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

July 15, 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. 79 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 were only able to approve Saad M. Ibrahim, M.D. as an authorized user for materials in 10 CFR 35.1000, limited to yttrium-90 SIRspheres for permanent brachytherapy.

We were unable to approve the addition of the yttrium-90 TheraSphere delivery system, permitted by 10 CFR 35.1000, because the information in your letter dated April 13, 2020, was insufficient for us to complete our review.

We were also unable to approve Jonathan Lee, M.D. as an authorized user for the yttrium-90 TheraSphere delivery system, permitted by 10 CFR 35.1000, only because we could not add this new authorization to your license.

If you wish to pursue these authorizations, please provide the information requested below and follow the response instructions in section B.1. below. We will then resume our review.

A. The document entitled "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance" dated March 20, 2020, Revision 10.1 was used to evaluate the commitments and requests made in your letter dated April 13, 2020.

   The following sections of this guidance, located on our website at https://www.nrc.gov/docs/ML2008/ML20080J208.pdf were found to be either missing

from your letter dated April 13, 2020, lacking relevant detail or incomplete: 6.1, 6.2, 6.2.1, 6.2.2, 6.3, 6.6, 6.7 and 6.8.

Please provide appropriately detailed, comprehensive written responses for each of the above sections to ensure your commitments and the description of your proposed TheraSphere program is complete. The level of detail needed is reflected in each section in the guidance itself.

B. This also refers to our letter to you dated October 23, 2019, concerning your authorization for gadolinium-153 under 10 CFR 35.500.

To date, we have not received any further information from you regarding the status of this authorization or your plans to resolve our questions concerning your request for removing it from your license.

Within 30 days of the date of this letter, please provide a written response to the items below, excerpts of which we are repeating here from our letter to you dated October 23, 2019. If you need to make an alternate, definitive timeframe arrangement for response, please contact me at 630-829-9841 or, best, email me at colleen.casey@nrc.gov.

It is your responsibility to keep the license current. We look forward to establishing a dialogue with you to resolve this matter.

"This also refers to your letter ("the letter") dated July 16, 2019, in which you requested that materials permitted by 10 CFR 35.500 be deleted from your license as "they have not been used at the facility for many years."

The only material currently listed on your license under 10 CFR 35.500 is gadolinium-153.

We were unable to approve the deletion of this material because the information in your letter was insufficient to complete our review.

Please provide only one complete, written response that is addressed to my attention at the above address, as "additional information to control numbers 613710 and 618630."

Please be sure to accompany/transmit your response with a brief business style letter that identifies your license by name, mailing address and license number; control number as given above; is currently dated; is physically and legibly signed by a senior management representative; is addressed to my attention; and completely resolves the information requested below to continue our review. This will help ensure that your response is processed correctly in our offices. We will then continue our review.

Under no circumstances should you submit more than one, complete, written response, even by different means of transmission, such as email, regular mail, etc. To do so will introduce confusion and delay in the processing and review of your response.

1. Your letter states that "they have not been used at the facility for many years," referring to materials in 10 CFR 35.500, i.e., the gadolinium-153.

But this statement is insufficient to justify the removal of these sources from your license.

For historical context, please state when the approximate last date of use was for the gadolinium-153 sources.

What has happened to the gadolinium-153 sealed sources since the last date of use, where are they?

Please note that we will corroborate your response with a review of your inspection history.

2. Your letter did not indicate whether it was also your intention to remove areas of use and/or locations of use from the license, where the gadolinium-153 sealed sources were ever received, possessed, used or stored, for unrestricted use.

   In your response, please clearly state whether you wish to have areas of use and/or locations of use removed from the license where these materials were ever received, possessed, used or stored, for unrestricted use.

   Please state specifically which areas of use and/or locations of use you wish to have removed from the license for unrestricted use.

   Please submit complete diagrams of each affected facility (area(s) of use and/or locations/addresses of use) with exposure rate survey and wipe test results keyed to specific locations, as appropriate. In the alternative, it may be possible for you to submit the final leak tests for these sealed sources prior to their final transfer for disposal.

