



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

MAR 28 2018

Thomas J. Moenster  
Radiation Safety Officer  
Missouri Baptist Medical Center  
3015 N. Ballas Road  
St. Louis, MO 63131

Dear Mr. Moenster:

Enclosed is Amendment No. 90 to your NRC Material License No. 24-11128-02 in accordance with your request.

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.

This amendment approves the authorization of yttrium-90 Sirtex Medical, Inc., microspheres, as permitted by 10 CFR 35.1000, and the authorization for medical use of this new authorization by Drs. Karageorgiou and Heller.

This amendment authorizes the use of this new authorization only at the 3015 N. Ballas Rd., St. Louis, Missouri location.

As noted in my email to you on March 28, 2018, this amendment does not authorize you to allow future changes to your yttrium-90 SIRspheres microsphere program because your letter dated December 1, 2017, did not include the necessary explicit commitments to do so.

If you choose to pursue this added feature, please make the explicit commitments in the section titled "Radiation Protection Program Changes" in NRC's Guidance document dated February 12, 2016, Rev. 9, entitled "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance."

You may address it to my attention as additional information to control number 602606, using the usual business-style letter for transmission and a current date and appropriate signature.

Please note that, at this time, we deleted Condition No. 13, as it appeared on Amendment No. 89, because it was no longer necessary for your licensed program, with Subitem Nos. 6. through 9. K. authorized for storage only, pending disposal.

If you have any questions concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is 630-515-1078, which is also the fastest way to transmit amendment requests and responses to requests from us for additional information.

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

T. Moenster

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My email address is [colleen.casey@nrc.gov](mailto:colleen.casey@nrc.gov), which should not be used to transmit amendment requests and responses to requests from us for additional information, unless previously arranged with me personally.

NRC's Regulatory Issue Summary (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 ADAMS, the NRC's electronic document system.

Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390, 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 Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf> and the link for frequently asked questions regarding protection of security related sensitive information may be located at: <http://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 Publicly Available Records (PARS) component of NRC's document system (ADAMS).

The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

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>.

T. Moenster

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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.

Sincerely,

A handwritten signature in cursive script that reads "Colleen Carol Casey".

Colleen Carol Casey  
Materials Licensing Branch

License No. 24-11128-02  
Docket No. 030-08325

Enclosure:

Amendment No. 90