeframe noted above.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, I encourage you to contact me at (630) 829-9737 or via e-mail at Jason.Kelly@nrc.gov.

Sincerely,

Digitally signed by Jason M. Kelly
Date: 2023.03.10 11:30:38 -06'00'
Adobe Acrobat version: 2022.003.20310

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

Docket No.: 030-09398
License No.: 13-02128-03
Control No.: 634771