



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

January 20, 2017

EA-17-001

Joseph Rakowski, Ph.D.
Radiation Safety Officer
Karmanos Cancer Center
4100 John R Street
Detroit, MI 48201

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03009376/2016002(DNMS)
KARMANOS CANCER CENTER

Dear Dr. Rakowski:

On December 22, 2016, an inspector from the U.S. Nuclear Regulatory Commission (NRC) completed an in-office review of your letter, dated December 14, 2016, with attachments, providing notification that you identified potential non-compliance with NRC security requirements. The purpose of the in-office review was to determine whether activities authorized under your license were conducted in accordance with NRC security requirements. The enclosed Security Addendum presents the results of this in-office review.

Based on the results of this in-office review, apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violations are of a security-related nature. Details about the apparent violations are available in the enclosed Security Addendum. Mr. Robert Gattone of my staff discussed the circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective actions with you during the final exit meeting on December 22, 2016.

Your letter, dated December 14, 2016, with attachments, provided sufficient information such that you need not respond in writing to the apparent violations addressed in the Security Addendum in order for the NRC to make its enforcement decision. However, before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violations addressed in the Security Addendum within 30 days of the date of this

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Non-Safeguards Information. When
separated from Enclosure, this transmittal
letter is decontrolled.

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letter, or (2) request a Pre-decisional Enforcement Conference (PEC). **Please notify Aaron T. McCraw at 630-829-9650 or Aaron.McCraw@nrc.gov of your intended response within 10 days of the date of this letter.**

If you choose to provide a written response, it should be clearly marked as "Response to Apparent Violations in the Security Addendum; EA-17-001," and should include, for each apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the Information Notice on the NRC's website at <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. In addition, if you choose to provide a written response, please mark your entire response, "Security-Related Information – Withhold from Public Disclosure under Title 10 of the *Code of Federal Regulations* (CFR) 2.390." In accordance with 10 CFR 2.390(b)(ii), the NRC is waiving the affidavit requirements for your response to this letter. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information.

If you choose to request a PEC, it will afford you the opportunity to provide your perspective on the apparent violations and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. If a PEC is held, the NRC will issue a press release to announce the time and date of the conference; however, the conference will be closed to public observation because security-related information will be discussed. The NRC normally tries to schedule a PEC within 30 days of the date of the letter.

Please be advised that the number and characterization of the apparent violations may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>. The enclosure contains security-related information and its disclosure to unauthorized individuals could present a security vulnerability; therefore, the enclosure will not be made available electronically for public inspection.

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Please feel free to contact Robert Gattone of my staff if you have any questions concerning this in-office review. You can reach Mr. Gattone at 630-829-9823.

Sincerely,

/RA Kenneth O'Brien Acting for/

John B. Giessner, Director
Division of Nuclear Materials Safety

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

Enclosure: Security Addendum
(Non-Publicly Available)

cc: State of Michigan (w/out encl)

~~OFFICIAL USE ONLY — SECURITY-RELATED INFORMATION~~

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Letter to Joseph Rakowski, Ph.D. from John Giessner dated January 20, 2017

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DATE	1/18/2017		1/19/2017		1/19/2017		1/20/2017	

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