



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

March 14, 2022

EA-22-011

Ms. Mara Jelich
Executive Director, Radiation Oncology
and Imaging
Karmanos Cancer Center
4100 John R Street
Mail Code GE00R0
Detroit, MI 48201

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

Dear Ms. Jelich:

On July 20-23, 2021, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facilities in Detroit and Farmington Hills, Michigan, with continued in-office review through February 24, 2022. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included an assessment of findings and corrective actions. The enclosed inspection report presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, apparent violations of NRC requirements were identified, some of which are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy, a current version of which is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations were of a security-related nature; therefore, details of the violations, as well as the corrective actions that have since been taken to restore compliance with regulatory requirements, are discussed in the non-public Enclosure 2.

Enclosure 2 contains Sensitive Unclassified Non-Safeguards Information. When separated from the Enclosure, this transmittal letter and Enclosure 1 are decontrolled.

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Because the NRC has not made a final determination in this matter, the NRC is not issuing a Notice of Violation for these inspection findings at this time. Mr. Ryan Craffey of my staff discussed the circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action with your Radiation Safety Officer, Mr. Joseph Rakowski, at the inspection exit meeting on March 1, 2022.

Before the NRC makes its enforcement decision, we request that you provide additional information regarding your corrective and preventative actions for the violations. Please note that, in addition to the specific findings identified, the NRC was concerned to discover inadequate oversight of your access authorization and physical security programs for licensed material was a root cause of almost all of these findings. As you prepare your response to this letter, we request that you also specifically address this concern, including a description of additional measures that Karmanos Cancer Center has taken or plans to take to provide reasonable assurance to the NRC that these programs will have sufficient management oversight to ensure full compliance with NRC security requirements. You should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. 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 website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>.

The written response should be sent within 30 days of the date of this letter. It should be clearly marked as "Response to the Apparent Violations in Inspection Report No. 03009376/2021001(DNMS); EA-22-011," 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 was or will be achieved. Your response may reference or include previously docketed correspondence if the correspondence adequately addresses the required response. Your response should be sent to the NRC's Document Control Desk, Washington, DC 20555-0001, with a copy mailed to the NRC Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a pre-decisional enforcement conference (PEC).

In lieu of providing this written response, you may choose to provide your perspective on this matter including the significance, cause, and corrective actions, as well as any other information that you believe the NRC should take into consideration by: (1) requesting a PEC to meet with the NRC and present your views in person; or (2) requesting Alternate Dispute Resolution (ADR). If a PEC is held, the NRC will issue a press release to announce the time and date of the conference; however, the PEC will be closed to public observation. **Please contact Michael Kunowski, Chief of the Materials Inspection Branch, at 630-829-9618 or Michael.Kunowski@nrc.gov within ten days of receipt of this letter to notify the NRC of your intended response.**

If you choose to request a PEC, the meeting should be held within 30 days of the date of this letter. The conference 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 PEC may include the following: information to determine whether a violation occurred, information to

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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.

You may also request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a third party neutral. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the “mediator”) works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC’s program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC’s program as a neutral third party. **Please contact ICR at 877-733-9415 within 10 days of receipt of this letter if you are interested in pursuing resolution of this issue through ADR.** The ADR mediation session should be held within 45 days of the date of this letter

The PEC or the ADR would be closed to public observation because they would involve security related information. However, the time and date of the PEC or ADR will be publicly announced.

As your facility has not been the subject of escalated enforcement action within the last two years or two inspections, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. In addition, based upon NRC’s understanding of the facts and your corrective actions, it may not be necessary to conduct a PEC in order to enable the NRC to make a final enforcement decision. Our 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.

In addition, please be advised that the number and characterization of the apparent violations 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.

In accordance with the NRC’s “Rules of Practice” in 10 CFR 2.390, a copy of this letter and Enclosure 1 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>. However, Enclosure 2 and your written response, if you choose to provide one, will not be made available electronically for public inspection because of the security-related information that is or would be contained in each.

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Please feel free to contact Mr. Craffey of my staff if you have any questions regarding this inspection. Mr. Craffey can be reached at 630-829-9655 or Ryan.Craffey@nrc.gov.

Sincerely,

 Signed by Brock, Kathryn
on 03/14/22

Kathryn M. Brock, Acting Director
Division of Nuclear Materials Safety

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

Enclosure:

1. IR 03009376/2021001(DNMS)
(publicly available)
2. Security Addendum to Inspection Report
(non-public)

cc w/encl: Mr. Joseph Rakowski, Radiation Safety Officer

cc w/encl public: State of Michigan

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Letter to Mara Jelic from Kathryn M. Brock dated, March 14, 2022.

