



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

August 4, 2020

Randall J. Phillips, M.D.
Radiation Safety Officer
IOM Health System, LP
d/b/a Lutheran Hospital of Indiana
7950 West Jefferson Boulevard
Fort Wayne, IN 46804-1677

Dear Dr. Phillips:

Enclosed is Amendment No. 80 to your NRC Material License No. 13-01535-01 in accordance with your request.

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. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

If you have any questions concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is 630-515-1078. My email address is colleen.casey@nrc.gov and email is the best way to reach me.

In this amendment we approved the addition of the yttrium-90 TheraSphere delivery system, permitted by 10 CFR 35.1000, and we approved Jonathan Lee, M.D. as an authorized user for the yttrium-90 TheraSphere delivery system, permitted by 10 CFR 35.1000.

This amendment also deletes the authorization for gadolinium-153, permitted by 10 CFR 35.500, from your license. With the deletion of this authorization in Subitem Nos. 6. through 9 G., as it appeared on Amendment No. 79, we also deleted this authorization from the following authorized users in Condition No. 12.B.: Doctors Arata, Borman, Decamp, Hagedorn, Heatwole, Janizek, Kowalski, Parker, Pasalich, Patel, Phillips, Sibley, Stephens, Stovall, Strange and Thomas.

Please note that, with these changes, some of your Subitem Numbers and Conditions have been re-ordered. Please check your amended license very carefully and contact me if you have any questions.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with 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 General Statement of Policy and Procedure for NRC Enforcement Actions.

Since serious consequences to employees and the public can result from failure to comply with 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 which NRC expects of its licensees.

The 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 NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

We strongly 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 NRC-regulated activities.

Sincerely,

Colleen C.
Casey

Digitally signed by Colleen C.
Casey
Date: 2020.08.04 17:05:20
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Colleen Carol Casey
Materials Licensing Branch

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

Enclosure:

Amendment No. 80