



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

JUN 07 2017

Mark L. Gates, M.D.
Radiation Safety Officer
Saint Francis Medical Center
211 Saint Francis Dr.
Cape Girardeau, MO 63703

Dear Dr. Gates:

Enclosed is Amendment No. 73 to your NRC Material License No. 24-00158-03 in accordance with your two March 7, 2017 letters, with the exception of adding an authorization for yttrium-90 as SIR-Spheres. The referenced letters have been assigned accession numbers ML17068A355 and ML17068A351, in the NRC's electronic Agencywide Documents Access and Management System (ADAMS). Please note that we have added Condition Nos. 13 and 14, in response to commitments contained in your letter requesting an authorization for the use of yttrium-90 as TheraSpheres. Also, as discussed, we updated Authorized User (AU) Dr. Brummit's name to include his middle initial and correct his degree to "D.O." Finally, please note that we have updated authorized use descriptions in accordance with standard language in our new Web-Based Licensing System.

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 may provide appropriate corrections and answers.

As discussed with Gail Allen via a June 7, 2017 phone conversation, additional information is needed to add an authorization for the use of yttrium-90 as SIR-Spheres resin microspheres. Training and experience documentation in the use of SIR-Spheres is needed for at least one AU, in order to add a SIR-Spheres authorization to the license. To resubmit your request for SIR-Spheres, please submit a signed and dated letter containing the following information:

1. List the radionuclide, form, maximum possession limit, and authorized use being requested;
2. Confirm that commitments contained in the March 7, 2017 letter (ML17068A355) will apply for both TheraSpheres and SIR-Spheres;
3. List the name of at least one qualified AU to be listed for the use of yttrium-90 as SIR-Spheres; and
4. For each AU to be authorized for the use of yttrium-90 as SIR-Spheres (if already authorized for the use of TheraSpheres), include:
 - Documentation of training received either from an AU or a manufacturer representative in the operation of the SIR-Spheres delivery system, safety procedures associated with the use of the SIR-Spheres delivery system, and clinical use of SIR-Spheres; and

- For individuals receiving training from the SIR-Spheres manufacturer, commitments that:
 - i. each individual will complete at least the first three hands-on patient cases in the physical presence of a SIR-Spheres representative, and
 - ii. the licensee will submit documentation from the manufacturer to the NRC Region III office within 30 days of when these three patient cases have been satisfactorily completed.

Please refer to the NRC's licensing guidance for yttrium-90 microspheres, issued pursuant to Title 10 of the *Code of Federal Regulations* Section 2.390, for training and experience guidelines for proposed AUs. The guidance, "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance," revision 9 (February 12, 2016), may be found at the NRC's Medical Uses Licensee Toolkit Web site, found at <https://www.nrc.gov/materials/miau/med-use-toolkit.html>.

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.

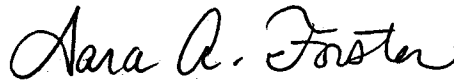
The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material 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.

M. Gates

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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,

A handwritten signature in cursive script that reads "Sara A. Forster".

Sara A. Forster, M.S.
Health Physicist
Materials Licensing Branch

License No. 24-00158-03
Docket No. 030-02269

Enclosure: Amendment No. 73