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

DISTRIBUTION w/encl:

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OFFICE	RIII-DNMS	C	RIII-DNMS	C	RI-EAGLT	RIII-EICS	C	RIII-DNMS	C
NAME	RCraffey		MKunowski		MMcLaughlin	SLewman		KBrock	
DATE	03/7/22		03/9/22		03/9/22	03/10/22		03/14/22	

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**U.S. Nuclear Regulatory Commission
Region III**

Docket No. 030-09376

License No. 21-04127-06

Report No. 03009376/2021001(DNMS)

EA No. EA-22-011

Licensee: Karmanos Cancer Center

Facilities Inspected: 4100 John R Street
Detroit, MI

3901 Beaubien Boulevard
Detroit, MI

31995 Northwestern Highway
Farmington Hills, MI

Inspection Dates: July 20 through 23, 2021

Exit Meeting Date: March 1, 2022

Inspector: Ryan Craffey, Senior Health Physicist

Approved By: Michael Kunowski, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Enclosure 2 contains Sensitive Unclassified Non-Safeguards Information. When separated from the Enclosure, this transmittal letter and Enclosure 1 are decontrolled.

Enclosure 1

EXECUTIVE SUMMARY

**Karmanos Cancer Center
NRC Inspection Report 03009376/2021001(DNMS)**

This was an announced routine inspection of a cancer treatment center and a positron emission tomography facility on the premises of the Detroit Medical Center in Detroit, Michigan and a satellite facility in Farmington Hills, Michigan. The center was authorized by U.S. Nuclear Regulatory Commission Materials License No. 21-04127-06 to use diagnostic and therapeutic radiopharmaceuticals as well as various sources and devices for brachytherapy, teletherapy, and gamma stereotactic radiosurgery.

As a result of this inspection, no violations of safety requirements were identified. However, apparent violations of security requirements were identified, and several are being considered for escalated enforcement action. The circumstances of these violations, as well as the corrective actions the licensee has since taken to restore compliance with regulatory requirements and to address the potential for recurrence of similar violations, are discussed in the non-public Security Addendum to this inspection report.

REPORT DETAILS

1 Program Overview and Inspection History

Karmanos Cancer Center (Karmanos, the licensee) was authorized by U.S. Nuclear Regulatory Commission Materials License No. 21-04127-06 to use diagnostic and therapeutic radiopharmaceuticals as well as various sources and devices for brachytherapy, teletherapy, and gamma stereotactic radiosurgery.

At the Gershenson Radiation Oncology Center on John R Street in Detroit, the licensee routinely used a teletherapy unit for total body irradiations, a high dose-rate remote afterloading brachytherapy (HDR) unit for treating gynecological and breast cancer and had begun administering yttrium-90 (Y-90) microspheres for treating liver cancer. The licensee also routinely administered therapeutic doses of radium-223 Xofigo and lutetium-177m Lutathera. Though authorized for cesium-131 GammaTile treatments, the licensee had not yet performed any. The licensee also possessed several sources in storage, including a teletherapy head originally commissioned for research, a cesium-137 instrument calibrator, and a curium-244 reference source.

At the Positron Emission Tomography (PET) Center on Beaubien Boulevard in Detroit, the licensee performed diagnostic administrations daily using an Intego infusion device and fluorine-18 fluorodeoxyglucose (FDG) manufactured on-site under Karmanos' cyclotron license (21-03298-06). Both the Gershenson Radiation Oncology Center and the PET Center are located on the premises of the Detroit Medical Center.

At the Weisberg Cancer Center in Farmington Hills, the licensee used a gamma stereotactic radiosurgery (GSR) unit for treating brain tumors and neurologic disorders.

The last routine inspections of the licensee were on April 2-3, 2019, and before that on May 23-24, 2017. No violations were identified during either inspection.

The NRC also performed a special inspection on April 16-17, 2019, to observe the installation of the gamma stereotactic radiosurgery unit in Farmington Hills. No violations were identified during this inspection.

2 Gershenson Radiation Oncology Center

2.1 Inspection Scope

On July 20-23, 2021, the inspector visited the Gershenson Radiation Oncology Center at the Detroit Medical Center to review the implementation of the licensee's radiation safety program there. The inspector toured the facility, observed licensed activities, conducted interviews, and reviewed a selection of records.

2.2 Observations and Findings

The inspector noted that all areas of the facility were adequately posted. Independent measurements of radiation exposure in unrestricted areas of the facility were well below regulatory limits to members of the public, and no residual contamination was noted. All

licensed material was adequately secured by the end of the inspection; however, several apparent violations of security requirements were identified and are discussed more in the non-public Security Addendum to this report.

The inspector observed two ring and tandem HDR treatments including treatment planning and daily spot checks, as well as a Lutathera administration including hazardous package receipt. The inspector also observed demonstrations of teletherapy unit spot checks and treatment planning, as well as demonstrations of yttrium-90 microsphere treatments. The inspector interviewed licensee management, authorized users and authorized medical physicists; all were knowledgeable of radiation safety principles, licensee procedures and safety requirements.

The inspector reviewed a selection of records for teletherapy treatments, spot checks and annual calibrations; HDR source exchange documentation and annual safety training; Y-90 microsphere treatments; and Lutathera waste handling. The inspector also reviewed personnel dosimetry reports generated since the last inspection and the most recent annual audit of the radiation safety program.

2.3 Conclusions

The inspector had no findings with respect to the licensee's implementation of its radiation safety program at the Gershenson Radiation Oncology Center.

3 PET Center

3.1 Inspection Scope

On July 21, 2021, the inspector visited the PET Center at the Detroit Medical Center to review the implementation of the licensee's radiation safety program there. The inspector toured the facility, observed licensed activities, conducted interviews, and reviewed a selection of records.

3.2 Observations and Findings

The inspector noted that all areas of the facility were adequately posted. Independent measurements of radiation exposure in unrestricted areas of the facility were well below regulatory limits to members of the public, and no residual contamination was noted. All licensed material was adequately secured.

The inspector observed several injections of F-18 FDG using an Intego automated infusion machine and interviewed several nuclear medicine technologists; all were knowledgeable of radiation safety principles, licensee procedures and applicable regulatory requirements.

The inspector reviewed a selection of records for Intego quality control, as well as recent quarterly audits of the radiation safety program as implemented at the PET center.

3.3 Conclusions

The inspector had no findings with respect to the licensee's implementation of its radiation safety program at the PET Center.

4 Weisberg Cancer Center

3.1 Inspection Scope

On July 21, 2021, the inspector visited the Weisberg Cancer Center in Farmington Hills to review the implementation of the licensee's radiation safety program there. The inspector toured the facility, observed licensed activities, conducted interviews, and reviewed a selection of records.

3.2 Observations and Findings

The inspector noted that all areas of the facility were adequately posted. Independent measurements of radiation exposure in unrestricted areas of the facility were well below regulatory limits to members of the public. All licensed material was adequately secured, although an apparent violation of programmatic security requirements was identified here and is discussed more in the non-public Security Addendum to this report.

The inspector observed two radiosurgery treatments as well as daily spot checks of the GSR unit. The inspector interviewed the authorized users and medical physicists and found all to be knowledgeable of radiation safety principles, licensee procedures and safety requirements.

The inspector also reviewed a selection of records for GSR treatments and daily spot checks.

3.3 Conclusions

The inspector had no findings with respect to the licensee's implementation of its radiation safety program at the Weisberg Cancer Center.

4 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following the onsite inspection on July 23, 2021. The NRC also held a final exit meeting with the licensee by telephone on March 1, 2022. The licensee did not identify any documents or processes reviewed by the inspector as proprietary. The licensee acknowledged the findings presented.

LIST OF PERSONNEL CONTACTED

Geoffrey Baran, MS – Medical Physicist
Constance Brown – Radiation Therapist
Jay Burmeister, PhD – Authorized Medical Physicist

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Michael Dominello, MD – Authorized User
Ahmad Hammoud – Chief Dosimetrist
Mara Jelich – Executive Director, Radiation Oncology and Imaging
Jordan Maier, MD – Authorized User
Cindi Manrique – Nuclear Medicine Technologist
Steven Miller, MD – Authorized User
Andrew Mosquah – Nuclear Medicine Technologist
Adrian Nalichowski, MS – Authorized Medical Physicist
Joseph Rakowski, PhD – Radiation Safety Officer
Marvin Thomas – Radiation Therapist

Attended exit meeting on March 1, 2022.

INSPECTION PROCEDURES USED

87131 – Nuclear Medicine Programs, Written Directive Required
87132 – Brachytherapy Programs
87133 – Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs