



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

MAR 27 2018

Kenneth P. Tarr, D.O.
Radiation Safety Officer
McLaren Oakland
50 N. Perry St.
Pontiac, MI 48342

Dear Dr. Tarr:

Enclosed is Amendment No. 61 to your NRC Material License No. 21-04081-03 in accordance with your request.

Please note that at this time we are not able to authorize the addition of the 10 CFR 35.1000 yttrium-90 microspheres to your license because the information provided in letters dated December 14, 2017, and March 13, 2018, did not adequately address the location (specific address) where the materials will be used, written directives and patient release procedures. Specifically, please address the following deficiencies:

- a. In your request, you did not indicate a specific location (the address of the facility) where the material will be used or stored. In order to complete our review, you will need to provide the location (address) where the materials will be used or stored.
- b. In your request, and the additional information provided, you did not provide a complete commitment on written directives. Specifically, you did not provide the following commitment: "For the purpose of written directive and medical event reporting requirements in the Y-90 microsphere guidance, "prescribed dose" means the total dose (rad or Gy). Alternatively, prescribed activity (mCi or GBq) may be used in lieu of prescribed dose. If prescribed activity is used in lieu of prescribed dose, activity should be used for all documentation and evaluations." In order to complete our review, you will need to provide this commitment in writing.
- c. In your request, and the additional information provided, the information provided for patient release was inadequate in that it did not include a commitment to develop procedures to ensure patients are released in accordance with 10 CFR 35.75. In order to complete our review, you will need to provide the following commitment: "The licensee commits to develop procedures that describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research subject permits his or her release in accordance with 10 CFR 35.75."

In addition, while you did provide documentation that the radiation safety officer has received training in the radiation safety, regulatory issues and emergency procedures for the device, a preceptor attestation was not provided. If you wish to pursue this matter, please provide a complete, written response that is currently dated and signed by a senior management official for this license, pursuant to 10 CFR 35.12(a).

In addition, the NRC staff has reviewed the information you have provided in letter dated March 14, 2018. The staff has concluded that residual radioactive material attributable to licensed activities does not exceed current NRC criteria. Based on these conclusions no further actions with respect to NRC regulated material is required and your facility located at 5625 Water Tower Plaza, STE G-33, Clarkston, Michigan, is released for unrestricted use.

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.

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.

In accordance with 10 Code of Federal Regulations 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>.

Sincerely,



Jennifer L. Bishop
Health Physicist
Materials Licensing Branch

License No. 21-04081-03
Docket No. 030-02041

Enclosure: Amendment No. 61