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

May 2, 2022

Wallace Fuhrman
Radiation Safety Officer
St. Mary's Health Center
6420 Clayton Rd.
St. Louis, MO 63117

Dear Mr. Fuhrman:

We have reviewed the licensee's request dated January 2, 2022, to renew its U.S. Nuclear Regulatory Commission (NRC) Material License No. 24-08960-02 for St. Mary's Health Center. 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 and dated letter, please provide the following information by June 2, 2022:

1. Please provide the commitment: "We have developed and will implement written procedures for safe use of unsealed byproduct material that meet the requirements of Title 10 of the *Code of Federal Regulations* (CFR) 20.1101 and 10 CFR 20.1201."

2. Please provide the medical license numbers for the following physicians:

    - Manoj K. Eapen, MD
    - Garrett A. Hagen, M.D.
    - Razi Muzaffer, D.O.

3. Facility diagram - 6420 Clayton Rd., St. Louis, Missouri:

    a. Specify the material use at this location of use (e.g. 10 CFR 35.100, 35.200, etc.).
    b. Provide a diagram of the department after renovations are completed by clearly showing boundaries/walls of the rooms where material is used and the door entries.
    c. Label each room where radioactive material is used and stored (e.g. hot lab, imaging room, stress test room, injection room, etc.).
    d. Illustrate and label each adjacent room/area including above and below.
    e. Provide the address on the diagram and show the direction of north.
    f. Provide the room dimensions/scale on the diagram for each room where material is used.
    g. Describe measures to secure the material when in storage (i.e. illustrate locked doors, locked storage cabinets, etc.).

h. Illustrate on the diagram and describe areas/equipment inside the hot lab (e.g. radioactive waste storage, material receipt, work area, radioactive material storage, fume hood, sink).
i. Describe the storage location for the 10 CFR 35.400 material.
j. Describe and provide diagrams where 10 CFR 35.400 material is administered.
k. Describe the emergency response equipment when handling 10 CFR 35.400 material.

4. Facility diagram at 1027 Bellevue, St. Louis. Missouri. Specifically, address the following:

   a. Specify the material use at this location of use.
   b. Address questions 3.b.-3.h. for this location of use.

5. Facility diagram-High Dose Rate (HDR) Remote Afterloader:

   a. Provide a diagram illustrating the HDR treatment room.

   b. Illustrate all adjacent rooms/areas surrounding the HDR treatment room, including the areas above and below.

   c. State the street address on the diagram and show the direction of north.

   d. Provide the dimensions of the HDR treatment room or the scale.

   e. Indicate on the diagram whether the HDR treatment room and the adjacent rooms/area including above and below, are restricted or unrestricted area in accordance with 10 CFR 20.1003 definition.

   f. Indicate on the diagram where you anticipate the patient/"exposed source" to be located within the room during treatments.

   g. Illustrate/describe the location in the room where the HDR device will be stored.

6. Shielding Evaluation-HDR treatment room:

   a. Please provide a shielding evaluation; showing your work, barrier transmission factors; explain assumptions; define terms, equations, constants, substitutions and parameters to demonstrate that radiation levels in all adjacent areas, including above and below the HDR treatment room will not exceed the levels in 10 CFR 35.1301 for members of the public and radiation workers.

   b. Please include the following details in your calculations:

      - occupancy factors and transmission factors used for all adjacent areas, including areas above and below;
      - the activity of the source during treatment;
      - any other assumptions.

c. For each barrier in each direction of the HDR room, including the ceiling, specify the **existing** shielding material/s:

- Provide the type of the existing shielding material (ordinary concrete, lead, etc.).
- Provide the thicknesses of the existing material/s.
- Provide the distances from the patient/exposed source to the adjacent rooms in all directions including above and below.
- Illustrate/label the calculated dose rates/points on the diagram.

7. Please describe any physical/administrative controls to limit access to any adjacent areas in order to reduce exposure, if applicable based on the expected dose rates.

8. Other equipment and controls related to the use of the HDR unit:

a. Describe the process for controlling the HDR treatment room door keys, the HDR unit storage keys, and the console keys when the unit is in storage to ensure the keys are inaccessible to unauthorized personnel (i.e. describe the storage location for the keys and personnel with access).

b. Describe warning systems and restricted area controls:

- Signs
- warning lights
- alarms
- interlock system

c. Describe the viewing and intercom systems.

d. Describe the area radiation monitoring equipment to indicate radiation levels in the HDR treatment room.

e. Describe steps to ensure that no radiation-producing equipment can be operated simultaneously with the HDR unit. Describe other radiation-producing equipment in the HDR treatment room.

f. Describe the emergency equipment available in the HDR treatment room.

9. Please provide steps/procedures to perform each of the spot checks in accordance with 10 CFR 35.643 to ensure the systems/equipment function/s as designed:

- electrical interlocks
- source exposure indicator lights on the HDR unit, on the control console, and in the facility
- viewing and intercom systems
- emergency response equipment
- radiation monitors used to indicate the source position
- Timer accuracy
- Clock in the unit’s computer
- Decayed source activity

In accordance with 10 CFR 2.390, a copy of this letter 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: 2022.05.02 14:16:06 -05'00'

Magdalena R. Gryglak
Health Physicist
Materials Licensing Branch

License No. 24-08960-02
Docket No. 030-02351