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

FEB 27 2015

Ronald Palmer, M.D.
Radiation Safety Officer
SSM DePaul Health Center
Department of Nuclear Medicine
12303 DePaul Drive
Bridgeton, MO 63044

Dear Dr. Palmer:

Enclosed is Amendment No. 67 to your NRC Material License No. 24-02490-03 in accordance with your request. Please note that the changes made to your license are printed in **bold** font.

Please note that, based on the request to remove Dr. Paskar and Dr. Ernst from your license, the associated Subitem No. 6.F. regarding the authorization for 10 CFR 31.11 use was deleted.

The licensee requested authorization for Dr. Fischer for the use of 10 CFR 35.100, 35.200, and 35.1000 limited to Y-90 TheraSphere microspheres; however, based on the provided information Dr. Fischer does not meet the requirements specified in 10 CFR 35.190, 35.290, and 35.1000 (refer to the licensing guidance "Microsphere Brachytherapy Sources and Devices"). Therefore, we are unable to add Dr. Fischer to the license.

The licensee requested authorization for Dr. Mueller for the use of 10 CFR 35.1000 limited to Y-90 TheraSphere microspheres; however, based on the provided information Dr. Muellller does not meet the requirement specified in 10 CFR 35.1000 (refer to the licensing guidance "Microsphere Brachytherapy Sources and Devices"). Therefore, we are unable to add Dr. Mueller for 10 CFR 35.1000, limited to TheraSphere microspheres to the license.

Lastly, we did not add Y-90 TheraSphere microspheres to the license because 1) the current license does not list any authorized user for Y-90 Therasphere microspheres use, and 2) the licensee did not provide the commitments as specified in the licensing guidance "Microsphere Brachytherapy Sources and Devices".

The above were discussed with the licensee's representative and a request for additional information was sent to him. On February 17, 2015, a status inquiry email was sent to him. However, as of February 27, 2015, we have not received any response. If you would like to continue with the request above, please provide a complete NRC Form 313 (AUD) for Dr. Fischer, and provide information as discussed in the licensing guidance "Microsphere Brachytherapy Sources and Devices" for the request for Y-90 TheraSphere microspheres 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.

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

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.

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 Code of Federal Regulations 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 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,

Frank P. D. Tran
Health Physicist
Materials Licensing Branch

License No. 24-02490-03
Docket No. 030-02308

Enclosure: Amendment No. 67