



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

January 19, 2024

Randall J. Phillips, M.D.
Radiation Safety Officer
IOM Health System, LP
d/b/a Lutheran Hospital of Indiana
7950 W. Jefferson Blvd.
Fort Wayne, IN 46804

SUBJECT: AMENDMENT NO. 82 TO RADIOACTIVE MATERIALS LICENSE FOR IOM HEALTH SYSTEM, LP, D/B/A LUTHERAN HOSPITAL OF INDIANA, U.S. NRC MATERIALS LICENSE NO. 13-01535-01

Dear Dr. Phillips:

Enclosed is Amendment No. 82 to your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-01535-01 in accordance with the letter dated November 17, 2023, signed by David Brooks, Chief Operating Officer.

This amendment accounts for the following requested changes:

- addition of a new area of use at your licensed facility;
- removal of the former location at 7916 W Jefferson Blvd., Fort Wayne, Indiana;
- addition of Brady Laughlin, D.O., as an Authorized User with authorization to use licensed materials described in Title 10 of the *Code of Federal Regulations* (10 CFR) §35.300 and §35.1000 (limited to yttrium-90 as TheraSpheres); and
- updated the manufacturer's/distributor's names of the yttrium-90 SIR-Sphere and TheraSphere microspheres and delivery system.

The request identified that all licensed materials have been removed from your former location and transferred to your licensed facility located at 7950 W. Jefferson Blvd., Fort Wayne, Indiana. The accompanying documentation also included a closeout survey report documenting the absence of remaining residual radioactive material.

Based on the statements and the review of the closeout survey report, it appears that all licensed radioactive material has been removed from your former facility and residual radioactive material attributable to licensed activities does not exceed current U.S. NRC criteria. Your facility is suitable for release to unrestricted use.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. NRC Region III office at (630) 829-9887 so that appropriate corrections and answers may be provided.

An environmental assessment for this action is not required because this action is categorically excluded under 10 CFR §51.22(c).

You will be periodically inspected by the U.S. NRC. Failure to conduct your program in accordance with U.S. NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with U.S. NRC will result in enforcement action against you. This could include issuance of a notice of violation; or imposition of a civil penalty; or an Order suspending, modifying, or revoking your license as specified in the U.S. NRC Enforcement Policy. Since serious consequences to employees and the public can result from failure to comply with U.S. NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance that U.S. NRC expects of its licensees.

The U.S. NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on U.S. NRC's safety culture website at <https://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. I encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in U.S. NRC-regulated activities.

In accordance with 10 CFR §2.390 of the U.S. NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the U.S. NRC Public Document Room or from the U.S. NRC's ADAMS, accessible from the U.S. NRC website at <https://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

Jason M. Kelly, MPH, CPH
Health Physicist
Materials Licensing Branch

Docket No.: 030-01594
License No.: 13-01535-01

Enclosure: Amendment No. 82 to U.S. NRC Materials License No. 13-01535-01