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

July 28, 2017

EA-17-015

Ms. Michela Logan, RN, BSN, ONC
Administrative Director, Cancer Services
Research Medical Center
Midwest Gamma Knife Center
2316 E. Meyer Blvd.
Kansas City, MO 64132

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03033507/2016001(DNMS) AND NOTICES OF VIOLATION – RESEARCH MEDICAL CENTER – MIDWEST GAMMA KNIFE CENTER

Dear Ms. Logan:

On November 17-18, 2016, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facility in Kansas City, Missouri, 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 in-depth assessment of several inspection findings. Ms. Deborah A. Piskura of my staff conducted a final exit meeting by telephone with you and other licensee representatives on June 29, 2017, to discuss the inspection findings. This letter and its enclosures present 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, the NRC has determined that Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. One safety-related violation involving the licensee's failure to have an authorized physician user to be physically present throughout a patient treatment involving its gamma stereotactic radiosurgery unit, as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 35.615(f)(3), was identified by the inspector and is being cited in the enclosed Notice of Violation (Enclosure 1). Details of the violation, as well as the corrective actions that have been taken to restore compliance, are discussed in the enclosed inspection report (Enclosure 3).

Enclosures 2 and 4 contain Sensitive Unclassified Non-Safeguards Information. When separated from Enclosures 2 and 4, this transmittal letter and Enclosures 1 and 3 are decontrolled.

The other violations are of a security-related nature and are cited in the enclosed, non-public Notice of Violation (Enclosure 2). The violations are being cited in Enclosure 2 because they were identified by the inspector. Details of the violations, as well as the corrective actions that have been taken to restore compliance, are discussed in the enclosed, non-public Security Addendum to the inspection report (Enclosure 4).

You are required to respond to this letter regarding all of the violations and should follow the instructions specified in the enclosed Notices when preparing your response. The guidance in 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's website at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

During this inspection, the inspector also evaluated the implementation of corrective actions for a security-related violation of NRC requirements cited previously in NRC Inspection Report No. 3033507/2014001(DNMS). The inspector found that corrective actions had been taken as stated in the report, and that the violation had not recurred. Therefore, this violation is closed.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, Enclosures 1 and 3, and your response to the safety-related violation 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/readingrm/adams.html. However, Enclosures 2 and 4 and your response to the non-public Notice of Violation will not be made available electronically for public inspection because they contain security-related information. Please mark the top of each page of your response to the non-public Notice of Violation with "Security-Related Information – Withhold Under 10 CFR 2.390." To the extent possible, your response to both Notices of Violation should not include any personal privacy, proprietary, or safeguards information.

Please feel to contact Ms. Piskura if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

Sincerely,

/RA/

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

Docket No. 030-33507
License No. 24-17998-02

Enclosures:
1. Notice of Violation (public)
2. Notice of Violation (non-public)
3. IR No. 03033507/2016001(DNMS) (public)
4. Security Addendum to IR (non-public)

cc w/o encls 2 & 4: State of Missouri

Letter to Michela Logan from John Giessner, dated July 28, 2017.

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03033507/2016001(DNMS) AND NOTICES OF VIOLATION – RESEARCH MEDICAL CENTER – MIDWEST GAMMA KNIFE CENTER

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DATE	7/20/2017		7/28/2017		7/28/2017		Click here to enter a date.	

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NOTICE OF VIOLATION

Research Medical Center
Midwest Gamma Knife Center
Kansas City, Missouri

License No. 24-17998-02
Docket No. 030-33507

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on November 17-18, 2016, with continued in-office review through June 29, 2017, one violation of NRC safety requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> Title 10 of the *Code of Federal Regulations* (CFR) Section 35.615(f)(3) states that a licensee shall, for gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.
>
> Condition 13 of Amendment 17 of NRC Radioactive Materials License No. 24-17998-02 states that notwithstanding the requirements of 10 CFR 35.615(f)(3), a neurosurgeon trained in gamma stereotactic radiosurgery may be physically present during patient treatments involving gamma stereotactic radiosurgery units, in place of an authorized user, in accordance with the conditions described in the licensee's letter dated September 20, 2002.
>
> Contrary to the above, on November 17, 2016, the licensee did not require an authorized user or a neurosurgeon trained in gamma stereotactic radiosurgery to be physically present throughout a patient treatment involving its gamma stereotactic radiosurgery unit. Specifically, the licensee's authorized user was located in an adjacent room from the unit console, approximately 20 feet away. Additionally, no neurosurgeon trained in gamma stereotactic radiosurgery was physically present in place of the authorized user.

