January 10, 2008

EA-07-316

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

SUBJECT: NRC INSPECTION REPORT 030-09376/2007-001(DNMS)
KARMANOS CANCER CENTER

This refers to the special inspection conducted between October 29 and November 6, 2007, at your facility located in Detroit, Michigan, with continuing in-office review through December 14, 2007. The in-office review consisted of a review of the NRC medical consultant's report dated December 5, 2007. A copy of his report is enclosed for your review. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions to a reported medical event that occurred October 24, 2007. The findings of the inspection were discussed with you and selected members of your staff on October 30, 2007. The enclosed report presents the results of this inspection.

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/enforcement-pol.html. The apparent violation involves your staff's failure to have procedures to verify that the magnetic resonance imaging scans were taken in the correct mode and orientation prior to implementation of gamma knife treatments. The circumstances surrounding this apparent violation, the significance of the issue, and the need for lasting and effective corrective action were discussed with you on October 30, 2007. As a result, it may not be necessary to conduct a predecisional enforcement conference in order to enable the NRC to make an enforcement decision.

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 VI.C.2 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 either: (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. If a conference is held, it will be open for public observation. Please contact John Madera at (630) 829-9834 within 7 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. 03009376/2007-001(DNMS); EA-07-316" 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. 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 violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required elements of the response. 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 predecisional enforcement conference.

In addition, please be advised that the number and characterization of any 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 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be 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.

We appreciate your cooperation and will gladly discuss any questions you have concerning this inspection.

Sincerely,
/RA by K. O'Brien Acting for/
Steven A. Reynolds, Director
Division of Nuclear Materials Safety

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

Enclosures:
1. Inspection Report 030-09376/2007-001(DNMS)
2. Excerpt from NRC Information Notice 96-28
3. NRC medical consultant's report

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

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Letter to Debra Herring from Steven A. Reynolds dated January 10, 2008

SUBJECT: NRC INSPECTION REPORT 030-09376/2007-001(DNMS)
KARMANOS CANCER CENTER

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REGION III

Docket No.:	030-09376
License No.:	21-04127-06
Report No.:	030-09376/2007-001(DNMS)
Licensee:	Karmanos Cancer Center
Location:	4100 John R Detroit, MI
Dates of Inspection:	October 29 through November 6, 2007
Inspectors:	Darrel G. Wiedeman, Senior Health Physicist Deborah Piskura, Health Physicist
Reviewed By:	John R. Madera, Chief Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Karmanos Cancer Center
Detroit, Michigan
Inspection Report No. 030-09376/2007-001(DNMS)

This was a special, announced 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. The reported event was associated with their stereotactic radiosurgery unit, a.k.a., "gamma knife." The patient was a 63-year-old female that was being treated for a metastatic brain tumor in the right cerebellum. Due to an error in the setup of the magnetic resonance imaging (MRI) unit, the MRI scan was reversed (right side of the head was on the left side and visa versa). Prior to the administration of the treatment the medical physicist, authorized user physician and neurosurgeon reviewed the MRI scan and treatment plan and all failed to notice the reversed MRI images. The reversed MRI image was scanned into the gamma knife treatment planning computer and a treatment plan was generated. The treatment plan was again reviewed and approved by the authorized user physician and neurosurgeon and again the reversed MRI images were not detected. The treatment was administered to the left side of the patient's brain rather than the right side.

After the treatment plan was generated the medical physicist was still concerned that the stereotactic head frame measurements and MRI images did not match and consulted with several colleagues including the gamma knife manufacturer (Elekta). Discussions were also held with the neurosurgeon, authorized user, neuroradiologist and chief physicist. After the treatment was administered it was subsequently discovered that the MRI scans were reversed and the left side of the patient's brain was treated rather than the right side. The licensee did not expect the patient to experience any major adverse medical effects as a result of the medical event other than possible mild edema. An NRC medical consultant reviewed this case to determine if any deterministic effects are expected. The medical consultant indicated that in his opinion he did not expect any significant deterministic effects to the patient.

The inspector identified one violation of NRC requirements involving the licensee's failure to ensure each administration is in accordance with the written directive prior to patient treatment. Specifically, the licensee's procedures for the implementation of treatment plans with its stereotactic radiosurgery unit as required by 10 CFR 35.41 did not require a check and verification of the treatment plan parameters prior to the treatment to ensure correct MRI scan orientation. The root cause of the apparent violation was the MRI technologist inadvertently performing the MRI scans in the "caudal" (jaw to top of the head) mode rather than the "cranial" (top of the head to the jaw) mode which caused the MRI scans to be reversed and the licensee's failure to identify that the images were reversed. As a result, the licensee administered a dose of 1,800 centigray to the wrong side of the patient's brain.

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) weekly meetings among the physics staff to discuss technical issues, focusing on the importance of good communications with other physics staff, and (2) new written procedures and policies were implemented for the MRI staff and gamma knife facility that required dual verification of the various steps in the process to ensure that the correct treatment plan is generated from the MRI image and the administered dose is in accordance with the written directive.

Report Details

1 Program Scope and Inspection History

The NRC License Number 21-04127-06 authorizes Karmanos Cancer Center (licensee) to use a variety of byproduct materials for medical therapy purposes, including sealed source therapy using a high dose rate (HDR) remote afterloading brachytherapy device, teletherapy and a stereotactic radiosurgical unit.

One Severity Level IV violation was identified during an Increased Controls inspection conducted on June 14, 2006. No violations were identified during routine inspections conducted on March 12, 2004 and June 13, 2006.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

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

2.2 Observations and Findings

On October 24, 2007, a patient was to be treated for a brain tumor in the right cerebellum with the stereotactic radiosurgical unit. A written directive was completed by the authorized user physician that called for a single treatment of 1,800 centigray (cGy) to the right cerebellum. On the morning of October 24, 2007, the neurosurgical team fitted the patient with a stereotactic head frame and the patient was sent to the magnetic resonance imaging (MRI) department for a stereotactic MRI brain scan. During the scanning process an error in the setup of the MRI unit occurred. This error in the setup resulted in the MRI scan being reversed (right side of the head was on the left side and visa versa). The reversed MRI image was scanned into the gamma knife treatment planning computer and a treatment plan was generated.

The authorized medical physicist (AMP) noticed a discrepancy between the contour of the patient's head when compared to the MRI image and the bubble helmet measurements (a device used to take precise measurements of the patient's head). The AMP contacted the gamma knife manufacturer (Elekta) by phone and discussed the discrepancy with the physics staff at Elekta. A decision was made to proceed with the treatment using the bubble helmet measurements. The neurosurgeon, authorized user physician and the medical physicist reviewed the treatment plan and all parties agreed with the treatment plan and to proceed with the treatment. However, none of these individuals realized that the MRI scan was reversed. The treatment was administered and the patient received a dose of 1,800 cGy to the left cerebellum of the brain rather than the right side.

After the treatment was administered the AMP discovered that the MRI images were acquired in an unconventional way. The AMP immediately contacted the authorized user physician, neurosurgeon and neuroradiologist and all parties reviewed the

treatment plan and again agreed that the treatment was administered appropriately. On the evening of October 24, 2007, the AMP discussed the discrepancy with the chief medical physicist and it was at that time that the AMP realized that the MRI images were reversed and the treatment was administered to the wrong side of the brain. On October 25, 2007, the licensee notified NRC that a medical event occurred involving the stereotactic radiosurgery unit, a.k.a, "gamma knife." The licensee concluded that the root cause of the medical event was due to an error in the setup of the MRI scan and the licensee's failure to recognize that the MRI images were reversed.

10 CFR 35.41(a) requires that for any administrations requiring a written directive, licensees develop, implement, and maintain written procedures to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).

The inspectors determined that prior to October 29, 2007, the licensee's written procedures did not provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee's written procedures for the implementation of treatment plans with its stereotactic radiosurgical unit did not require a check of the treatment plan parameters to ensure that the MRI brain scan was in the correct orientation. As a result, the licensee failed to administer a single treatment to the correct side of the patient's brain. This is an apparent violation of 10 CFR 35.41(a).

