



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

November 16, 2023

David E. Sieffert, M.S., DABR,
Medical Physicist and Radiation Safety Officer
Lakeland Medical Center - St. Joseph
1234 Napier Ave.
St. Joseph, MI 49085

Dear Mr. Sieffert:

This letter is regarding your request dated October 19, 2023, to amend your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-04177-01.

The U.S. NRC's guidance document for your type of license, which I refer to below as "the guidance," is NUREG-1556, Volume 9, Rev. 3, dated September 2019, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses." This guidance is available on the U.S. NRC website at:
<https://www.nrc.gov/docs/ML1925/ML19256C219.pdf>

Upon review of the request, I identified the following areas requiring additional or clarifying information:

1. Section 8.2, "Item 2: Name and Mailing Address of Applicant," of the guidance, specifies that the applicant must identify the legal name of the applicant's corporation or other legal entity with direct control over use of radioactive material.

Your request identified that legal name identified in the license should be changed to *COREWELL HEALTH – SOUTHWEST MICHIGAN*.

A check with the Michigan Department of Licensing and Regulatory Affairs' (LARA') Corporations Division revealed that the requested name is a fictitious name registered by the legal entity identified as *LAKELAND REGIONAL HEALTH SYSTEM*.

Therefore, please confirm that the legal name to be identified on the license is *LAKELAND REGIONAL HEALTH SYSTEM, d/b/a Corewell Health – Southwest Michigan*.

2. Section 8.2, "Item 2: Name and Mailing Address of Applicant," of the guidance, specifies that the applicant must identify the legal name of the applicant's corporation or other legal entity with direct control over use of radioactive material.

The license was previously issued to *LAKELAND MEDICAL CENTER – ST. JOSEPH*, which according to filings with the Michigan LARA Corporations Division is a fictitious name formerly associated with the legal entity identified as *LAKELAND HOSPITALS AT NILES AND ST. JOSEPH, INC.*

LAKELAND HOSPITALS AT NILES AND ST. JOSEPH, INC. is a distinct and separate legal entity from *LAKELAND REGIONAL HEALTH SYSTEM*. Each legal entity has a

separate identification number on file with the Michigan LARA Corporation Division, including identification numbers 800878253 and 800796560 respectively.

Therefore, the change of legal name does appear to be a change of control subject to review and approval in accordance with [Title 10 of the Code of Federal Regulations \(10 CFR\) §30.34\(b\)\(1\)](#). If applicable, please request consent to the transfer of control by providing all information specified in Appendix E, "Information Needed for Transfer of Control Application," from the U.S. NRC's NUREG-1556, Volume 15, Rev. 1, "Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," which is available at the following link:

<https://www.nrc.gov/docs/ML1618/ML16181A003.pdf>

3. Section 11, "Termination of Activities," of the guidance, identifies the information (i.e., results of final status surveys and results of leak tests of sealed sources) needed to support the release to unrestricted use of areas where licensed materials were previously stored and used.

You requested the removal of licensed material described in Subpart H of Items 6, 7, 8 and 9 of your license. This license provision included authorization for possession and use of yttrium-90 microspheres for medical use in accordance with 10 CFR §35.1000 (limited to yttrium-90 as SIR-Spheres).

Identify if your facility had previously acquired and used the yttrium-90 microspheres. Submit applicable records demonstrating the appropriate transfer/disposal of any associated waste, including the return of any unused patient dosages.

If you will be releasing areas within your facility previously dedicated to the use and storage of the yttrium-90 microspheres, please submit final status surveys demonstrating that those locations are acceptable for release in accordance with [10 CFR §20.1402](#).

In accordance with [10 CFR §2.390](#) of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made 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 <https://www.nrc.gov/reading-rm/adams.html>.

To continue review of your request, please submit your response to this letter within 20 calendar days from the date of this letter. In your response, please refer to the license, docket, and control number specified below. I will assume that you do not wish to further pursue this licensing action if I do not receive a reply within the specified timeframe noted above.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, I encourage you to contact me at (630) 829-9737 or via e-mail at Jason.Kelly@nrc.gov.

Sincerely,

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

Docket No.: 030-02049
License No.: 21-04177-01
Control No.: 637602