



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

January 24, 2022

Christopher M. Durbin, Ph.D.
Radiation Safety Officer
St. Luke's Hospital
Radiology Department
232 S. Woods Mill Rd.
Chesterfield, MO 63017

SUBJECT: RENEWAL OF RADIOACTIVE MATERIALS LICENSE FOR ST. LUKE'S
HOSPITAL, NRC LICENSE NO. 24-01570-03

Dear Dr. Durbin:

Enclosed is Amendment No. 70 renewing your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 24-01570-03, in accordance with your July 27, 2021 renewal application.

Please note that, we did not add Yttrium-90 SIR-Spheres microsphere as permitted by 10 CFR 35.1000 and its authorized users to your license because we did not have sufficient information as discussed in the Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIRSpheres® Licensing Guidance dated April 20, 2021. Specifically, the following information have not been provided: 1) the manufacturer of the Yttrium-90 SIR-Spheres microsphere (only the manufacturer(s) named in the Sealed Source and Device Registry (SSDR) are permitted by the licensing guidance), 2) a description of the location where the Y-90 microspheres will be used and stored, 3) a copy of the permits to use SIR-Spheres microsphere under 10 CFR 35.1000 issued by the Radiation Safety Committee of Mercy Hospital – St. Louis, NRC License No. 24-00794-03, for Guillermo Gonzalez-Araiza, M.D. and Andrew L. Warren, M.D., 4) information that the Radiation Safety Officer (RSO) has completed the training in radiation safety, regulatory issues, and emergency procedures for Y-90 microsphere use, and 5) a commitment that the licensee will use the SIR-Spheres microsphere for permanent brachytherapy in a delivery system as listed in the SSDR. Please resubmit the request for possess and use of SIR-Spheres microsphere as permitted by 10 CFR 35.1000 in accordance with the Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIRSpheres® Licensing Guidance. A digital copy of this current guidance can be found at <https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html>.

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 we may provide appropriate corrections and answers.

An environmental assessment for this action is not required because this action is categorically excluded under Title 10 of the *Code of Federal Regulations* (CFR) Section 51.22(c).

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

The enclosed document contains sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.

C. Durbin

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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 NRC Enforcement Policy. 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 that 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 <https://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.

NRC's Regulatory Issue Summary (RIS) RIS 2005-31 provides criteria to identify security related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through NRC's ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability. The RIS may be located on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" at <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/>, and the link for frequently asked questions regarding protection of security-related sensitive information may be located at <https://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

Frank P. Tran

Digitally signed by Frank P. Tran
Date: 2022.01.24 10:18:20
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Frank P. D. Tran
Health Physicist
Materials Licensing Branch

Docket No.: 030-02305
License No.: 24-01570-03
Control No.: 628104

Enclosure: Amendment No. 70 to NRC License No. 24-01570-03