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

February 18, 2021

Khuraam Rashid, M.D.
Radiation Safety Officer
St. Joseph Mercy - Oakland
44405 Woodward Ave.
Pontiac, MI 48341

Dear Dr. Rashid:

We have reviewed the licensee's request dated January 26, 2021, to renew its U.S. Nuclear Regulatory Commission (NRC) Material License No. 21-11651-01 for St. Joseph Mercy – Oakland. Based on our review of the information, we have identified that additional information is needed to proceed with the renewal process. Please refer to NUREG 1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses," which is accessible at https://nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html for guidance when preparing your response.

In a signed by management and dated letter, please provide the following information by March 30, 2021:

1. Please clarify whether you are requesting authorization of any byproduct material permitted by Title 10 *Code of the Federal Regulations* (CFR) 35.300 material or iodine-131 permitted by 10 CFR 35.300 only.

2. Please provide the Sealed Source and Device Registry certificate number for the use of palladium-103 sealed sources.

3. Please provide the history of use for the cesium-131 sealed sources. Specifically, please provide the date when the material was last used at your facility and disposal documents (sealed source inventory and decay-in-storage documentation or documentation demonstrating the sources were returned to the manufacturer, and acknowledgment of receipt of the sealed sources).

4. Please provide the history of use for iridium-192 sealed sources. Specifically, please provide the date when the material was last used at your facility and disposal documents (sealed source inventory and decay-in-storage documentation or documentation demonstrating the sources were returned to the manufacturer, and acknowledgment of receipt of the sealed sources).

5. Radiation Safety Officer (RSO) qualifications:

    a. Please provide documentation of the additional training for the RSO in accordance with 10 CFR 35.57(a) associated with the use of 10 CFR 35.1000 (TheraSpheres) material.
    b. Please provide signed and dated Delegation of Authority Letter (see Appendix I in NUREG 1556, Volume 9, Revision 3 for a sample Delegation of Authority Letter).

6. Facility diagram:

    a. Please resubmit diagrams 8.9.1.a, and 8.9.1.c. and label rooms/areas adjacent to every room where radioactive material is used and stored (some rooms are not labeled/blank, also label “outside” if applicable).
    b. Please describe/label rooms/areas which are above and below rooms where radioactive material is used and stored.
    c. Please describe/illustrate rooms/areas where the brachytherapy seeds are implanted.

7. Please describe any specialized equipment you have when using unsealed radiopharmaceuticals such as fume hood, etc.

8. For 10 CFR 35.300 and 35.400 material, please confirm that patients will be released in accordance with 10 CFR 35.75 requirements. If you will have in-patient rooms (patients will be hospitalized after injection/intake/implant of 10 CFR 35.300 or 10 CFR 35.400 material), please provide a diagram of the in-patient rooms and adjacent areas/rooms indicating restricted and unrestricted areas, occupancy factors for all adjacent rooms including above and below, distances between the source and the adjacent rooms, the type and thickness of the shielding material. Also, please provide an evaluation demonstrating that the dose levels in all directions from the patient in the adjacent rooms will not exceed the NRC regulatory limits.

9. Resubmit the commitment for Area Surveys: “We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.”

10. Resubmit the commitment for Waste Management: “We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92.”

11. Please provide documentation signed by an Authorized User (AU)/Program Director attesting that Dr. Seedial received training under supervision of an AU in:

a. preparing and administering patient dosages, and
b. evaluating patient or research subject's treatments to determine whether the administered dosage was in accordance with the written directive or if a medical event has occurred.

In accordance with 10 CFR 2.390, a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Magdalena R. Gryglak

Digitally signed by Magdalena R. Gryglak
Date: 2021.02.18 14:10:47 -06'00'

Magdalena R. Gryglak
Health Physicist
Materials Licensing Branch

License No. 21-11651-01
Docket No. 030-02104