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

August 28, 2009

Ms. Debra K. Herring
Vice President Ambulatory Operations
Karmanos Cancer Center
4100 John R Street
Detroit, Michigan 48201

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03009376/09-01(DNMS)
KARMANOS CANCER CENTER

Dear Ms. Herring:

On July 7, 2009, a Nuclear Regulatory Commission (NRC) inspector conducted a reactive inspection at your Karmanos Cancer Center in Detroit, Michigan. Subsequently, the inspector followed-up the inspection activities with an in-office review to determine if additional violations were warranted. The focus of the in-office review was the effectiveness of the October 27, 2007, commitments made surrounding a previous medical event involving the gamma knife as they relate to this event. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for a medical event that occurred on February 18, 2008, which was discovered during an annual chart audit conducted during June 2009. The enclosed report presents the results of the inspection.

The inspection consisted of an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of the inspection, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated 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.

Because this violation was identified during your annual self audit (i.e., "self-identified") the violation is being treated as a Non-Cited Violation (NCV) consistent with Section VI.A of the Enforcement Policy. The NCV and the circumstances surrounding it are described in detail in the subject inspection report. The violation involves the failure to prepare a written directive prior to the administration of a gamma knife treatment. The circumstances surrounding the violation, the significance of the issue, and the need for lasting and effective corrective actions were discussed with you and other members of your staff at the onsite exit meeting on July 7, 2009.

If you contest the violation or the significance of the NCV, you should provide a response within 30 days of the date of this inspection report with the basis of your denial, and send it to: (1) U. S. Nuclear Regulatory Commission ATTN: Document Control desk, Washington, DC 20555, with a copy to the Regional Administrator, Region III; and (2) the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Sincerely,

/RA by K. J. Lambert Acting For/

Tamara Bloomer, Chief
Materials Inspection Branch

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

Enclosure:
Inspection Report 030-09376/09-01(DNMS)

If you contest the violation or the significance of the NCV, you should provide a response within 30 days of the date of this inspection report with the basis of your denial, and send it to: (1) U. S. Nuclear Regulatory Commission ATTN: Document Control desk, Washington, DC 20555, with a copy to the Regional Administrator, Region III; and (2) the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Sincerely,

/RA by K. J. Lambert Acting For/

Tamara Bloomer, Chief
Materials Inspection Branch

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

Enclosure:
Inspection Report 030-09376/09-01(DNMS)

DISTRIBUTION:
Docket File
C. Pederson, RIII
S. Reynolds, RIII
K. O'Brien, RIII
J. Choe, RIII
P. Pelke, RIII

DOCUMENT NAME: Y:\DNMSIII\SEC\Work in progress\IR-KARMONOS(PARKER).doc
☒ Publicly Available ☐ Non-Publicly Available ☐ Sensitive ☒ Non-Sensitive
To receive a copy of this document, indicate in the concurrence box "C" = Copy without attach/encl "E" = Copy with attach/encl "N" = No copy

OFFICE	RIII		RIII		RIII		RIII	
NAME	GOParker:jc		KLambert for TEBloomer					
DATE	08/27/09		08/28/09					

OFFICIAL RECORD COPY

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-09376
License No.:	21-04127-06
Report No.:	030-09376/2009-001(DNMS)
Licensee:	Karmanos Cancer Center
Location:	4100 John R St. Detroit, MI
Date of Inspection:	July 7, 2009 (On site) In Office review through July 31, 2009
Inspector:	George Parker, Health Physicist
Reviewed By:	Tamara Bloomer, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Karmanos Cancer Center
Detroit, Michigan
Inspection Report No. 030-09376/09-01(DNMS)

This was a reactive inspection to review the circumstances, root and contributing causes, and corrective actions associated with a reported medical event that occurred at the Karmanos Cancer Center, Detroit, Michigan on February 18, 2008. The licensee detected the event during their 2008 annual quality management review of gamma knife cases, which they performed beginning April of 2009. The reported event was associated with their stereotactic radiosurgery unit (gamma knife). The patient was being treated for metastatic brain tumors in the right cerebellum and right occipital lobe. Treatment plans were developed for treatment of both the right cerebellum and right occipital lobe. The authorized user reviewed and initialed the treatment plan associated with the right cerebellum and the one for the right occipital lobe. The authorized user then completed the written directive for treating the right cerebellum. However the authorized user failed to complete a written directive for treatment of the right occipital lobe. Treatment of both the right cerebellum and right occipital lobe occurred on February 18, 2008, and was performed in accordance with the respective treatment plan.

