



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

JUN 21 2018

Joseph T. Rakowski
Radiation Safety Officer
Karmanos Cancer Center
4100 John R. St.
Detroit, MI 48201

Dear Mr. Rakowski:

Enclosed is Amendment No. 78 to your U.S. Nuclear Regulatory Commission (NRC) Material License No. 21-04127-06 for Karmanos Cancer Center in accordance with your request dated May 14, 2018. Please note that we took no action regarding your requests dated March 28 and May 9, 2018. As you indicated in your letter dated June 18, 2018, you will provide additional information pertaining to the final design of the facility, pre-operational testing procedures and completion of training for the Radiation Safety Officer, Authorized Users, and Authorized Medical Physicists. When submitting the additional information, please reference previous correspondence that is relevant to the current request.

We also reviewed your request dated May 2, 2018 regarding the addition of Actinium-225 to your license. As discussed with you on June 1, 2018, additional information is needed to complete our review of the request. Specifically, please provide the following: 1) an Investigative New Drug or New Drug Application registration number with the U.S. Food and Drug Administration; 2) the manufacturer's name and license number within U.S.; and 3) the method of production of the pharmaceutical. When submitting the additional information, please reference your letter dated May 2, 2018.

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.

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. The NRC may issue a notice of violation, 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 enclosed document contains sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.

J. Rakowski

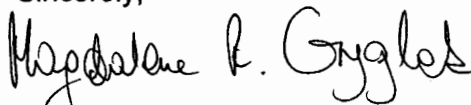
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The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. 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 Title 10 of the *Code of Federal Regulations* (CFR) Section 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 ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,



Magdalena R. Gryglak
Health Physicist
Materials Licensing Branch

License No. 21-04127-06
Docket No. 030-09376

Enclosure: Amendment No. 78