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

November 10, 2022

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

Dear Dr. Salmon:

This letter is in reference to the application dated July 19, 2022, signed by James Callaghan, M.D., President and CEO, requesting the renewal of your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-02128-03.

The U.S. NRC's guidance document for your proposed type of license 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 the request, I identified the following areas requiring additional or clarifying information:

1. NRC Form 313, "Application for Materials License," indicates that the license application should be prepared following the instructions provided in the current volume of NUREG-1556, "Consolidated Guidance About Materials Licenses."

   Your application was not prepared in accordance with the current guidance and did not adequately address all required items. Therefore, you may revise and resubmit your application using Appendix C, "Suggested Format for Providing Information Requested in Items 5 through 11, of the U.S. NRC Nuclear Regulatory Commission Form 313," from the guidance.

   Additional items in this letter address the specific areas in which additional or clarifying information is requested. Additional information regarding completion of the license application may be found in Section 8, "Contents of an Application," of the guidance.

   Further, your application included several procedures (e.g., ALARA Policy) from your Radiation Protection Program that the guidance does not require to be submitted. This additional information is either redundant to your procedures and commitments elsewhere included in your license application or is otherwise not required to be submitted with your application for license renewal.

2. Section 8.3, “Item 3: Address(es) Where Licensed Material Will Be Used or Possessed,” of the guidance, specifies that applicants should provide the street address, city, and State for each facility at which licensed material will be used or stored.

   Accordingly, your request identified an additional PET/CT imaging facility. This additional site will result in the number of licensed sites increasing from five locations to a total of six locations, which will result in an increase in your license fee in accordance with Title 10 Code of Federal Regulations (10 CFR) §171.16. Though, it appears that your additional site may qualify as a contiguous licensee-controlled geographic area.

   A contiguous licensee-controlled geographic area, such as a campus or licensee-owned/operated/controlled business campus or park, is considered a single “location of use” and only one address will be listed on the license. Sites that are not contiguous but are located in separate parts of a city, different city or State, are separate “locations of use” and separate addresses are listed on the license.

   Clarify if your proposed PET/CT imaging facility is within a contiguous licensee-controlled geographic area, such as a campus or licensee-owned/operated/controlled business campus or park.

3. Section 8.5, “Item 5: Radioactive Material,” and Section 8.6, “Item 6: Purpose(s) for Which Licensed Material Will Be Used,” of the guidance, explain that that your application must identify the radioactive materials requested and the intended use.

   Your application requests authorization to possess and use byproduct material described in 10 CFR §35.300. Though, your application does not indicate whether therapeutic radiopharmaceuticals are administered on an inpatient basis as well as on an outpatient basis.

   In your response, please clarify whether therapeutic radiopharmaceuticals are administered on an inpatient and/or outpatient basis. In accordance with 10 CFR §35.315(a) provide a description of the rooms where patients will be housed if they cannot be released under 10 CFR §35.75, as applicable.

4. Section 8.5, “Item 5: Radioactive Material,” and Section 8.6, “Item 6: Purpose(s) for Which Licensed Material Will Be Used,” of the guidance, explain that that your application must identify the radioactive materials requested and the intended use.

   Your application requests authorization to possess and use an additional quantity of yttrium-90 SIR-Spheres for uses permitted by 10 CFR §35.1000. Though, your application did not specifically identify this as a requested change in bold italic font as your requested changes were elsewhere identified.

   Further, your request identifies that licensed material described in Item 6.A. will be utilized at your proposed additional PET/CT imaging facility. It appears that this is a typographical error as PET radionuclides for imaging are described in Item 6.B.

   In your response, please clarify if the above references are correct or if these are only typographical errors.

5. Section 8.8, "Item 8: Training for Individuals Working in or Frequenting Restricted Areas," of the guidance, identifies that individuals working with or in the vicinity of licensed material must have adequate safety instructions, as required by 10 CFR Part 19 *and* 10 CFR Part 35.

   Your application does not identify how you will provide safety instructions to your workers.

   The "Response from Applicant" section of the guidance states that the following should be provided:

   The statement, "We have developed and will implement and maintain written procedures for a program for training required under 10 CFR 19.12 for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training."

