



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

JUN 17 2013

Tyre K. Jones, M.D.  
Radiation Safety Officer  
McLaren Medical Center - Bay Region  
Nuclear Medicine  
1900 Columbus Avenue  
Bay City, MI 48708

Dear Dr. Jones:

Enclosed is Amendment No. 52 to your NRC Material License No. 21-18585-01 in accordance with your request. **Please note, as discussed with Steve Gerhardt of your staff, we are unable to authorize you for possession and use of Yttrium-90 microspheres at this time. This is based on your not having met all of the training requirements as specified in the NRC guidance, "Licensing Microsphere Brachytherapy Sources and Devices (rev. June 2012)."** Specifically, it is necessary that you successfully complete training in the operation of the delivery system, safety procedures, and clinical use for each type of Y-90 microspheres for which authorization is sought. As described in Item B of the guidance document (accessible at <http://pbadupws.nrc.gov/docs/ML1217/ML12179A353.pdf>), this specific training may be satisfied by completion of a training program provided by either: **Pathway 1**: an Authorized User (AU) who is authorized for the type of microsphere for which you are seeking authorization. The clinical use experience should include at least three supervised hands-on cases for each type of Y-90 microsphere for which you are seeking AU status; or **Pathway 2**: a Y-90 microsphere manufacturer, in which the clinical use experience included at least three supervised hands-on *in-vitro* simulated cases for each type of Y-90 microsphere for which you are seeking AU status. Under this pathway, following the license amendment that names you as an AU for Y-90 microsphere use, the first three patient cases completed by you should be hands-on and supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which you are authorized.

**Please also note that we have revised Subitems 6 and 8, and have removed Condition 14, in accordance with current NRC licensing policy.** Please note that the major changes made to your license are printed in **bold font**.

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.

A copy of this letter 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,



Dennis P. O'Dowd  
Health Physicist  
Materials Licensing Branch

License No. 21-18585-01  
Docket No. 030-13900

Enclosure: Amendment No. 52