

April 15, 2011

EA-11-053

Mr. Gary B. Morrison
Executive Vice President
and Chief Operations Officer
Karmanos Cancer Center
4100 John R
Detroit, Michigan 48201

SUBJECT: NRC INSPECTION REPORT NO. 030-09376/2011-002(DNMS) AND NOTICE
OF VIOLATION – KARMANOS CANCER CENTER

Dear Mr. Morrison:

This refers to the inspection conducted on January 31 through and February 4, 2011, at the Karmanos Cancer Center facility in Detroit, Michigan with continuing U.S. Nuclear Regulatory Commission review through March 17, 2011. The continuing NRC in-office review was to evaluate your actions to ensure compliance with security regulations. The enclosed report presents the results of this inspection.

The inspection was an examination of activities conducted under your license as they relate to public health and safety, common defense and security, and to compliance with the Commission's rules and regulations, orders, and with the conditions of your license. Within these areas, the inspection consisted of selected examinations of procedures and representative records, observations, and interviews with personnel. On March 17, 2011, the inspection findings were discussed with you and Dr. Joseph Rakowski of your staff and Michael LaFranzo of my staff via telephone.

Based on the results of this inspection, one apparent violation was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at: (<http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>). The apparent violation involves security issues. The circumstances surrounding the apparent violation, the significance of the issue and the need for lasting and effective corrective action was discussed with you and members of your staff during the exit meetings on-site February 4, and via telephone March 17, and are described in detail in the enclosed non-public inspection report.

Enclosures Contain Sensitive Unclassified Non-Safeguards Information. When separated from enclosures, this transmittal letter is decontrolled.
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In addition, since your facility has not been the subject of escalated enforcement actions within the last two inspections, and based on our understanding of your corrective action, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. The final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond to the apparent violation addressed in this inspection report within 30 days of the date of this letter or (2) request a Predecisional Enforcement Conference (PEC). If a PEC is held, the conference will be closed to public observation since Security-Related Information will be discussed. Please contact Tamara E. Bloomer at 630-829-9627 within seven days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a "Response to An Apparent Violation in Inspection Report No. 030-09376/2011-002(DNMS); EA-11-053" and should include for the 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 the NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find the Information Notice on the NRC website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or the NRC has not granted an extension of time, the NRC will proceed with its enforcement decision or schedule a PEC.

In addition, if you choose to provide a written response, please mark your entire response "Security Related Information-Withhold from Public Disclosure under 10 CFR 2.390." In accordance with 10 CFR 2.390(b)(1)(ii), the NRC is waiving the affidavit requirements for your response to this letter; however, to the extent possible, your response should not include personal privacy, proprietary, or safeguards information.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violation 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.

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 violation. In addition, please be advised that the number and characterization of the apparent violation described in the enclosed inspection report 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.

G. Morrison

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Based on the results of this inspection, the NRC also determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The violation is cited in the enclosed non-public Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the non-public inspection report. The violation is being cited because it was identified by the NRC.

The NRC has concluded that information regarding the reason for the Severity Level IV violation, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed on the docket in non-public Inspection Report No. 030-09376/2011-002(DNMS). Therefore, you are not required to respond to the Notice 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.

In accordance with Title 10 of the Code of Federal Regulations Section 2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available in the NRC Public Document Room or from NRC's Agencywide Documents Access and Management System (ADAMS); however, the material enclosed herein contains Security-Related Information; its disclosure to unauthorized individuals could present a security vulnerability. Therefore, the enclosures will not be made available for public inspection. The enclosures to this letter must be protected from unauthorized disclosure. Protection of 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 at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions concerning this matter, please contact Tamara E. Bloomer of my staff at 630-829-9627.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

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

Enclosures:

1. Notice of Violation (Non-Public Security-Related Information)
2. Inspection Report (Non-Public Security-Related Information)

cc w/encls: Dr. Joseph Rakowski, Radiation Safety Officer
Mara Jelich, Director of Radiation Oncology
State of Michigan

G. Morrison

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Mara Jelich, Director of Radiation Oncology
State of Michigan

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Letter to G. Morrison dated April 15, 2011

SUBJECT: NRC INSPECTION REPORT 030-09376/2011-002(DNMS) AND NOTICE OF VIOLATION – KARMANOS CANCER CENTER

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