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

July 30, 2021

Alexander Georgiades, M.S.
Radiation Safety Officer
Columbus Regional Hospital
Radiology Department
2400 E 17th St.
Columbus, IN 47201

Dear Mr. Georgiades:

We have reviewed the licensee's request dated May 12, 2021, to renew its U.S. Nuclear Regulatory Commission (NRC) Material License No. 13-01631-05 for Columbus Regional Hospital. 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 August 31, 2021:

1. Please provide the Sealed Source and Device Registry (SSDR) number for your cesium-137 source, model 067-6500.

2. Please provide the medical license numbers for all Authorized Users to be retained on your license. Further, please specify whether Parag Sevak, M.D. is to be removed or retained on the license. If the physician is to be retained on the license, specify the material use.

3. For Title 10 of the Code of Federal Regulations (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/patient and the adjacent rooms, and 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 10 CFR Part 20 dose limits.

4. Please describe measures to secure the radioactive material when in storage in the Nuclear Medicine Department.

5. Facility diagram - PET/CT Department:

    a. Specify areas above and below the injection rooms.
    b. Provide a shielding evaluation for the PET hot lab and the injection rooms to ensure dose rates do not exceed the 10 CFR Part 20 dose limits. In your evaluation, specify the adjacent rooms and whether the rooms are restricted, the occupancy factors for all adjacent rooms including above and below, distances between the source and the adjacent rooms, and the type and thickness of the shielding material.
    If other controls (i.e. shielding, administrative controls) are used to ensure the 10 CFR Part 20 dose limits are not exceeded in those rooms, please describe.
    c. Specify area/s below and above the PET/CT Imaging room, provide the distances to the area/s rooms above and below, and the type and thickness of the shielding material, if applicable.
    d. Confirm that all brachytherapy sealed sources are stored in the Positron Emission Tomography (PET)/CT hot lab.
    e. Describe measures to secure the material when in storage.
    f. Describe any additional equipment (e.g. remote handling devices, storage containers) for handling PET material, if applicable.

6. Facility diagram- Room A125A:

    a. Clarify what the “Cesium storage” is.
    b. Provide dimensions of room A125A.
    c. Describe measures to secure the iridium-192 source/s when in storage during source exchange.

7. Facility diagram-High Dose Rate (HDR) Remote Afterloader Room (A117A):

    a. Clarify the HDR unit storage location (i.e. the diagrams provided show the HDR storage in various locations).
    b. Indicate whether the HDR room and each adjacent room/area including above is restricted or unrestricted area in accordance with the 10 CFR 20.1003 definition.
    c. Resubmit the shielding evaluation for the Iridium-192 source with an activity of 12 curies.
    d. For each barrier in each direction of the HDR room, including the ceiling, clarify 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.
    - Illustrate the calculated dose rates/points on the diagram (please note that your letter dated October 2, 2017 contained the necessary information).

e. 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).

f. Describe warning systems and restricted area controls (e.g. signs, warning lights, alarms) in the HDR room.

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

h. Confirm that there is no other radiation producing equipment in room A117A, which could be operated simultaneously with the HDR unit.

8. Please provide steps (i.e. procedures) to perform each of the spot checks in accordance with 10 CFR 35.643 to ensure the systems/equipment function/s as designed.

9. Please provide the date when the last iridium-192 source was used in room A123A, a leak test record for the source and the disposal record.

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: 2021.07.30 10:01:07 -05'00'

Magdalena R. Gryglak
Health Physicist
Materials Licensing Branch

License No. 13-01631-05
Docket No. 030-01597