August 29, 2012

EA-12-172
EN 48085
NMED No. 120405 (Closed)

Mr. Terry Hamilton, President
St. John Macomb-Oakland Hospital
11900 E. Twelve Mile Road, Suite 315
Warren, Michigan 48093

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002005/2012001(DNMS) – ST. JOHN MACOMB-OAKLAND HOSPITAL

Dear Mr. Hamilton:

On July 19-20, 2012, with continued U.S. Nuclear Regulatory Commission (NRC) in-office review through July 25, 2012, an NRC inspector conducted a reactive inspection at the St. John Macomb-Oakland Hospital in Warren, Michigan. The in-office review included completion of a confirmatory dose assessment and review of your 15-day written report for this medical event. The purpose of this inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for a medical event that your staff reported to the NRC on July 10, 2012. The enclosed report presents the results of this inspection.

Based on the results of this inspection, an apparent violation was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current NRC Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violation being considered for escalated enforcement involves the licensee's failure to develop procedures to provide high confidence that a high dose-rate remote afterloader brachytherapy treatment was in accordance with the written directive, as required by Title 10 of the Code of Federal Regulations (CFR), 35.41(a). Specifically, your facility's written procedures did not address the verification of the correctness of the connections to the high dose-rate remote afterloader (HDR) unit, and as a result, a medical event occurred during a treatment on July 9, 2012. The circumstances surrounding this apparent violation, the significance of the issues, and the need for lasting and effective corrective actions were discussed with select members of your staff during a final exit meeting on August 2, 2012, and are described in detail in the subject inspection report.

The NRC has not made a final determination on this matter; therefore, a Notice of Violation is not being issued for this inspection finding at this time. Because your facility has not been the subject of escalated enforcement actions within the last two years and based upon the NRC's understanding of your corrective actions, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond to the apparent violation addressed in this inspection report within 30 days of the date of this letter; (2) request a Predecisional Enforcement Conference (PEC); or (3) provide no further response. If a PEC is held, it will be open for public observation, and the NRC will issue a press release to announce the time and date of the conference. Please contact Kenneth

Lambert at 630-829-9633 within ten 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 “Response to the Apparent Violation in Inspection Report No. 03002005/2012001(DNMS); EA-12-172,” 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. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the requested response. If a 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.

If you choose to request a PEC, it will be open for the public. The PEC will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken.

If you choose to provide no further response, the NRC will use information gathered during the inspection and information included in previously docketed correspondence to assess the significance of the apparent violation and proceed with its enforcement decision. This option is being provided to you because, based on our initial assessment, the information regarding the reason for the apparent violation, the corrective actions taken and planned to correct the apparent violation and prevent recurrence, and the dates when full compliance was or will be achieved is already adequately addressed in the enclosed inspection report.

Please be advised that the number and characterization of the apparent violation 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 your response, if you choose to provide one, will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, if you choose to provide a response your 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 have any questions regarding this correspondence, please contact Aaron McCraw of my staff at 630-829-9650 or Aaron.McCraw@nrc.gov.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-02005
License No. 21-01190-05

Enclosure:
Inspection Report No. 03002005/2012001(DNMS)

cc w/encl: Laura Smith, Radiation Safety Officer
State of Michigan

If you have any questions regarding this correspondence, please contact Aaron McCraw of my staff at 630-829-9650 or Aaron.McCraw@nrc.gov.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-02005
License No. 21-01190-05

Enclosure:
Inspection Report No. 03002005/2012001(DNMS)

cc w/encl: Laura Smith, Radiation Safety Officer
State of Michigan

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NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-02005
License No.:	21-01190-05
Report No.:	03002005/2012001(DNMS)
EA No.:	12-172
Licensee:	St. John Macomb-Oakland Hospital
Location:	11800 E. Twelve Mile Road Warren, Michigan
Dates of Inspection:	July 19 and 20, 2012, with continued in-office review through July 25, 2012
Exit Meeting:	August 2, 2012
Inspector:	Aaron T. McCraw, Senior Health Physicist
Reviewed By:	Tamara E. Bloomer, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

St. John Macomb-Oakland Hospital
Warren, Michigan
Inspection Report 03002005/2012001(DNMS)

The U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection on July 19-20, 2012, to review the circumstances associated with a medical event that the licensee reported to the NRC on July 10, 2012. The medical event occurred because the patient's treatment catheters were incorrectly connected to the high dose-rate remote afterloader (HDR) unit. The patient's treatment catheters were connected to one-meter long transfer tubes that were connected to the HDR unit, instead of being directly connected to the HDR unit per the manufacturer's instructions. As a result, the treatment site did not receive any dose during the treatment. Per Title 10 of the Code of Federal Regulations (CFR) 35.3045(a)(1)(i), the treatment resulted in a medical event because the dose delivered differed from the prescribed dose by more than 50 rem to an organ and more than 20 percent. The radioactive source remained outside the body and delivered an estimated dose of 1.8 rad to the patient's skin on left shoulder and upper arm. The licensee did not anticipate any effects on the patient's skin as a result of the medical event. The licensee completed the intended treatment in accordance with the written directive on July 27, 2012.

