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

May 1, 2023

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 regarding the letter dated December 20, 2022, signed by Terri S. Ruff, MBA, MHA, Chief Operating Officer, providing additional information for 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 in which additional or clarifying is still needed:

1. 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 Title 10 of the *Code of Federal Regulations* (10 CFR) §20.1502.

   Your revised commitment identifies that your institution 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.

   Title 10 CFR 20.1502(a), identifies that licensees must monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring by:

   - Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in §20.1201(a),
   - Minors likely to receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);
   - Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv); and
   - Individuals entering a high or very high radiation area.

It is not apparent that your revised commitment accounts for monitoring workers that are likely to receive a radiation dose in excess of the regulatory limits requiring monitoring or who may enter a high radiation area in the event of an emergency and/or unusual event.

Please provide an acceptable and complete response.

2. 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.

Upon review of the submitted HDR Remote Afterloader Emergency Procedure, I was unable to locate where your procedure describes the process for restricting access to the treatment area to minimize the risk of inadvertent exposure.

Please revise and resubmit your HDR Remote Afterloader Emergency Procedure addressing the process for restricting access to the treatment area.

3. 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.

Your application includes excerpts from the relevant licensing guidance entitled, “Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance,” Revision 10.2, dated April 20, 2021. Though, the format and content of these excerpts do not represent a procedure or commitment. Further, the excerpts are included under Section 8.8, “Item 8: Training for Individuals Working in or Frequenting Restricted Areas,” rather than a separate section of your Radiation Protection Program addressing your Y-90 SIR-Spheres and Y-90 TheraSpheres Procedures.

Please revise and resubmit your Y-90 SIR-Spheres and Y-90 TheraSpheres Procedures and Commitments including applicable procedures and commitments.

4. Your request identified that you have ceased all licensed operations involving IsoAid, LLC, Advantage I-125 radioactive seeds for radioactive seed localization permitted by 10 CFR §35.1000 as previously authorized in Items 6, 7, 8 and 9, Subitem J, of your license.

Your response included a return summary from IsoAid, LLC., that appears to identify sources received by the manufacturer/distributor for disposal. Though, the documentation is unclear and does not clearly state that. Please provide a receipt letter from the manufacturer/distributer acknowledging receipt of the sources from your institution for disposal.

5. Your request included a closeout survey for areas in which the IsoAid, LLC, Advantage I-125 radioactive seeds were previously used and stored. Though, the closeout survey reports do not include all required information, which should include all of the following, as applicable:

- Specify each location/address of use that corresponds to the areas of use you are requesting to release for unrestricted use;
- Diagrams of each facility (area(s) of use and/or locations/addresses of use) with exposure rate survey and wipe test results keyed to specific locations, as appropriate;
- The name and position of the person(s) performing the survey;
- The last date(s) of use for each radioactive material possessed, used or stored in the areas of use you are requesting to release for unrestricted use. This includes sealed and unsealed materials;
- The date(s) when the surveys were performed;
- The instrument(s) used for exposure rate measurements and for analysis of the wipes;
- Background readings and each instruments' efficiency or correction factor. Include the energy level(s) and energy level "windows" you counted for;
- The date(s) that the survey instrument(s) were last calibrated;
- The action levels for both exposure rate measurements and wipe tests. Include the functional identity of areas exceeding these levels, corrective actions taken and results of corrective actions taken. A reasonable sampling of all surfaces likely to exhibit residual radioactive material or to contain radiation sources should be taken. Specify whether and where previous spills occurred and how they were remediated;
- If sealed sources were used in the affected areas/locations, please include a copy of the most recent inventory and leak test results for each source. These records must include all of the information required by 10 CFR §35.2067(b) and §35.2067(a) for inventories and leak tests, respectively.

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 website at https://www.nrc.gov/reading-rm/adams.html.

To continue review of the 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: 2023.05.01 16:30:00 -05'00'
Adobe Acrobat version: 2023.001.20143

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

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