This is a Severity Level IV Violation (Section 6.3).

Pursuant to the provisions of 10 CFR 2.201, Research Medical Center – Midwest Gamma Knife Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; EA-17-015" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or its severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or

Enclosures 2 and 4 contain Sensitive Unclassified Non-Safeguards Information. When separated from Enclosures 2 and 4, this transmittal letter and Enclosures 1 and 3 are decontrolled.

revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response 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. To the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 28th day of July, 2017.

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-33507
License No.	24-17998-02
Report No.	03033507/2016001(DNMS)
Licensee:	Research Medical Center Midwest Gamma Knife Center
Location:	1316 E. Meyer Blvd. Kansas City, Missouri
Inspection Dates:	November 17-18, 2016, with in-office review through June 29, 2017
Exit Meeting Date:	June 29, 2017
Inspector:	Deborah A. Piskura Senior Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosures 2 and 4 contain Sensitive Unclassified Non-Safeguards Information. When separated from Enclosures 2 and 4, this transmittal letter and Enclosures 1 and 3 are decontrolled.

Enclosure 3

EXECUTIVE SUMMARY

Research Medical Center – Midwest Gamma Knife Center
NRC Inspection Report 03033507/2016001(DNMS)

The U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection of Research Medical Center – Midwest Gamma Knife Center (the licensee) on November 17 and 18, 2016, with continued in-office review through June 29, 2017. The in-office review included an in-depth assessment of several inspection findings.

The inspector identified one Severity Level IV violation of NRC safety requirements involving the licensee's failure to require an authorized user or a neurosurgeon trained in gamma stereotactic radiosurgery (GSR) to be physically present throughout a patient treatment involving its gamma stereotactic radiosurgery unit, as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 35.615(f)(3) and License Condition 13 of NRC Radioactive Materials License No. 24-17998-02. Specifically, the licensee's authorized user sat at a computer terminal in an adjacent room from the unit console, approximately 20 feet away, and there was not a neurosurgeon trained in GSR physically present in place of the authorized user. The licensee's immediate corrective actions for this violation included installing a communication line at the GSR console to enable the authorized user to sit at the immediate area and use the computer.

In addition, the inspector identified security-related violations. Details of the security-related violations, as well as the corrective actions that have been taken to restore compliance, are discussed in the non-public Security Addendum to this Inspection Report.

REPORT DETAILS

1.0 Program Overview

Research Medical Center – Midwest Gamma Knife Center (licensee) was authorized under NRC License No. 24-17998-02 to use cobalt-60 sealed sources within a GSR unit. The licensee used its GSR unit to treat approximately 70 patient cases annually. The licensee staffed the gamma knife department with two authorized gamma knife physicists, three authorized users, two nurses, and seven neurosurgeons. License Condition 13 authorized the licensee for an exemption to the physical presence requirements in 10 CFR 35.615(f)(3); the licensee may permit a neurosurgeon trained in GSR to be physically present during patient treatments in place of an authorized user.

The last routine inspection was conducted on December 2, 2014, with continued in office review through December 19, 2014. One security-related violation was identified during the last inspection. The licensee's corrective actions for the previous security-related violation were reviewed during this inspection. The previous inspection, conducted on November 13 and 14, 2012, identified no violations of NRC requirements.

2.0 GSR Operations

2.1 Inspection Scope

The inspector interviewed licensee personnel, reviewed select records, toured the department, and performed independent radiation measurements. The inspector observed the licensee use the GSR unit for one patient treatment. The inspector reviewed the written directive and the treatment plan for the procedure. The inspector also interviewed the RSO, the authorized medical physicist, the authorized user, the neurosurgeon, and the nurse who attended the patient.

2.2 Observations and Findings

On November 17, 2016, the inspector observed the licensee administer a patient treatment; the treatment was in progress at the time of the inspector's arrival. The inspector reviewed the written directive and the treatment plan; these documents contained all the information required by 10 CFR 35.41. The inspector also reviewed the record for the safety checks performed on November 17, 2016, performed in accordance with 10 CFR 35.615(a) through (e) prior to the treatment.

During the patient treatment, the inspector noted that the authorized medical physicist and the gamma knife nurse were physically present at the treatment console. However, the inspector observed, during the treatment, that the authorized user sat at a computer terminal, facing perpendicular, in an adjacent treatment planning room, approximately 20 feet from the GSR unit console. Although License Condition 13 allows the licensee to have a neurosurgeon trained in GSR to be physically present at the treatment console in lieu of an authorized user, the inspector did not observe a neurosurgeon trained in GSR physically present at the treatment console to serve as a substitute for the authorized user.