   Please respond by stating how you will provide safety instructions to your workers.

6. Resubmit your facility diagrams and descriptions, expanding on the level of detail and clarity in accordance with Section 8.9.1, "Facility Diagram," of the guidance. Specifically, please provide all of the following:

   - Facility diagrams and/or drawings with room dimensions and/or scale identified. The direction of north should be indicated.

   - Location, room numbers, and principal use of each room, including patient treatment rooms or area where byproduct material is prepared, used, and stored.

   - 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) facilities.

   - Doors should be indicated, and specify which doors are access controlled (i.e., locked).

   - Shielding calculations for PET facilities, in-patient rooms for 10 CFR §35.300 and 10 CFR §35.400 use, High Dose-Rate (HDR) Remote Afterloaders. 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.

   - 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 10 CFR 35.1000 medical uses, provide the information described in the guidance on the U.S. NRC's Medical Use Licensee Toolkit webpage, including a

description of the location where yttrium-90 microspheres and iodine-125 seeds used for radioactive seed localization procedures will be used and stored. If tissues containing radioactive seeds are sent to pathology following surgery, both pathology and the surgical suite should also be included as locations of use.

7. Section 8.9.5, "Other Equipment and Facilities," of the guidance states that you should describe the equipment and facilities available for safe use and storage of licensed material.

Your request does not adequately describe the safety equipment and facilities available for safely handling and storing the requested licensed material.

Provide the following, as applicable:

- For PET radionuclides use and radiopharmaceutical therapy programs, identify the additional equipment (e.g., tungsten syringe shields and PET-grade L-block) for those uses, as applicable.
- For manual brachytherapy facilities, provide a description of the emergency response equipment.
- For HDR remote afterloader facilities, provide a description of the following:
  - Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room.
  - Area radiation monitoring equipment
  - Viewing and intercom systems (except for low dose-rate units)
  - Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) is in the treatment room.
  - Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons.
  - Emergency response equipment.
- For Radioactive Seed Localization Procedures permitted by 10 CFR §35.1000, provide a description of the emergency response equipment.

8. Section 8.10.2, "Occupational Dose," of the guidance specifies that licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure in accordance with 10 CFR §20.1502.

Your commitments and procedures referenced an outdated revision of NUREG-1556, Volume 9, Rev. 2, which was published in January 2008.

Your response identifies that you will either perform an evaluation demonstrating that unmonitored individual are not likely to receive a radiation dose in excess of the 10% of the allowable limits in 10 CFR Part 20 or you will provide dosimetry meeting the requirements listed under the "Criteria," in NUREG-1556, Vol. 9, Rev. 2. Your response

is not acceptable because it references an outdated revision of NUREG-1556, Vol. 9, Rev. 2, which was published in January 2008.

The "Response from Applicant" section of the current guidance states that the following should be provided:

- The statement, "We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502."; or
- The statement, "We will monitor individuals in accordance with the criteria in the section titled, 'Radiation Safety Program–Occupational Dose' in NUREG–1556, Vol. 9, Rev. 3, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees.'"; or, in lieu of these statements,
- Provide a description of an alternative method for demonstrating compliance with the referenced regulations.

Please provide an acceptable response refencing the current revision of the guidance. For additional information, you may refer to Section 8.10.2 and Appendix M, "Model Procedures for Occupational Dose Monitoring Program," of the guidance.

9. Section 8.10.6, "Emergency Procedures for Therapy Devices Containing Sealed Sources," identifies that you must develop, document, implement, and submit written emergency procedures in accordance with 10 CFR §35.610.

The Emergency Procedures must include:

- instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
- the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
- the names and telephone numbers of AUs, AMPs, and the RSO to be contacted if the unit or console operates abnormally.

A copy of your HDR Remote Afterloader Emergency Procedures was not included with your application.

With your response to this letter, please provide a copy of your HDR Remote Afterloader Emergency Response Procedures.

10. Section 8.10.10, "Material Receipt and Accountability," of the guidance, notes that licensees must establish procedures for securing licensed material, maintaining records of the receipt, transfer and disposal of licensed material and conducting physical inventories of licensed material.

Your application does not identify how you will maintain accountability of licensed material.