The licensee did not expect the patient to have experienced any adverse medical effects as a result of the medical event because the treatment was delivered as planned with no deviations.

The inspector determined that a Non-Cited Violation of NRC requirements occurred involving the licensee's failure to complete a written directive for treatment of the right occipital lobe prior to administration of the treatment. Specifically, on February 18, 2008, the licensee treated the right occipital lobe of a patient with its gamma knife without having completed a written directive as required by 10 CFR 35.40 (a) and 10 CFR 35.40 (b) (3). The root cause of the apparent violation was inattention to detail by the authorized user. A contributing cause of the violation was the authorized user's recent diagnosis with pancreatic cancer and his focus not being completely on work.

To reduce the likelihood of recurrence of a similar event, the licensee initiated several immediate and long-term corrective actions. The corrective actions included: (1) training the staff on this occurrence; (2) modifying the procedure requiring a "time out" before treatment to ensure a review of all details of the treatment prior to delivery including the presence of all required documents has occurred; (3) completing a quality management review of each gamma knife treatment immediately prior to the treatment by a second medical physicist; and (4) enhancing of the gamma knife quality assurance form to include a review of the written directive with the treatment plan.

Report Details

1 Program Scope and Inspection History

NRC License Number 21-04127-06 authorizes Karmanos Cancer Center (licensee) to use a variety of by-product materials for medical therapy purposes, including sealed source therapy using a high dose rate (HDR) remote after loading brachy therapy device, teletherapy and a stereotactic radio surgical unit (gamma knife).

The last routine inspection was conducted on May1, 2008. No violations were identified during that inspection. A reactive inspection was conducted from October 29, 2007 through November 6, 2007, for a medical event involving the gamma knife where the wrong portion of the brain was treated due to incorrect helmet positioning. That inspection resulted in the issuance of a Severity Level III violation involving the failure to have adequate procedures to insure that treatments were delivered in accordance with written directives.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspector reviewed the sequence of events that resulted in the medical event and the licensee's investigation report. In addition, the inspector interviewed selected licensee personnel, reviewed patient treatment records, procedures, and equipment associated with the medical event, and toured related facilities.

Subsequently, the inspector followed-up the inspection activities with an in-office review to determine if additional violations were warranted. The focus of the in-office review was the effectiveness of the October 27, 2007, commitments made surrounding a previous medical event involving the gamma knife as they relate to this event.

2.2 Observations and Findings

On February 18, 2008, a patient was treated for metastatic lesions in the right cerebellum and right occipital lobe with the gamma knife. Treatment plans were developed for treatment of both the right cerebellum and right occipital lobe. The authorized user reviewed and initialed the treatment plan for the right cerebellum and the plan for the right occipital lobe. The treatment plans called for a single dose of 20 Gy to the right cerebellum and a single dose of 20 gray (Gy) to the right occipital lobe. The physician (authorized user) completed a written directive for a single treatment of 20 Gy to the right cerebellum. However, the authorized user failed to complete a written directive for the 20 Gy treatment to the right occipital lobe.

In June of 2009, the licensee completed its annual quality management program review of gamma knife treatments performed during calendar year 2008. During that review it was noted that a treatment given on February 18, 2008, to the right occipital lobe of the patient was performed without a written directive having been completed. On June 30, 2009, the licensee determined that a medical event had occurred and notified the NRC of the occurrence. The licensee concluded that the root cause of the medical event was

inattention to detail by the authorized user. Contributing to the event was the fact that the authorized user had recently been diagnosed with pancreatic cancer and his primary focus was not on work.

The licensee's procedures require compliance with the regulations found in 10 CFR 35.40 (a) and 10 CFR 35.40(b)(3) for gamma knife treatments. Title 10 CFR 35.40 (a) requires in part that a written directive be dated and signed by an authorized user prior to any treatment requiring a written directive. Title 10 CFR 35.40(b) (3) requires in part that the written directive contain the patient or human research subject's name and for gamma stereotactic radiosurgery, the following information: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site.