   Please submit complete diagrams of each affected facility (area(s) of use and/or locations/addresses of use) with exposure rate survey and wipe test results keyed to specific locations, as appropriate.

   Do not submit blueprints or copies of blueprints. The diagrams you used to add the affected areas of use to the license; the diagrams you used for routine exposure rate surveys and wipe tests; and/or diagrams prepared in accordance with NUREG 1556 Vol. 9, Rev. 3, Figure 9.1 (add the direction of north) are examples of diagrams that will facilitate our understanding of the areas you wish to release for unrestricted use.

   Submitting diagrams of only certain components/fragments of the areas you are requesting to be released for unrestricted use, such as certain walls, hoods, sinks, floors, etc., without the full context of each entire affected area, is unacceptable and leads to confusion.

3. Please note that we cannot authorize licensees to release the "locations/addresses of use" or "areas of use" from licenses for unrestricted use (even by other staff members) until we have received and reviewed a copy of the results of final status surveys, i.e., "decommissioning" and "close-out surveys," for the affected facilities.

The final status surveys must include a complete historical review of all actual licensed materials possessed, used, stored, etc., including sealed sources and unsealed materials, spills, and contamination.

For the removal of the gadolinium-153 sealed sources from your license, if sources were transferred or disposed of please provide a copy of the final leak test result for the sealed source; a copy of an acknowledgment of receipt from the licensed entity who took possession of the source, with an appropriate level of detail to identify the source and recipient; the NRC license number or license copy of the recipient/transferee; and if the recipient/transferee is an Agreement State licensee, please include a current and complete, un-redacted copy of its license that clearly shows it is licensed to receive your sources.

The final leak test results and inventory results must contain the information required by 10 CFR 35.2067(a) and (b), respectively.

If your sealed sources were transferred to another appropriately licensed entity or transferred for disposal, and if the source transfer took place within 6 months of the source's receipt under your license, it may be possible to use the leak test provided by the vendor that accompanied the source initially.

If the transfer took place 6 months or more after the sources were initially received by you, then a leak test must have been performed prior to transfer or disposal.

Please note that common documents we often see submitted for the purpose of demonstrating that sealed sources have been transferred or disposed of to appropriately licensed entities, such as bills of lading, shipment manifests and shipping papers, do not usually contain sufficient information to demonstrate that materials have been safely received.

They typically indicate that materials were prepared for shipment or transfer only, not that they were received and accepted into the recipient's inventory under its license.

In addition, bills of lading, shipment manifests and shipping papers typically are prepared with a printing font too small to read. It may be necessary to adjust the copying function for such documents to permit readability, such that a font of approximately 11 results.

4. If you are still in possession of gadolinium-153 as sealed sources under 10 CFR 35.500, please note that it is expected that you are actively arranging the final transfer and disposal of this material.

   This is because 10 CFR 35.92 restricts the disposal of licensed material for "decay – in- storage" (DIS) to only those materials with a half- life of 120 days or less, provided that those materials meet the other requirements in 10 CFR 35.92.

   Gadolinium-153 has a half- life of 242 days, which excludes it from DIS.

   In your written response, please describe the measures you are taking to dispose of the gadolinium-153 on your license.

Please also include a reasonable, approximate near-term timeframe when you expect to have these materials disposed of to an appropriately licensed entity.

Only after all gadolinium-153 has been disposed of to an appropriately licensed entity and its contamination status verified with leak tests and/or wipe test surveys, will we be able to consider removing this authorization from your license.

5. The following references may assist you: 10 CFR 30.41; 10 CFR 30.51;10 CFR 35.92; 10 CFR 35.2092; and NUREG 1556 Vol. 9, Rev. 3.

6. Please also be reminded that 10 CFR 30.9(a) requires: "(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."

C. 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: 2020.07.15 21:34:49 -05'00'

Colleen Carol Casey
Materials Licensing Branch

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

Enclosure:

Amendment No. 79