



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

October 20, 2023

Nathan C. Davis, M.S.
Radiation Safety Officer
Hendricks Regional Health
1000 E Main St.
Danville, IN 46122

Dear Nathan C. Davis:

We have reviewed the licensee's request dated June 29, 2023, to renew its U.S. Nuclear Regulatory Commission (NRC) Material License No. 13-17082-01 for Hendricks Regional Health.

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: Program-Specific Guidance About Medical Use Licenses," which is accessible at <https://www.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 November 24, 2023:

1. For Title 10 of the *Code of Federal Regulations* (CFR) 35.300 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 of 10 CFR 35.300 material), please provide the following:

- submit a diagram of the in-patient rooms and adjacent areas/rooms;
 - indicate restricted and unrestricted areas;
 - indicate occupancy factors for all adjacent rooms including above and below;
 - indicate distances between the source/patient and the adjacent rooms;
 - indicate the type and thickness of the shielding material;
 - provide an evaluation demonstrating that the dose rates in all directions from the patient in the adjacent rooms will not exceed 10 CFR Part 20 dose limits.
2. Please provide a legible diagram for your Positron Emission Tomography (PET) suite demonstrating the following:
 - indicate the distances between the patient/source and the adjacent areas/rooms in all directions, including the ceiling;

- describe the inputs/assumptions and the resulting dose rates at the specific points on the diagram;
 - illustrate the restricted and unrestricted rooms/areas;
 - confirm that the currently installed shielding materials and thicknesses reflect the values provided in the shielding report dated May 26, 2017;
 - explain whether there is any separation/shielding installed between quiet bay 1 and quiet bay 2. If so, please provide the type of material and the thickness and the distances between the wall and the source/patient.
3. Describe equipment to handle PET material.
 4. Describe the control and security of the material in the PET suite.
 5. Please address measures to secure the high dose rate remote afterloader (HDR) unit and the keys when unattended as required by 10 CFR 35.610(a). Specifically, describe the following:
 - describe controls to secure the HDR vault or the HDR storage cabinet, the HDR unit, the HDR console, and the keys;
 - describe the location of storage for the keys (the HDR unit key, the console key, and the door key);
 - describe the individuals with access to the keys.
 6. Describe measures/systems required by 10 CFR 35.615 to safely operate the HDR unit:
 - locks, warning lights and alarms
 - the door interlock system
 - area radiation monitors and radiation detection equipment available
 - posting
 - viewing and communication system
 - emergency equipment available
 7. As required by 10 CFR 35.610(a)(3), please provide a commitment that only one radiation producing device will be used in the HDR treatment room at a time. If you have other radiation producing devices in the vault where the HDR is located, please describe measures to ensure no two radiation producing units can be operated simultaneously.
 8. As required by 10 CFR 35.643, please provide your procedure to perform periodic spot-checks. Please note the procedure should address how each spot-check is performed, designated individual to review the results of the spot-check, record retention, and actions to take if there is a malfunction identified.
 9. Please describe emergency scenarios that would require an immediate entry into the HDR treatment room and implementation of the emergency procedure. Please provide the hospital specific emergency procedure in accordance with 10 CFR 35.610.

N. Davis

-3-

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
Health Physicist
Materials Licensing Branch

License No. 13-17082-01
Docket No. 030-12163