The authorized user physician did not expect any major adverse medical effects to the patient as a result of the medical event. The licensee immediately initiated an investigation of the medical event and determined that the root and contributing causes were: (1) inattention to detail, (2) an error in the setup of the MRI brain, and (3) a failure to identify that the MRI images were reversed.

As part of the licensee's investigation, the licensee reviewed all gamma knife treatment plans, including MRI scans, from October 2006 to October 2007 to determine if the same error occurred during previous treatments and none were identified. The inspectors reviewed approximately 50 random selected treatment plans to determine if the same error occurred and did not identify any additional errors in the administration of the gamma knife treatments.

2.3 Conclusions

A medical event occurred on October 24, 2007, when the licensee administered a gamma knife treatment of 1,800 cGy to the left cerebellum rather than the right cerebellum. The authorized user physician did not expect the error in the treatment to result in any major adverse medical effects.

The medical event was caused by an error in the setup of the MRI brain scan and the licensee's failure to identify that the MRI images were reversed. In addition, the licensee's written procedures for implementation of stereotactic radiosurgical treatment plans did not require a check of the treatment plan parameters to ensure that the MRI scan was in the correct orientation. The inspectors identified a violation of NRC requirements associated with the failure of the licensee's written procedures to provide

high confidence that each administration is in accordance with the written directive. The NRC inspectors determined that this event was an isolated event.

3 Licensee Corrective Actions

3.1 Inspection Scope

The inspectors reviewed the licensee's proposed corrective actions to preclude similar events. The review included the licensee's November 6, 2007, written report regarding the medical event, interviews of selected licensee personnel, and the licensee's revised policies and procedures to ensure each administration is in accordance with the written directive prior to patient treatment.

3.2 Observations and Findings

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

(1) Created a gamma knife procedure documentation policy;
(2) Created a gamma knife quality assurance form;
(3) Instituted a secondary check of treatment parameters by another physicist;
(4) Reviewed all patient charts of previous treatments (October 2006 to October 2007) to ensure that this event was an isolated event;
(5) Implemented a procedure that required the neurosurgeon and radiation oncologist to verify the number and orientation of the brain lesion;
(6) Implemented a procedure for requiring a "time out" before commencing with a treatment to allow an overall review of all details of the treatment prior to delivery;
(7) Held a meeting with all groups in the department including physicists, dosimetrists, therapists, and nurses to assure a proper environment existed that encouraged peer and supervisory consultation and openness in the reporting of incidents; and,
(8) Created a new written procedure for the MRI staff to ensure that the correct MRI scan orientation was used on all future gamma knife patients.

3.3 Conclusions

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

4 Notifications and Reports

4.1 Inspection Scope

The inspectors 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 October 24, 2007, the licensee's Radiation Safety Officer determined that the patient's left side of the brain was treated rather than the right side which resulted in a medical event and 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 November 6, 2007. The inspectors determined that the written report included the information required by 10 CFR 35.3045(d).

The licensee notified the patient and patient's referring physician immediately after the event. The authorized user physician met with the patient and family and explained to them the possible side effects from the treatment.

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 inspectors determined that the licensee included all of the required information.

5 Exit Meeting

At the completion of the onsite inspection, the inspectors discussed the findings in this report with licensee management during an exit meeting. The inspectors 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
* Clifford Crabtree, R.Ph., Vice President Operations
* Bridget Brambs, Administrative Director
  Joseph Rakowski, Ph.D, Radiation Safety Officer, Authorized Medical Physicist
  Sandeep Mittal, M.D., Neurosurgeon
  Jay Burmeister, Ph.D., Chief of Physics
  Maria Vlachaki, M.D., Radiation Oncologist
  Mara Jelich, Manager, Operations
  Zubin Bharucha, Medical Physicist
  Ron Marshall, Manager, Diagnostic Imaging, MRI
  Roland Gardner, Supervisor, MRI
  Mark Manders, R.T., MRI Technologist
  Steven Jackson, R.T., MRI Technologist

* Attended the October 30, 2007, exit meeting