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

January 26, 2021

Nathan C. Davis, M.S.
Radiation Safety Officer
Reid Hospital and Health Care Services
1100 Reid Parkway
Richmond, IN 47374

Dear Mr. Davis:

We have reviewed the licensee's requests dated November 20, 2020, to renew its U.S. Nuclear Regulatory Commission (NRC) Material License No. 13-03284-02 for Reid Hospital and Health Care Services and December 29, 2020 to name a new Radiation Safety Officer (RSO). 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 1, 2021:

1. Appointment of a new RSO:

    a. Please provide a license number where Mr. Byrne is listed as the RSO for 10 CFR 35.400 material use or provide the additional training in accordance with 10 CFR 35.57(a).
    b. Because the proposed RSO is responsible for overseeing multiple facilities where radioactive material is used, please provide additional information regarding the proposed RSO's ability to perform RSO duties:
        - Confirm that the proposed RSO will allocate adequate time at the facility to permit the performance of the duties of the RSO as described in the regulations (you may state the minimum amount of onsite time (hours per week or days per quarter, as appropriate for the program, if desired).
        - Identify an in-house representative who will serve as the point of contact during the RSO's absence.
        - Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of the radiation safety program and related regulatory requirements.
        - Specify the maximum amount of time it will take the consultant-RSO to arrive at the facility in the event of an emergency that requires his presence.

2. Facility diagram-Nuclear Medicine Department:

a. Please resubmit the diagram for the Nuclear Medicine Department indicating the address of use and the direction of north.
b. Specify the radioactive material that is used in the Nuclear Medicine Department (e.g. Title 10 of the Code of Federal Regulations (CFR) 35.100, 35.200, etc.).
c. Provide an enlarged diagram of the hot lab and illustrate the storage area for the unsealed material, storage area for sealed sources, waste area, material receipt/work area, fume hood, sink etc.

3. Facility diagram-Nuclear Cardiology Department:

   a. Please resubmit the diagram for the Nuclear Cardiology Department indicating the address of use and the direction of north (the diagram was illegible).
   b. Provide scale or dimensions for each room/area where radioactive material is used.
   c. Specify the radioactive material that is used in the Nuclear Cardiology Department (e.g. 10 CFR 35.100, 35.200, etc.).
   d. Provide an enlarged diagram of the hot lab and illustrate the storage area for the unsealed material, storage area for sealed sources (if applicable), waste area, material receipt/work area, fume hood, sink etc.

4. Facility diagram-PET/CT Suite:

   a. Resubmit the PET/CT suite diagram indicating the address of use and direction of north.
   b. Specify the radioactive material that is used in the Nuclear Medicine Department (e.g. 10 CFR 35.100, 35.200, etc.).
   c. Provide an enlarged diagram of the hot lab and illustrate the storage area for the unsealed material, storage area for sealed sources (if applicable), waste area, material receipt/work area, fume hood, sink etc.
   d. Describe/illustrate measures to secure radioactive material in storage (e.g. locked doors, etc.)
   e. Confirm that the existing shielding material type and thickness in the imaging room, uptake room 1, uptake room 2, and the hot lab is as described as the recommended shielding material in your shielding evaluation dated March 15, 2008.

5. Facility diagrams for the 10 CFR 35.400 material use:

   a. Please resubmit the diagram/s for rooms 5A006 and HDR/Brachytherapy room and hot lab/s, if applicable, (you may provide one diagram for the same address of use and include Item 9) where the sealed sources are used indicating the address and the direction of north.
   b. Describe where the sealed sources are stored at each location of use.
   c. Describe measures to secure sealed sources when in storage.
   d. Describe/illustrate the rooms/areas adjacent to the brachytherapy rooms including above and below.
   e. Describe the emergency equipment available in each brachytherapy room in accordance with 10 CFR 35.415(b).

6. Please describe any specialized equipment you have when handling PET material, radiopharmaceuticals or sealed sources to reduce exposure (i.e. remote handling devices, storage containers, fume hoods, etc.).

7. 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, 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.

8. Facility diagram-High Dose Rate Room:

    a. Resubmit the diagram and indicate the address where the HDR unit is housed and direction of north.
    b. Provide the dimensions of the HDR treatment room or the scale.
    c. Describe the rooms/areas adjacent **including rooms/areas above and below**.
    d. Indicate/describe the storage room/area for the HDR unit (i.e. where is the HDR unit stored/secured when the room is used for a brachytherapy procedure).
    e. Indicate whether each adjacent room/area including above and below is restricted (R) or unrestricted (U) area in accordance with the 10 CFR 20.1003 definition.
    f. For each barrier in each direction of the HDR room, including the floor and ceiling, describe 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.

        You may reference the specific table/s in the Radiation Shielding Evaluation-High Dose Rate Afterloader Room, dated August 11, 2006 for shielding type, thickness and distance. However, please clarify the type of shielding you have in place in each direction (i.e. lead, ordinary concrete, high density concrete or a combination), confirm the thicknesses and distances in each direction.

9. Other Equipment and Facilities-HDR:

    a. Please describe the process for controlling the HDR unit keys, the treatment room door 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 the personnel with access).

10. Emergency procedures in accordance with 10 CFR 35.610:

    a. Resubmit the emergency hospital procedure (some flowcharts were illegible).
    b. Please describe situations/scenarios when the emergency procedure might be needed (provide other scenarios you may encounter in addition to HDR system path constriction such as patient intervention, other equipment malfunction, or loss of power, etc.) and the steps to take (you may reference a specific point in procedure/flow chart).
    c. Please clarify the relationship between the hospital emergency procedure and the manufacturer's emergency procedure (hospital procedure does not reference the manufacturer procedure).
    d. Clarify that an Authorized Medical Physicist must be present during treatments in accordance with 10 CFR 35.615 requirements.
    e. Clarify the name of individual/s to be responsible for implementing corrective actions in accordance with 10 CFR 35.610 and update emergency contact list, if applicable.
    f. Address the training requirements in 10 CFR 35.610(d) and (e) in your procedure.

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: 2021.01.26 09:07:30 -06'00'

Magdalena R. Gryglak
Health Physicist
Materials Licensing Branch

License No. 13-03284-02
Docket No. 030-01614