The root cause of the medical event was the licensee's written procedures failed to ensure that the patient's treatment catheters were appropriately connected to the HDR unit such that the administration would occur in accordance with the written directive. The inspector identified this as an apparent violation of 10 CFR 35.41(a), because the licensee failed to develop written procedures to provide high confidence that each administration is in accordance with the written directive.

The licensee implemented corrective actions to prevent a similar event and a similar violation that included: (1) revising the licensee's written procedures for HDR treatments to require the physicist and an independent staff member to review and verify the correctness of the connections to the HDR unit; (2) providing training to all affected users on the revision to the written procedure; (3) developing a comprehensive manual that includes narrative descriptions and photographs of treatment set-ups of all types of HDR treatments that are in accordance with the manufacturers' instructions; and (4) training other qualified staff to perform the secondary check to confirm the correctness of all connections to the HDR unit.

Report Details

1 Program Scope and Inspection History

St. John Macomb-Oakland Hospital (licensee) is a hospital authorized by NRC License No. 21-01190-05 to perform activities under 10 CFR 35.100, 200, 300, 400, 500, and 600; including HDR brachytherapy.

During the NRC's last routine inspection conducted on December 15, 2010, no violations of NRC requirements were identified.

During the previous routine inspection conducted on August 20, 2008, the inspector identified a Severity Level IV violation of 10 CFR 35.41 for HDR treatments not being in accordance with the written directives. The violation involved mathematical errors in determining the cumulative doses to HDR patients.

2 Sequence of Events

2.1 Inspection Scope

The inspector interviewed the authorized medical physicist (AMP), the radiation safety officer (RSO), and other licensee personnel to determine the sequence of events that resulted in the medical event. In addition, the inspector reviewed the licensee's policies and procedures for administering treatments requiring written directives and the licensee's compliance with regulatory requirements for HDR treatments.

2.2 Observations and Findings

On July 9, 2012, the licensee was using the HDR unit to perform an endobronchial brachytherapy procedure. The written directive called for a prescribed dose of 500 centiGray (cGy) to the treatment site to be delivered in one fraction. The treatment plan called for the prescribed dose to be delivered via a 6.1-curie iridium-192 source stopping at specified dwell positions for specified dwell times through three separate endobronchial catheters.

When setting up the HDR unit for the procedure, the AMP connected the three catheters to transfer tubes that were then connected to the HDR unit. According to the catheter manufacturer's instructions, the catheters should have been connected directly to the HDR unit. The AMP did not immediately recognize this error, and the procedure continued. The procedure was completed in accordance with the treatment parameters from the approved treatment plan; however, because of the additional length of the transfer tube (approximately one meter), the iridium-192 source never made it to the intended treatment site. Instead, the source remained outside of the body throughout the duration of the procedure, and the treatment site did not receive any of the prescribed dose.

The AMP realized the error after the treatment was completed and the patient was discharged. On July 10, 2012, the AMP informed the RSO of the error. The RSO recognized that the treatment resulted in a potential medical event because of the underdose to the treatment site and called the NRC Region III office to obtain clarification on the medical event criteria. After consulting with the NRC Region III office,

the RSO determined that a medical event had occurred and notified the NRC Headquarters Operations Center of the event on July 10, 2012. This treatment met the criteria for a medical event in 10 CFR 35.3045(a)(1)(i), because the dose delivered (0 cGy or 0 rad) differed from the prescribed dose (500 cGy or 500 rad) by more than 0.5 Sievert (50 rem) to an organ or tissue and the total dose delivered differed from the prescribed dose by 20 percent or more.

On July 19, 2012, an NRC inspector began a reactive inspection in response to the report of a medical event. In reviewing the facts and circumstances of the medical event, the inspector determined that the event occurred because the AMP inadvertently connected the patient's treatment catheters to transfer tubes that were connected to the HDR unit instead of connecting the patient's treatment catheters directly to the HDR unit in accordance with the catheter manufacturer's instructions.

The inspector identified the root cause of the medical event as the fact that the licensee's written procedures did not provide high confidence that each administration was in accordance with the written directive in that the licensee's written procedures did not require a verification that the treatment set-up (i.e., connections to the HDR unit were in accordance with the manufacturer's instructions for the applicator used) was correct. 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 develop written procedures to provide high confidence that HDR administrations are in accordance with the written directives is an apparent violation of 10 CFR 35.41(a).

Because the AMP recognized and reported that an error was made when setting up the HDR unit for the treatment, the licensee was able to identify the medical event and the NRC was afforded an opportunity to conduct a reactive inspection. The inspector recognized the potential for a similar error to be made during other types of HDR treatments and for the error to go undetected, because of the lack of verification of the treatment set-up. The licensee also recognized the applicability of the apparent violation to all types of HDR treatments; therefore, the licensee applied its corrective actions, detailed in Section 4.2 of this report, to all types of HDR treatments, not just endobronchial treatments. Because treatment set-ups are not documented in the patients' treatment files, the inspector could not conduct an effective extent-of-condition review to evaluate whether other endobronchial treatments, as well as other types of HDR treatments, resulted in medical events. Due to the distance the source was from the body in this medical event, there was limited exposure to the patient, which the licensee did not expect to cause any negative health effects; however, a similar error (e.g., wrong length transfer tube) with other types of applicators have been known to cause negative health effects, such as reddening of the skin, lesions, or necrosis of tissue. The licensee stated that no previous patients have presented any negative health effects that would have resulted from a medical event involving an HDR treatment.

The inspector identified five contributing causes to the medical event that demonstrate the importance of having an effective means of verifying the correctness of the treatment set-up prior to initiating treatment. One of the contributing causes was that this type of

HDR treatment is rare for this licensee. The previous endobronchial HDR treatment at this facility was August 2011. Another contributing cause was that most other HDR applicators require transfer tubes to connect the applicators to the HDR unit. Most other applicators are short in length and, therefore, require transfer tubes in order to make the connection to the HDR unit. Endobronchial catheters can be up to 1.5 meters in length and are already at the HDR unit's maximum treatment distance; therefore, transfer tubes are not necessary to facilitate the connection to the HDR unit.

A third contributing cause was that the preparations in the HDR treatment room, including the connections to the HDR unit, were hurried because the patient was under anesthesia. Most patients are not under anesthesia during HDR treatments, so there is not the same sense of urgency in initiating the treatment. Endobronchial HDR treatments are performed under anesthesia to minimize patient discomfort, as well as to minimize the possibility of catheter displacement due to patient movement.

A fourth contributing cause was that the HDR unit does not have a built-in function to check if the treatment catheter is longer than the unit's maximum treatment distance of 1,500 millimeters. HDR units have a built-in safety feature to determine if the treatment catheter is shorter than the intended treatment distance to prevent damage to the source; however, there is not an analogous check to determine if the treatment catheter is too long. If the treatment catheter is too long, the source can only go out to its maximum treatment distance; therefore, the intended treatment site will not receive the prescribed dose and another organ or tissue may receive a dose greater than intended.

The last contributing cause that the inspector identified was that the catheter and the transfer tube could be connected without causing a fault in the HDR unit that would prevent treatment. The endobronchial catheter has the exact same diameter as other treatment applicators. The endobronchial catheter and applicators used for prostate, breast, and interstitial HDR treatments all have an outer diameter of 6 French[1]. The other applicators are short compared to the endobronchial catheter and all require transfer tubes to facilitate their connection to the HDR unit. The similarity in outer diameter allowed the endobronchial catheter to be connected to the transfer without the HDR unit notifying the operator of a potential error from the connection to the unit.

2.3 Conclusion

The inspector identified an apparent violation of 10 CFR 35.41(a) concerning the licensee's failure to develop its written procedures to provide high confidence that HDR administrations are in accordance with the written directives.

3 Notifications and Reports

3.1 Inspection Scope

The inspector interviewed the RSO and the AMP to determine what event notifications had been made. The inspector reviewed the licensee's telephonic event notification to the NRC Headquarters Operations Center made on July 10, 2012, and the licensee's written report dated July 24, 2012. An electronic copy of the licensee's written report

[1] The French scale is commonly used to measure catheter diameter. A diameter of 6 French is equivalent to 2 millimeters.

can be found in the NRC's Agencywide Documents Access and Management Systems (ADAMS) using Accession Number ML12208A256.

3.2 Observations and Findings

On July 10, 2012, the licensee notified the patient, the referring physician, and other clinical staff about the treatment error. The RSO notified the NRC Headquarters Operations Center of the medical event by telephone on July 10, 2012. On July 24, 2012, the licensee submitted its written report of the event to the NRC in accordance with 10 CFR 35.3045(d), and it included all of the required information.

3.3 Conclusion

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

4 Licensee Corrective Actions

4.1 Inspection Scope

The inspector 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 July 24, 2012. The licensee provided supplemental information detailing its corrective actions to the NRC on August 8, 2012. An electronic copy of the licensee's supplemental information can be found in ADAMS under Accession Number ML12223A218.

4.2 Observations and Findings

To prevent recurrence of a similar medical event, the licensee immediately revised its procedure for "time outs" during treatment preparations. The "time out" was intended to provide the AMP an opportunity to review and confirm that the set up is correct for the treatment applicator being used. All affected users of the procedure had read and acknowledged the new requirements by the time of the reactive inspection.

Following the reactive inspection, the licensee further revised its written procedures to include an independent verification of the treatment set-up by a second staff member. The verification by a second staff member was intended to catch an oversight on the part of the AMP. The revised written procedure also included a reference to an HDR Instruction Manual. The Instruction Manual was a comprehensive reference document that the licensee put together. The Instruction Manual included narrative descriptions and photographs of treatment set-ups of all types of HDR treatments that HDR users can use as a quick reference to confirm and verify that treatment set-ups are correct and in accordance with the manufacturers' instructions for the procedure being performed.

As a long-term corrective action, the licensee planned to train additional staff members on how to verify treatment set-ups and confirm that they are correct prior to initiating treatment. The Instruction Manual will be used as part of this training. The licensee expected to complete this training by September 30, 2012.

4.3 Conclusion

The inspector determined that the licensee planned and implemented corrective actions in response to the medical event.

5 Patient Dose Assessment

5.1 Inspection Scope

The inspector reviewed the licensee's dose assessment, reviewed the treatment plan for this procedure, and performed a confirmatory dose assessment.

5.2 Observations and Findings

On July 10, 2012, the AMP and the RSO recreated the treatment set-up to confirm that the radioactive source would not have made it to the treatment site with the addition of the transfer tube on each of the three catheters and to estimate the potential doses to unintended organs or tissues. The licensee's treatment recreation revealed that the source would have remained outside of the body and would have been below the patient's hospital bed during the treatment. The licensee placed electronic dosimeters in areas representing the highest possible patient skin dose measurements. The licensee estimated the highest potential skin dose to be 1.8 cGy (1.8 rad). This number represents the total potential dose received by the patient's skin on the left shoulder and upper arm. Two of the three catheters were draped on the left side of the patient's body. The other catheter was draped on the patient's right side and would have received a smaller dose. Based on this number, the licensee did not expect any negative health effects on the patient from this unintended dose.

The inspector conducted a confirmatory dose assessment by manual calculation based on source strength, source position relative to the body, and total dwell times in each catheter. The inspector's dose assessment did not take into account any shielding provided by the patient bed or bedding materials, as the licensee's dose estimate would have. The inspector's dose assessment assumed that the source stayed at a position closest to the body (an estimated 30 centimeters) for the entire dwell time in each catheter. The inspector calculated that the patient's skin on the left shoulder and upper arm would have received a potential total dose of 2.4 cGy (2.4 rad). Given the conservatisms built into the inspector's dose assessment, the inspector concluded that the licensee's dose estimate of 1.8 cGy (1.8 rad) was more representative of the potential dose received by the patient's skin on the left shoulder and upper arm.

5.3 Conclusions

The licensee estimated that the patient's skin on the left shoulder and upper arm received a potential dose of 1.8 cGy (1.8 rad). The NRC concluded that the licensee's dose estimate was reasonable based on the shielding that was provided by the patient bed. The licensee did not expect any negative health effects on the patient from this dose.

6 Exit Meeting

At the completion of the onsite inspection, the inspector discussed potential issues and findings with the licensee during a preliminary debrief meeting. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature. The inspector conducted a telephonic exit meeting with the licensee on August 2, 2012.

Partial List of Persons Contacted

+^ Barbara Boudreau, Regulatory Compliance Specialist
^ Michelle Bradford, Regional Director for Medical Staff Services, Clinical Safety and Risk Management, and Regulatory Compliance
+ Debbie Condino, Vice President for Clinical Services
+ Linda Corriveau, Loss Prevention Specialist
+ Terry Hamilton, President
+ Yunsil, Ho, Ph.D., Medical Physicist
+^ Lorrie Lipa, Director for Radiation Oncology
+^ Laura Smith, Radiation Safety Officer

+ Attended the onsite preliminary debrief meeting on July 20, 2012
^ Participated in the telephone exit meeting on August 2, 2012