The inspector determined that on February 18, 2008, the authorized user failed to prepare a written directive for treatment of the right occipital lobe of the brain prior to the patient being treated by the gamma knife. This is a violation of 10 CFR 35.40 (a) and 10 CFR 35.40 (b) (3). This non-repetitive, licensee-identified and corrected violation (see Section 3 for corrective actions) is being treated as a Non-Cited Violation, consistent with Section V1.A.8 of the NRC Enforcement Policy.

The treatment was delivered in accordance with the treatment plan. The licensee did not expect any occurrence of adverse medical effects to the patient because of the medical event. Once the licensee identified the event, the licensee immediately initiated an investigation of the medical event and determined that the root and contributing causes were: (1) inattention to detail; and (2) the diagnosis of the authorized user with pancreatic cancer caused his focus not to be totally on his work.

As part of the licensee's investigation, gamma knife treatments conducted during 2008, were reviewed to determine if the same error occurred during any other gamma knife treatments. None were identified. The inspector reviewed approximately 40 randomly selected gamma knife treatment charts to determine if a written directive had been completed for each treatment and to determine if the treatments were in accordance with the treatment plans and the written directive. The inspector did not identify any additional errors which would have constituted a medical event in the administration of the gamma knife treatments.

2.3 Conclusions

A medical event occurred on February 18, 2008, when the licensee administered a gamma knife treatment of 20 Gy to the right occipital lobe prior to having completed a written directive. The licensee did not expect the error to have resulted in any adverse medical effects to the patient.

The medical event was caused by inattention to detail on the part of the authorized user. In addition, the authorized user's preoccupation with his own health was a contributing factor to the event. The inspector determined that a Non-Cited Violation of NRC requirements occurred associated with the failure to complete a written directive prior to treatment with the gamma knife. The NRC inspector determined that this event was an isolated event.

3 Licensee Corrective Actions

3.1 Inspection Scope

The inspector reviewed the licensee's proposed corrective actions to preclude similar events. The review included the licensee's June 30, 2008, written report regarding the medical event, interviews of selected licensee personnel, and the licensee's revised policies and procedures.

3.2 Observations and Findings

The inspector determined that the licensee initiated several immediate and long-term corrective actions to prevent recurrence of a similar event. The corrective actions included:

(1) Enhancing of the gamma knife quality assurance form to include a review of the written directive with the treatment plan;
(2) Performing a quality management review of the proposed treatment by another physicist prior to treatment delivery;
(3) Providing immediate training to the staff on this event; and
(4) Modifying the procedure to require a "time out" before commencing with a treatment to ensure a review of all details of the treatment prior to delivery including required documents has occurred.

3.3 Conclusions

The inspector determined that the licensee developed corrective actions to address the violation and prevent similar events.

4 Notifications and Reports

4.1 Inspection Scope

The inspector interviewed selected licensee staff and reviewed the licensee's notification to the NRC Operations Center and the associated 15-day written report to ensure compliance with NRC reporting requirements.

4.2 Observations and Findings

On June 30, 2009, the licensee's Radiation Safety Officer determined that the patient's right occipital lobe was treated with the gamma knife prior to the completion of a written directive which resulted in a medical event. The Radiation Safety Officer notified the NRC's Operations Center of the event within 24 hours. The licensee provided its written report of the event within 15 days of the telephone report in a letter dated June 30, 2009. The inspector determined that the written report included the information required by 10 CFR 35.3045(d). The licensee notified the patient's referring physician of the event. During the interval between when the medical event occurred and discovery of the event, the patient and authorized user have both succumbed to illness.

4.3 Conclusions

The licensee made all of the notifications and submitted the reports required by 10 CFR 35.3045 within the specified time period. The inspector determined that the licensee included all of the required information.

5 Exit Meeting

At the completion of the onsite inspection, the inspector discussed the findings in this report with licensee management during an exit meeting. The inspector discussed the sequence of events that led to the medical event, the root and contributing causes of the event, and the licensee's corrective actions. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.

Partial List of Persons Contacted

* Debra Herring, Vice President Ambulatory Operations
* Joseph Rakowski, Ph.D, Radiation Safety Officer, Authorized Medical Physicist
* Mara Jelich, Manager, Operations

* Attended the July 7, 2009, exit meeting