May 1, 2013

EN 48903
NMED 130168 (Closed)

Mr. Dennis Kehoe, M.S.
Radiation Safety Officer
MidMichigan Medical Center
4005 Orchard Drive
Midland, MI 48670

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002013/2013003(DNMS) AND NOTICE OF VIOLATION – MIDMICHIGAN MEDICAL CENTER

Dear Mr. Kehoe:

On April 18, 2013, with continued U.S. Nuclear Regulatory Commission (NRC) in-office review through April 23, 2013, two NRC inspectors conducted a reactive inspection at the Saginaw Radiation Oncology Center in Saginaw, Michigan, an authorized location of use on MidMichigan Medical Center's NRC radioactive materials license. The in-office review included receipt and review of the licensee's 15-day written report for the medical event. 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 on April 8, 2013. Aaron McCraw and Ryan Craffey of my staff discussed with selected members of your staff the findings of the inspection at a preliminary debrief on April 18, 2013, and at a final exit meeting on April 25, 2013. The enclosed report presents the results of this inspection.

Based on the results of this inspection, the NRC has determined that one 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 website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violation involved the licensee's isolated failure to implement written procedures to provide high confidence that high dose-rate remote afterloader brachytherapy administrations are in accordance with the written directives, as required by Title 10 of the Code of Federal Regulations (CFR) 35.41(a), which resulted in a medical event. The violation, which was identified by the inspectors, is cited in the enclosed Notice of Violation (Notice).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in your 15-day written report and in the enclosed NRC Inspection Report No. 03002013/2013003 (DNMS); therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

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 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, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

Please feel free to contact Aaron McCraw of my staff if you have any questions regarding this inspection. Mr. McCraw can be reached at (630) 829-9650 or Aaron.McCraw@nrc.gov.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-02013
License No. 21-01549-02

Enclosures:
1. Notice of Violation
2. Inspection Report No. 03002051/2012001(DNMS)

cc w/encls.: Guy Boike, M.D., Referring Physician
State of Michigan

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 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, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

Please feel free to contact Aaron McCraw of my staff if you have any questions regarding this inspection. Mr. McCraw can be reached at (630) 829-9650 or Aaron.McCraw@nrc.gov.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-02013
License No. 21-01549-02

Enclosures:
1. Notice of Violation
2. Inspection Report No. 03002051/2012001(DNMS)

cc w/encls.: Guy Boike, M.D., Referring Physician
State of Michigan

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NOTICE OF VIOLATION

MidMichigan Medical Center
Saginaw, Michigan

Docket No. 030-02013
License No. 21-01549-02

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted April 18, 2013, with continuing in-office review through April 23, 2013, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> Title 10 of the Code of Federal Regulations (CFR) 35.41(a) states that, for any administration requiring a written directive, licensees are required to 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).
>
> Contrary to the above, on April 8, 2013, the licensee failed to implement its written procedures to provide high confidence that each high dose-rate remote afterloader brachytherapy administration was in accordance with the written directive. Specifically, the licensee did not use the appropriate length catheter per its catheter length reference sheet during a high dose-rate remote afterloader brachytherapy administration, which resulted in a medical event.

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

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in your 15-day written report and in NRC Inspection Report No. 03002013/2013003(DNMS). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it 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.

If you choose to respond, 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. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

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.

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

Dated this 1st day of May 2013.

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-02013
License No.:	21-01549-02
Report No.:	03002013/2013003(DNMS)
Licensee:	MidMichigan Medical Center
Location:	Saginaw Radiation Oncology Center 4141 Tittabawasee Road Saginaw, Michigan
Dates of Inspection:	April 18, 2013, with continuing NRC in-office review through April 23, 2013
Exit Meeting:	April 25, 2013
Inspectors:	Aaron T. McCraw, Senior Health Physicist Ryan J. Craffey, Health Physicist
Reviewed By:	Tamara E. Bloomer, Chief Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

MidMichigan Medical Center
Saginaw, Michigan
NRC Inspection Report No. 03002013/2013003(DNMS)

The U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection on April 18, 2013, to review the facts and circumstances associated with a medical event that MidMichigan Medical Center (the licensee) reported to the NRC on April 9, 2013. The medical event occurred on April 8, 2013, because the licensee used a longer catheter to connect the high dose-rate remote afterloader brachytherapy (HDR) unit to the treatment applicator than intended and as described in the treatment plan for the first full fraction of an intended three-fraction treatment. As a result, a small volume of vaginal wall tissue four centimeters (cm) inferior to the intended treatment site received more dose than expected based on the planned treatment. The treatment dosimetry revealed that the unintended treatment site received a total dose of 525.9 centiGray (cGy) (525.9 rad) during the course of treatment. The site was expected to receive a total dose of 233.7 cGy (233.7 rad) during the course of the intended treatment, a difference of 292.2 cGy (292.2 rad) or 225 percent deviation from the expected dose. Because the treatment resulted in a dose to tissue other than the treatment site that differed from the prescribed dose by more than 0.5 Sievert[1] (Sv) (50 rem) and a total dose delivered that differed from the prescribed dose by 20 percent or more, the treatment constitutes a medical event per NRC's definition in Title 10 Code of Federal Regulations (CFR) 35.2. The licensee replanned subsequent fractions to account for the underdosing of the intended treatment site due to the error on the first fraction. The licensee did not anticipate any adverse medical effects on the patient as a result of the medical event.

