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

August 25, 2022

Carmen R. Kmety-Stevenson, Ph.D., DABR
Medical Physicist and Radiation Safety Officer
Methodist Hospital of Gary, Inc.
8701 Broadway
Merrillville, IN 46410

Dear Dr. Kmety-Stevenson:

This letter is regarding your request dated June 17, 2022, to amend your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-16558-01.

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's 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 Diagrams," of the guidance, specifies that a description of the proposed Positron Emission Tomography (PET) facility should include:

   - facility diagram (including the scale and the direction of north);
   - shielding installed;
   - specialized handling equipment; and
   - survey results to ensure to ensure the regulatory limits in 10 CFR §20.1201, "Occupational dose limits for adults," and 10 CFR 20.1301, "Dose limits for individual members of the public," are not exceeded.

   Additional items in this letter address the specific areas in which additional or clarifying information is requested. Further information for preparing your request may be found in Section 8, "Contents of an Application," of the guidance and AAPM Task Group 108, "PET and PET/CT Shielding Requirements," 2005.

2. Please resubmit your facility diagram identifying the following:

   - scale or dimensions of each room;
   - direction of north;
   - specific hot lab detail, including where radioactive materials are received, prepared and stored. Illustrate the locations of available sink(s), shielded cave, L-block, dose calibrator and cabinets for storing radioactive waste as applicable; and
   - label the boundary of the restricted area, which appears to be the yellow highlighted area depicted in your diagram.

3. Describe how you control radioactive material from unauthorized access (e.g., locking doors, cabinets, etc.). Please also identify all doors on the facility diagram, specifying which doors are accessed controlled (i.e., locked).

4. Identify the shielding material and the minimum thicknesses to be installed at your proposed PET facility.

   Your request listed the recommended shielding material and thicknesses specified by the medical physicist with whom you contracted to perform the shielding evaluation.

   Please confirm that you will install these recommended shielding materials and thicknesses. Otherwise, specify the shielding material and the minimum thickness to be installed in lieu of those recommended.

5. 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).

6. Section 8.9.1, “Facility Diagrams,” of the guidance, indicates that applicants should provide a description of whether the areas are restricted or unrestricted as defined by 10 CFR §20.1003.

   Your request identifies areas that are controlled versus uncontrolled.

   Please confirm that your reference to a controlled area is the same as a restricted area defined in the above referenced regulation.

7. Section 8.13, “Item 13: Certification,” and 10 CFR §35.12(a) specifies that a management representative of the legal entity must sign and date the amendment request. The representative signing the request must be authorized to make binding commitments and to sign official documents on behalf of the applicant (i.e., a certifying official).

   Therefore, please have the response to this request also signed by a management representative. For additional information, you may refer to Chapter 3, “Management Responsibility,” of the guidance.

In accordance with 10 CFR §2.390, “Rules of Practice,” a copy of this letter will be made available electronically for public inspection in the U.S. NRC Public Document Room or from the U.S. NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the U.S. NRC website 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 Jason.Kelly@nrc.gov or at (630) 829-9737.

Sincerely,

Digitally signed by Jason M. Kelly
Date: 2022.08.25 12:32:02 -05'00'
Adobe Acrobat version: 2022.002.20191

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

License No. 13-16558-01
Docket No. 030-11234
Control No. 631612