



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

May 31, 2022

EA-22-011

Ms. Mara Jelich
Executive Director, Radiation Oncology
and Imaging
Karmanos Cancer Center
4100 John R Street
Mail Code GE00RO
Detroit, MI 48201

SUBJECT: NOTICE OF VIOLATION – KARMANOS CANCER CENTER
NRC INSPECTION REPORT NO. 03009376/2021001(DNMS)

Dear Ms. Jelich:

This letter refers to the routine inspection conducted July 20-23, 2021, with continued in-office review through February 24, 2022, of activities performed under the U.S. Nuclear Regulatory Commission (NRC) license issued to Karmanos Cancer Center. The purpose of the inspection was to examine Karmanos Cancer Center's licensed activities as they relate to radiation safety, compliance with the Commission's regulations, and the conditions in the license. Based on the results of the inspection, the NRC identified apparent violations (AVs) of NRC requirements. NRC staff discussed the AVs with Mr. Joseph Rakowski of your staff during a telephonic exit meeting on March 1, 2022, and described the AVs in the non-publicly available security addendum to the NRC inspection report sent to you by letter dated March 14, 2022 (ML22063B147)¹. The security addendum and the AVs described therein concern Security-Related Information in accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390(d)(1), and disclosure to unauthorized individuals could present a security vulnerability. Consequently, the security addendum enclosed with the March 14, 2022, letter and inspection report was not publicly available, and details regarding the AVs were provided in a non-public enclosure.

In the letter transmitting the inspection report, we informed you that some of the AVs identified in the report were being considered for escalated enforcement action. We requested that you provide information about corrective actions for the AVs in either a written response or by attending a predecisional enforcement conference (PEC) before we made our final enforcement decision. In non-publicly available letters dated April 4, 2022, and May 16, 2022, you provided written responses that discussed the actions taken and planned for the AVs.

Enclosure transmitted herewith contains Sensitive, Unclassified, Non-Safeguards Information. When separated from the Enclosure, the transmittal document is decontrolled.

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.

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Based on the information identified during the inspection, the NRC has determined that violations of NRC requirements occurred. Four violations have been categorized in accordance with the NRC Enforcement Policy at Severity Level IV nonescalated violations and others have been assessed as escalated enforcement. The violations are cited in the Notice of Violation (Notice), provided as a non-public enclosure, and the circumstances surrounding them are described in detail in the subject inspection report.

In accordance with the NRC Enforcement Policy, a base civil penalty is considered for escalated enforcement violations. 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. The NRC staff determined that Karmanos Cancer Center took prompt and comprehensive corrective actions, and therefore, credit is warranted. Enclosure 2 (non-public) provides an explanation of the severity level determinations and a description of Karmanos Cancer Center's corrective actions to address the violations. 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 constitute an escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in the non-publicly available security addendum to Inspection Report No. 03009376/2021001 and your letters dated April 4, 2022, and May 16, 2022. 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.

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 ADAMS, accessible from the NRC Website at <http://www.nrc.gov/reading-rm/adams.html>. However, the material enclosed herewith contains Security-Related Information as described above. Therefore, the material in the enclosure will not be made available electronically for public inspection in the NRC Public Document Room or from ADAMS. If you choose to respond and Security-Related Information is necessary to provide an acceptable response, please mark your entire response Security-Related Information in accordance with 10 CFR 2.390(d)(1) and follow the instructions for withholding in 10 CFR 2.390(b)(1). The NRC also includes significant enforcement actions on its web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

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If you have any questions concerning this matter, please contact Mr. Ryan Craffey of my staff at 630-829-9655 or Ryan.Craffey@nrc.gov.

Sincerely,



Signed by Giessner, Jack
on 05/31/22

John B. Giessner
Regional Administrator

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

Enclosures:

1. Notice of Violation (non-public)
2. Determination of Severity Level
and Description of Corrective Actions (non-public)