The inspectors identified one violation in reviewing the facts and circumstances of this case. The violation involved an isolated failure on the part of the licensee to implement its written procedures to provide high confidence that each administration was in accordance with the written directive, as required by 10 CFR 35.41(a).

To prevent recurrence of a similar medical event, the licensee implemented a new "time out" checklist that will be used for each treatment fraction to help ensure that the actual catheter length is in accordance with the catheter length used during treatment planning. This checklist went into effect on April 18, 2013. The licensee also attached labels to each catheter in order to provide a quick visual reference to the appropriateness of the catheter for use with the intended applicator. This action was completed prior to the onsite inspection on April 18, 2013.

[1] The Sievert (rem) is a unit of dose equivalent, or effective dose, and the Gray (rad) is a unit of absorbed dose. For purposes of this report, one Gray from iridium-192 is equivalent to one Sievert; therefore 100 centiGray equals one Sievert.

REPORT DETAILS

1 Program Scope and Inspection History

The NRC License Number 21-01549-02 authorizes the licensee to use, in part, byproduct material for diagnostic and therapeutic administrations, which includes the use of iridium-192 in an HDR unit, at its facility in Saginaw, Michigan. The licensee performed on average 1-2 fractionated HDR treatments per month at the Saginaw facility, primarily for the treatment of gynecological cancers.

During the NRC's last routine inspection conducted on July 11-12, 2012, with continued in-office review through August 9, 2012, the NRC issued a Severity Level III violation for the licensee's failure to fully implement security requirements and two Severity Level IV violations. The two Severity Level IV violations involved the licensee's failure to implement other security requirements and the licensee's failure to notify the NRC within 30 days of allowing two authorized users to act as temporary Radiation Safety Officers (RSO).

During the previous routine inspection conducted on April 28, 2010, the NRC issued a Severity Level IV violation for the licensee's failure to perform adequate periodic spot checks on an HDR unit.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspectors interviewed the authorized user, the authorized medical physicist (AMP), the RSO, and other licensee personnel to determine the sequence of events that resulted in the medical event. In addition, the inspectors reviewed selected licensee records and procedures, and reviewed compliance with regulatory requirements relative to the HDR procedure.

2.2 Observations and Findings

On April 8, 2013, the licensee initiated an HDR treatment on a patient diagnosed with a vaginal wall tumor. Per the written directive and treatment pre-plan, the licensee was to administer 1,200 cGy (1,200 rad) to the prescription point, a point 0.5 cm from the vaginal cylinder applicator surface in the tissue of the vaginal wall in the area of the tumor. The prescribed dose was to be administered over the course of three fractions, each delivering 400 cGy (400 rad) per fraction. One fraction was to be delivered per day during the course of treatment. The treatment plan called for the prescribed dose to be delivered via an 8.4-curie[2] iridium-192 source.

During the second fraction on April 9, 2013, the AMP realized that the catheter used when connecting the HDR unit to the applicator was longer than the planned catheter used during development of the treatment plan. The treatment plan was based on a catheter length of 116cm; whereas, a 120-cm catheter was used to connect the

[2] Source strength, as calculated at the start of the first fraction.

applicator to the HDR unit. The second fraction was immediately terminated upon discovering the error, approximately one minute into the treatment while the source was still in the first dwell position. Upon further review of the catheter length error, the AMP realized that the same error had been made on the previous day for the first fraction.

As a result of the error, the actual dwell positions for the first fraction and the terminated second fraction were approximately 4 cm inferior to the intended dwell positions due to the the 4-cm difference in length between the planned catheter and the actual catheter used. The active treatment length of the dwell positions was 5 cm; therefore, there was some overlap between the first dwell position(s) of the first fraction and the final dwell position(s) of the intended treatment plan. Because of this, the licensee evaluated the dose that had been delivered to the treatment site and decided on a course of action to compensate for the underdosing to the intended treatment site. In consultation with the authorized user, the AMP and the dosimetrist created a revised plan for the second fraction to correct for the partial treatment on April 9, 2013. The licensee developed a new treatment plan for the third fraction that took into account the dose received by the intended treatment site during the first fraction on April 8, 2013. The licensee added a fourth fraction to the overall treatment plan that was in accordance with the originally intended treatment plan to bring the total dose delivered to the treatment site to the prescribed dose of 1,200 cGy (1,200 rad). Revisions to the written directive were made in accordance with 10 CFR 35.40(c). The revised second, third, and fourth fractions were delivered in accordance with their respective treatment plans and the revised written directive.

On April 18, 2013, two NRC inspectors began a reactive inspection in response to the licensee's report of a medical event that was made to the NRC Headquarters Operations Center on April 9, 2013. In reviewing the facts and circumstances of the medical event, the inspectors determined that the event occurred because a longer catheter was used during the first fraction and the terminated second fraction than was intended per the treatment plan.

The inspectors identified the root cause of the medical event as human error in that the licensee failed to implement its written procedures to provide high confidence that each administration was in accordance with the written directive and the treatment plan. Title 10 CFR 35.41(a) states that, for any administration requiring a written directive, licensees are required to 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 licensee's failure to implement its written procedures to provide high confidence that HDR administrations are in accordance with the written directives is an violation of 10 CFR 35.41(a). Specifically, the licensee had a written reference sheet for the appropriate lengths of the catheters for each of the applicators used by the licensee posted in various locations throughout the HDR suite, and that sheet was not referenced immediately before the first fraction or the terminated second fraction. Otherwise, the error may have been detected prior to initiation of treatment.

The inspectors identified several contributing causes to the selection of the wrong catheter. First, the AMP stated that the drawer in the HDR suite where the catheters are

stored was not well organized, making the appropriate catheters difficult to locate. The licensee has since organized the drawer and labeled the catheters to make them easier to identify. Second, the catheters were not applicator specific, which allowed the longer catheter to be used in place of the shorter catheter. The 120-cm-long catheter was used for tandem and ovoid treatments, while the 116-cm-long catheter was used for vaginal cylinder treatments. The two lengths of catheters had the same diameter, and the coupling device to attach the catheter to the applicator was not applicator specific; therefore, the catheters could be used on either type of applicator. The licensee's action to label the catheters should circumvent this contributing cause also.

The inspectors reviewed five other recent HDR administrations to determine whether this error had been made during previous treatments. The licensee's records from the five other treatments indicated that the correct catheter length was used in all cases. The inspectors concluded that the licensee's use of the wrong catheter that resulted in this medical event was isolated.

With assistance from the licensee, the inspectors review the dosimetry for the medical event based on mock treatment plans developed by the licensee to simulate the treatment error. Based on the mock treatment plan, the unintended treatment site received a total dose of 525.9 cGy (525.9 rad) during the course of treatment. The site was expected to receive a total dose of 233.7 cGy (233.7 rad) during the course of the intended treatment, a difference of 292.2 cGy (292.2 rad) or 225 percent deviation from the expected dose. Because the treatment resulted in a dose to tissue other than the treatment site that differed from the prescribed dose by more than 0.5 Sievert (Sv) (50 rem) and a total dose delivered that differed from the prescribed dose by 20 percent or more, the treatment constitutes a medical event per NRC's definition in 10 CFR 35.2. The licensee did not anticipate any adverse medical effects on the patient as a result of the medical event.

2.3 Conclusions

The inspectors identified a violation of 10 CFR 35.41(a) concerning the licensee's isolated failure to implement its written procedure to provide high confidence that HDR administrations are performed in accordance with the respective written directives and treatment plans.

3 Notifications and Reports

3.1 Inspection Scope

The inspectors interviewed the RSO, the AMP, and the authorized user to determine what event notifications had been made. The inspectors reviewed the licensee's initial event notification to the NRC Headquarters Operations Center on April 9, 2013, and the licensee's written report dated April 19, 2013. An electronic copy of the licensee's written report can be found in the NRC's Agencywide Documents Access and Management Systems (ADAMS) using Accession Number ML13113A133.

3.2 Observations and Findings

On April 9, 2013, the licensee notified the patient, the referring physician, and other clinical staff about the treatment error. The AMP notified the NRC Headquarters Operations Center of the medical event by telephone on April 9, 2013. On April 22, 2013, the licensee submitted its written report of the event, dated April 19, 2013, to the NRC in accordance with 10 CFR 35.3045(d). The licensee's written report included all of the required information.

3.3 Conclusions

The inspectors concluded that the licensee made all required notifications in a timely manner.

4 Licensee Corrective Actions

4.1 Inspection Scope

The inspectors reviewed the licensee's proposed corrective actions to prevent a similar medical event by interviewing selected staff and reviewing the licensee's written report dated April 19, 2013.

4.2 Observations and Findings

To prevent recurrence of a similar medical event, the licensee implemented a new "time out" checklist that will be used for each treatment fraction to help ensure that the actual catheter length is in accordance with the catheter length used during treatment planning. This checklist went into effect on April 18, 2013. The licensee also attached labels to each catheter in order to provide a quick visual reference to the appropriateness of the catheter for use with the intended applicator. This action was completed prior to the onsite inspection on April 18, 2013.

4.3 Conclusions

The inspectors determined that the licensee planned and implemented corrective actions to prevent a similar medical event.

5 Exit Meeting Summary

The inspectors discussed the conclusions described in this report with the licensee during a preliminary debrief at the licensee's facility on April 18, 2013. The licensee did not identify any information provided to the inspectors during this inspection as proprietary in nature. A final exit meeting was conducted on April 25, 2013.

LIST OF PERSONS CONTACTED

+ Shawna Buda, Lead Therapist
+^ Dennis Kehoe, Radiation Safety Officer
+^ Paul Kocheril, M.D., Radiation Oncologist
^ April McGinnis, Department Manager
+^ Ian Reineck, Physicist
John Szelesi, Dosimetrist

+ Participated in the preliminary debrief on April 18, 2013
^ Participated in the final exit meeting on April 25, 2013