The "Response from Applicant," section of the guidance, indicates that the following may be provided:

The statement, "We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:

- license possession limits are not exceeded;
- licensed material in storage is secured from unauthorized access or removal;
- licensed material not in storage is maintained under constant surveillance and control; and
- records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."

Please submit an acceptable response. For additional information, please refer to Section 8.10.10, "Material Receipt and Accountability," of the guidance.

11. Section 8.10.11, "Leak Tests," of the guidance, identifies that licensees must perform leak testing of sealed sources possessed under 10 CFR Part 35 (e.g., calibration, transmission, reference, or brachytherapy sources), in accordance with 10 CFR §35.67, "Requirements for possession of sealed sources and brachytherapy sources." Further, licenses must perform leak testing of all other sealed source possessed under 10 CFR Part 30 (e.g., survey instrument calibration sources) in accordance with 10 CFR §20.1501.

Your application identifies that you have developed and will implement procedures for leak-testing sealed sources; however, additional statements in your application suggest that you will use a contractor to perform leak testing.

If a contractor is used to perform leak testing, the "Response from Applicant," section of the guidance, indicates that the following response should be provided:

- the statement, "Leak test sample collection and analysis will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits or sample analysis services to other licensees and according to the instructions provided in the leak test sample collection kit."

Please clarify if you perform leak tests in-house or if you contract with a licensed third party to perform and analyze leak test samples. For additional information, particularly regarding the establishment of an in-house leak testing program, please refer to Section 8.10.11, "Leak Tests," and Appendix Q, "Model Leak Test Program," of the guidance.

12. Section 8.10.14, "Safe Use of Unsealed Licensed Material," of the guidance, identifies that licensees are responsible for developing, documenting, and implementing procedures to ensure the security and safe use of all licensed material, from the time it arrives at their facilities until it is used, transferred, and disposed of.

Your application included the following statement: “We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.”

It appears that a typographical error was made. Rather that the reference to 10 CFR §20.1301, “Dose limits for individual members of the public,” it appears that the intended reference is to 10 CFR §20.1201, “Occupational dose limits for adults.”

Please revise your commitment to match that suggested in the guidance, which should include the statement: “We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1201.”

13. Your application does not provide specific procedures and commitments related to your use of Yttrium-90 SIR-Spheres and TheraSpheres for medical use as permitted by 10 CFR §35.1000.

Submit your yttrium-90 SIR-Spheres and TheraSpheres procedures and commitments developed in accordance with the current license guidance for the 10 CFR §35.1000 medical use as described in:

“Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance,” Revision 10.2, dated April 20, 2021.

The procedures and commitments must address the procedures and commitments identified in Sections 5.4 and 6 of the licensing guidance including the following:

- Y-90 MicroSpheres Procedures Team Member Training
- Procedures for Administration
- Written Directives
- Medical Event Reporting
- Sealed Source and Device Use
- Inventory
- Labeling
- Patient Release
- Surveys
- Radiation Protection Program Changes

14. Your application does not provide specific procedures and commitments related to your use of iodine-125 seeds for Radioactive Seed Localization procedures as permitted by 10 CFR §35.1000.

Submit your Radioactive Seed Localization procedures and commitments developed in accordance with the current license guidance for the 10 CFR §35.1000 medical use as described in:

“Low Activity Radioactive Seeds Used for Localization of Non-Palpable Lesions and Lymph Nodes Licensing Guidance,” Revision 1, dated October 7, 2016

The procedures and commitments must address the following subjects identified in Sections 5, 7 and 8 the licensing guidance:

- Radioactive Seed Localization Procedures Team member training for:
  - Radiologist
  - Surgeons
  - Pathology Personnel
- Medical Event Reporting
- Radiation Safety Precautions and Instructions for Radioactive Seed Locations

In accordance with 10 CFR §2.390 of the U.S. NRC's "Rules of Practice," a copy of this letter and its enclosure 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 Web site at https://www.nrc.gov/reading-rm/adams.html.

To continue review of the request, please submit your response to this letter within 30 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: 2022.11.10 12:00:00 -06'00'
Adobe Acrobat version: 2022.003.20263

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

Docket No.: 030-09398
License No.: 13-02128-03
Control No.: 631886