UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

July 18, 2017

Ms. Mara Jelich
Executive Director, Radiation
Oncology / Imaging Services
Karmanos Cancer Center
4100 John R Street
Detroit, MI 48201

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03009376/2017001(DNMS)
KARMANOS CANCER CENTER

Dear Ms. Jelich:

On May 23 and 24, 2017, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facility in Detroit, Michigan, with continued in-office review through June 29, 2017. 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 evaluation of security-related information. On June 29, 2017, Mr. Ryan Craffey of my staff conducted an exit meeting by telephone with Dr. Joseph Rakowski of your staff to discuss the inspection findings. The enclosed inspection report (Enclosure 1) and its non-public Security Addendum (Enclosure 2) 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.

During this inspection, the NRC identified one unresolved item of a security-related nature. This item and the immediate compensatory measures that Karmanos Cancer Center implemented to address it are described in Enclosure 2. The NRC will continue to review this unresolved item, and you will be advised by separate correspondence of the results of our deliberation on this matter. Because this item remains under NRC review, you are not required to respond to this letter at this time. Please be advised that the number and characterization of the issues described in the report may change as a result of further NRC review.

In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the

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

NRC's Public Document Room or from the NRC's Agency wide Documents Access Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. However, Enclosure 2 will not be made available electronically for public inspection because it contains security-related information.

Please feel free to contact Mr. Craffey if you have any questions regarding this inspection. Mr. Craffey can be reached at 630-829-9655.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

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

Enclosures:
1. IR 03009376/2017001(DNMS) (public)
2. Security Addendum (non-public)

cc w/encls: Joseph Rakowski, Ph.D.,
Radiation Safety Officer
cc w/encl 1: State of Michigan

Letter to Mara Jelich from Aaron McCraw dated July 18, 2017

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03009376/2017001(DNMS)
KARMANOS CANCER CENTER

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-09376
License No.	21-04127-06
Report No.	03009376/2017001(DNMS)
Licensee:	Karmanos Cancer Center
Facility:	4100 John R Street Detroit, MI 48201
Inspection Dates:	May 23-24, 2017
Exit Meeting Date:	June 29, 2017
Inspector:	Ryan Craffey, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

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

Enclosure 1

EXECUTIVE SUMMARY

Karmanos Cancer Center
NRC Inspection Report 03009376/2017001(DNMS)

This was announced routine inspection of the Gershenson Radiation Oncology Center at the Karmanos Cancer Institute in Detroit, Michigan. The Center was authorized by NRC Materials License No. 21-04127-06 to use byproduct material principally for diagnostic and therapeutic medical purposes. The inspection included a review of the content and implementation of the licensee's radioactive material program.

As a result of the inspection, the NRC identified one unresolved item of a security-related nature. The licensee immediately implemented compensatory measures to address this item. This unresolved item remains under NRC review.

REPORT DETAILS

1 Program Overview and Inspection History

Karmanos Cancer Center (the licensee) was authorized by NRC Materials License No. 21-04127-06 to use licensed material principally for diagnostic and therapeutic medical purposes at the Gershenson Radiation Oncology Center at the Karmanos Cancer Institute, located at the Detroit Medical Center in downtown Detroit, Michigan. At the time of the inspection, the licensee actively used a gamma stereotactic radiosurgery (GSR) unit, a teletherapy unit for total body irradiations, and a high dose-rate remote afterloader (HDR) unit. The licensee treated two to three patients per week with each unit, on average. The licensee also performed around six prostate seed implants per year, and actively administered radium-223 Xofigo® to prostate cancer patients, and technetium-99m for breast lymphoscintigraphy. The licensee also possessed a GammaBeam panoramic irradiator for the irradiation of biological materials and radiation biology studies. However, the unit, which remained in storage pending disposal, had not been used since before the last inspection.

The last routine inspection of the licensee was on June 17-18, 2015. As a result of that inspection, the NRC identified apparent violations of a security-related nature, and two Severity Level IV violations of NRC requirements for HDR use. A followup inspection on April 7, 2016, subsequently reviewed and closed these violations.

On December 22, 2016, the NRC also performed an in-office review of violations of a security-related nature that the licensee self-identified and self-reported. As a result of that special inspection, the NRC issued a Non-Cited Violation.

2 Gamma Stereotactic Radiosurgery

2.1 Inspection Scope

The inspector toured the GSR suite, observed activities associated with a GSR treatment, interviewed staff, and reviewed a selection of records.

2.2 Observations and Findings

The inspector observed the licensee's staff perform daily quality assurance, and planning and delivery of one GSR treatment during the inspection. The inspector reviewed the associated written directive, and discussed various aspects of the treatment process with the attending authorized medical physicist and authorized user.

2.3 Conclusions

The inspector reviewed aspects of the licensee's use of the GSR unit. The inspector had no findings in this area.

3 Teletherapy

3.1 Inspection Scope

The inspector toured the teletherapy (also known as the Total Body Irradiator or TBI) suite, observed demonstrations of activities associated with TBI treatments, interviewed staff, and reviewed a selection of records.

3.2 Observations and Findings

The inspector observed the licensee's staff demonstrate daily quality assurance checks and emergency response procedures for an incident involving a TBI treatment. The inspector reviewed a selection of written directives, monthly quality assurance checks, and the most recent full calibration. The inspector discussed various aspects of the treatment process with the licensee's authorized medical physicists.

3.3 Conclusions

The inspector reviewed aspects of the licensee's use of the TBI unit. The inspector had no findings in this area.