Title 10 CFR 35.615(f)(3) states that a licensee shall, for gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit. License Condition 13 states that, notwithstanding the requirements specified in 10 CFR 35.615(f)(3), a neurosurgeon trained in GSR may be physically present during patient treatments involving GSR units, in place of an authorized user, in accordance with the conditions described in the licensee's letter dated September 20, 2002. The licensee's failure to require an authorized user or a neurosurgeon trained in GSR to be physically present throughout a patient treatment involving its GSR unit is a violation of 10 CFR 35.615(f)(3) and License Condition 13.

The inspector reviewed the information in Regulatory Issue Summary (RIS) 2005-23, "Clarification of the Physical Presence Requirement During Gamma Stereotactic Radiosurgery Treatments" with licensee management. The inspector pointed out the explanation in the RIS that the authorized user and the authorized medical physicist "must be physically located at or near the treatment console such that each can communicate with the other within hearing distance of normal voice. As stated earlier [in the RIS document], a raised voice would not constitute a normal voice." The inspector also pointed out that the RIS stated, if the authorized user or the authorized medical physicist enters a separate room or moves to a distance, such that the authorized user or the authorized medical physicist would need to raise his or her voice to communicate with the individual located at the treatment console, or vice versa, then the physical presence requirement would not be met.

The inspector attributed the root cause of the violation to a lack of understanding of the requirements. The licensee management acknowledged the information in the RIS and evaluated the GSR work center for the staff. The licensee installed a communication line at the GSR unit console to enable authorized users to sit at the console while working on a computer. The licensee also instructed its authorized users to remain at the console during the entire patient treatment.

2.3 Conclusions

The inspector identified one violation of NRC requirements involving the licensee's failure to require an authorized user to be physically present throughout a patient treatment involving its GSR unit, as required by 10 CFR 35.615(f)(3) and License Condition 13. Specifically, the licensee's authorized user was located in an adjacent room from the unit console, approximately 20 feet away, and there was not a neurosurgeon trained in GSR physically present in place of the authorized user. The licensee implemented corrective actions to prevent recurrence of this violation.

3.0 Other Areas Inspected

3.1 Inspection Scope

The inspector reviewed other aspects of the licensee's GSR program including: (1) security of the unit; (2) full calibration measurements and dosimetry equipment; (3) periodic spot checks; and (4) training. The inspector reviewed select records and interviewed select licensee personnel.

3.2 Observations and Findings

The inspector examined the GSR unit and noted it to bear a clearly visible label identifying the source radionuclide and total source activity. The inspector observed that the licensee posted a copy of NRC Form 3. The inspector also observed that the area where licensed material was used and stored were appropriately locked and posted with "CAUTION-RADIOACTIVE MATERIALS" and "CAUTION RADIATION AREA" signs. The GSR treatment console area was also posted with emergency procedures and contacts. The inspector performed radiation surveys around GSR unit and the treatment room. The licensee staff involved with GSR treatments attended annual in-services with practice sessions on the emergency procedures (last December 2015 and January 2016).

3.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspector identified no violations of NRC requirements in these areas.

4.0 Exit Meeting Summary

The NRC inspector presented the inspection findings during the on-site inspection on November 18, 2016, and during the telephonic exit meeting on June 29, 2017. Security-related material received during the inspection was returned to the licensee or destroyed. The licensee acknowledged the findings presented.

LIST OF PERSONNEL CONTACTED

Patrick Avila, Vice President, Operations
*Jeff Chung, RN, Gamma Knife Nurse
Steve Garner, Security Supervisor
*#Michaela Logan, RN, Administrative Director, Cancer Services
*#Robert Gilliam, M.S., Gamma Knife Physicist
Gregory W. Hornig, M.D., Pediatric Neurosurgeon
Bill Ludwig, Director, Security
Charlotte O'Neal, Vice President, Human Resources
Jay S. Robinow, M.D, Radiation Oncologist
Michael Scott, Revenue Cycle Manager
#Suzanne Schultz, M.S., Chief Physicist
*Stephen Slack, Ph.D., Radiation Safety Officer, Gamma Knife Physicist

*Individuals present at on-site exit meeting on November 18, 2016
#Individuals present during the final telephonic exit conference on June 29, 2017

SUPPLEMENTAL INFORMATION

INSPECTION PROCEDURES USED

87133, "Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs"