



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

January 14, 2016

EA-15-167

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

SUBJECT: NOTICE OF VIOLATION – KARMANOS CANCER CENTER; NRC INSPECTION
REPORT NO. 03009376/2015001(DNMS)

Dear Dr. Rakowski:

This refers to the inspection conducted on June 17 and 18, 2015, at your Detroit, Michigan, facilities with continued in-office review through September 21, 2015. During the inspection, apparent security violations of NRC requirements were identified. The significance of the issues and the need for lasting and effective corrective actions were discussed with you during the exit meeting on September 21, 2015. Details regarding the apparent violations were provided in NRC Inspection Report No. 03009376/2015001(DNMS), dated October 1, 2015.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by either providing a written response or requesting a predecisional enforcement conference. In a letter, dated October 19, 2015, you provided a response to the apparent violations.

Based on the information developed during the inspection, and the information that you provided in your response, dated October 19, 2015, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the Notice of Violation (Notice) in Enclosure 1 (Non-Public) and the circumstances surrounding them are also described in detail in our inspection report, dated October 1, 2015. The violations are of concern to the NRC for the reasons stated in Enclosure 2 (Non-public). Therefore, the violations have been categorized, in accordance with the NRC Enforcement Policy, as a Severity Level III problem.

Enclosures 1 and 2 contain Sensitive
Unclassified Non-Safeguards Information.
When separated from Enclosures, this
transmittal document is decontrolled.

J. Rakowski

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In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is normally considered for a Severity Level III violation.

Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for Corrective Action in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. In NRC Inspection Report No. 03009376/2015001(DNMS), the NRC described its understanding of the corrective actions taken to correct the violations. In your response dated October 19, 2015, your staff described the corrective actions taken to correct the violations and to prevent recurrence. These corrective actions are also documented in Enclosure 2. Based on these corrective actions, the NRC has determined that Corrective Action credit is warranted.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of these violations constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations, and the date when full compliance was achieved, is adequately addressed on the docket in NRC Inspection Report No. 03009376/2015001(DNMS), dated October 1, 2015, and in your response, dated October 19, 2015. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice. Additionally, if you choose to respond, please mark your entire response "Security Related Information – Withhold from Public Disclosure under 10 CFR 2.390." In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390(b)(1)(ii), the NRC is waiving the affidavit requirements for any response to this letter. However, to the extent possible, your response, if any, should not include any personal privacy, proprietary, or safeguards information.

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 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>. However, because of the Security-Related Information contained in the enclosures, and in accordance with 10 CFR 2.390, copies of the Enclosure 1 and 2 will not be available for public inspection.

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Additionally, Enclosures 1 and 2 must be protected from unauthorized disclosure. Security-Related Information is discussed in Regulatory Information Summary RIS-2005-031, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information" (ML053480073), which is available on the NRC Web site or in ADAMS.

Sincerely,

/RA/

Cynthia D. Pederson
Regional Administrator

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

Enclosures:

1. Notice of Violation (Non-Public)
2. Final Determination of Significance (Non-Public)

cc: State of Michigan

J. Rakowski, Ph.D.

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Sincerely,

/RA/

Cynthia D. Pederson
Regional Administrator

Docket No. 030-09376
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¹ OE concurrence provided by e-mail from K. Norman dated January 8, 2016

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Letter to Joseph Rakowski, Ph.D. from Ms. Cynthia Pederson dated January 14, 2016

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REPORT NO. 03009376/2015001(DNMS)

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