4 High Dose-Rate Remote Afterloading Brachytherapy

4.1 Inspection Scope

The inspector toured the HDR suite, observed demonstrations of activities associated with HDR treatments, interviewed staff, and reviewed a selection of records.

4.2 Observations and Findings

The inspector observed the licensee's staff demonstrate daily quality assurance checks and emergency response procedures for an incident involving an HDR treatment. The inspector reviewed a selection of written directives and documentation of the most recent source exchange, confirmed that the licensee's dosimetry equipment had been calibrated as required, and discussed various aspects of the treatment process with the licensee's radiation therapists and authorized medical physicists.

4.3 Conclusions

The inspector reviewed aspects of the licensee's use of the HDR unit. The inspector had no findings in this area.

5 Therapeutic Radiopharmaceuticals

4.1 Inspection Scope

The inspector toured the radiation oncology hot lab and injection suite, observed demonstrations of activities associated with Xofigo® administrations, interviewed involved staff, and reviewed a selection of relevant records.

4.2 Observations and Findings

The inspector observed the licensee's staff demonstrate procedures for the preparation and administration of doses, and handling of radioactive waste. The inspector reviewed a selection of written directives, verified the licensee's decay-in-storage inventory, and discussed various aspects of the administration process with the licensee's authorized medical physicists.

4.3 Conclusions

The inspector reviewed aspects of the licensee's use of therapeutic radiopharmaceuticals. The inspector had no findings in this area.

5 Diagnostic Radiopharmaceuticals

5.1 Inspection Scope

The inspector toured the breast center hot lab and injection suite, observed activities associated with the administration of diagnostic radiopharmaceuticals for lymphoscintigraphy, interviewed staff, and reviewed a selection of records.

5.2 Observations and Findings

The inspector observed the preparation of a unit dose of technetium-99m, reviewed a selection of routine nuclear medicine records (including quarterly consultant audits and hazmat training certificates, among other documents), and discussed various aspects of the administration process with the licensee's authorized nuclear medicine technologist and an authorized user for diagnostic administrations.

5.3 Conclusions

The inspector reviewed aspects of the licensee's use of diagnostic radiopharmaceuticals. The inspector had no findings in this area.

6 Surveys

6.1 Inspection Scope

The inspector conducted surveys of the licensee's facility, observed the conduct and demonstration of various surveys, interviewed staff, and reviewed a selection of records.

6.2 Observations and Findings

The inspector observed the conduct of package receipt and area surveys at the breast center hot lab, and observed demonstrations of the conduct of package receipt and area surveys at the radiation oncology hot lab, and HDR post-treatment surveys.

The inspector conducted independent surveys using a ThermoFisher Scientific RadEye G gamma survey meter (calibrated on February 22, 2017) and a Ludlum 2403 survey meter with a model 44-9 pancake probe (calibrated on September 20, 2016). The including in the GSR and TBI control rooms with the respective sources exposed.

inspector conducted exposure surveys in the vicinity of the GSR, TBI, and HDR units, Readings in unrestricted areas did not exceed regulatory limits to members of the public. The inspector conducted contamination surveys in and around the breast center and radiation oncology hot labs and injection rooms. The inspector found no evidence of residual contamination in these areas.

The inspector found that a selection of the licensee's instruments were appropriate for the radiation encountered in this program, and were calibrated annually. The licensee's staff also demonstrated a satisfactory understanding of the operation and proper use of these instruments.

6.3 Conclusions

The inspector conducted independent surveys and reviewed the conduct of surveys by licensee staff. The inspector had no findings in this area.

7 Other Areas Inspected

7.1 Inspection Scope

The inspector toured various areas of facility to evaluate the licensee's measures for materials security, hazard communication, and exposure control, interviewed staff, and reviewed a selection of relevant records.

7.2 Observations and Findings

The inspector found that all licensed material was adequately secured against unauthorized access, including a strontium-90 eye applicator in storage.

The inspector reviewed a selection of treatment plans, written directives, and treatment verifications for prostate seed implants, verified the licensee's decay-in-storage inventory of unused prostate seeds, and discussed various aspects of the administration process with the licensee's authorized medical physicists.

The inspector also reviewed documentation of the licensee's review of the content and implementation of the radiation safety program and recent dosimetry reports.

5.3 Conclusions

The inspector reviewed other aspects of the radiation safety program not previously discussed. The inspector had no findings in these areas.

4 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following the onsite inspection. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary. The licensee acknowledged the findings presented. On June 29, 2017, the inspector conducted an exit meeting by telephone with the licensee.

LIST OF PERSONNEL CONTACTED

Todd Bossenberger, M.S. – Authorized Medical Physicist
Jay Burmeister, Ph.D. – Authorized Medical Physicist
Terenice Jackson – Radiation Therapist II
Robert Halford – Authorized Medical Physicist
Mara Jelich – Executive Director, Radiation Oncology / Imaging Services
Harold Kim, M.D. – Authorized User
Kathryn Masi, M.S. – Authorized Medical Physicist
Adrian Nalichowski, M.S. – Authorized Medical Physicist
Heather Nichols – Nuclear Medicine Technologist
Michael Petrich, M.D. – Authorized User
Joseph Rakowski, Ph.D. – Radiation Safety Officer
Michael Snyder, M.S. – Authorized Medical Physicist

Attended exit meeting on June 29, 2017.

INSPECTION PROCEDURES USED

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