



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

May 20, 2021

Khurram Rashid, M.D.
Radiation Safety Officer
St. Joseph Mercy – Oakland
44405 Woodward Ave.
Pontiac, MI 48341

Dear Dr. Rashid:

Enclosed is Amendment No. 67 to your U.S. Nuclear Regulatory Commission (NRC) Material License No. 21-11651-01 for St. Joseph Mercy - Oakland in accordance with your request dated January 26, 2021 to renew your license. Please note the license has been renewed for 15 years.

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

Please note that, in accordance with your request dated January 26, 2021, the enclosed amendment has authorized Stephen Seedial, M.D. for the use of yttrium-90 TheraSphere administrations, as permitted by Title 10 of the *Code of Federal Regulations* (CFR) 35.1000. The authorization is conditioned on Dr. Seedial's completion of at least three in-vivo TheraSphere administrations, while under the supervision of a manufacturer representative (if cases are completed before November 8, 2021) or an Authorized User (AU). You will need to provide a written attestation signed by an AU that Dr. Seedial completed the three in-vivo cases (including dates and name of the supervising individual) and that he is able to independently fulfill the radiation safety-related duties as an AU for the administration of yttrium-90 TheraSpheres.

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. The NRC may issue a notice of violation, 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.

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

Sincerely,

Magdalena R. Gryglak
Health Physicist
Materials Licensing Branch

License No. 21-11651-01
Docket No. 030-02104

Enclosure: Amendment No. 67