February 27, 2013

EN 48520
NMED 120689 (Closed)

Ms. Susan Stellini, Director
Cancer Center
Oakwood Hospital and Medical Center
18101 Oakwood Boulevard
Dearborn, Michigan 48123-2500

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002051/2012001(DNMS) AND NOTICE OF VIOLATION – OAKWOOD HOSPITAL AND MEDICAL CENTER

Dear Ms. Stellini:

On November 28 and 29, 2012, with continued U.S. Nuclear Regulatory Commission (NRC) in-office review through February 11, 2013, an NRC inspector conducted a reactive inspection at Oakwood Hospital and Medical Center in Dearborn, Michigan. The in-office review included receipt and review of the licensee's dosimetry evaluations of the treatment that resulted in 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 September 18, 2012. Aaron McCraw of my staff discussed with selected members of your staff the findings of the inspection at a preliminary debrief on November 29, 2012, and at a final exit meeting on February 11, 2013. The enclosed report presents the results of this inspection.

Based on the results of this inspection, the NRC has determined that three 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. The first violation involved the licensee's failure to develop written procedures to provide high confidence that interstitial brachytherapy implants are in accordance with the written directives, as required by Title 10 of the Code of Federal Regulations (CFR) Part 35.41(a), which resulted in a medical event, was determined to be an isolated occurrence. The second violation involved the licensee's failure to notify the NRC of the medical event in the timeframe required by 10 CFR 35.3045(c). The third violation involved the licensee's failure to notify the individual who was the subject of the medical event in the timeframe required by 10 CFR 35.3045(e). The violations, which were all identified by the inspector, are cited in the enclosed Notice of Violation (Notice).

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

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. 030-02051
License No. 21-04515-01

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

cc w/encls.: Jerry Drake, M.D., Radiation Safety Officer
Christine Kupovits, Assistant Director, Cancer Center
Taljit Sandhu, Ph.D., Chief Physicist
Jorge Torriglia, M.D., Referring Physician
State of Michigan

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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.

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NAME	ATMcCraw:jc*ATM		TEBloomer*TEB					
DATE	02/25/13		02/27/13					

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NOTICE OF VIOLATION

Oakwood Hospital and Medical Center
Dearborn, Michigan

Docket No. 030-02051
License No. 21-04515-01

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted November 28-29, 2012, with continuing in-office review through February 11, 2013, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 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 September 18, 2012, the licensee failed to have written procedures in place that would provide high confidence that each interstitial brachytherapy implant was in accordance with the written directive.

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

B. Title 10 CFR 35.3045(c) requires the licensee to notify the NRC Operations Center, by telephone, no later than the next calendar day after discovery of the medical event.

Contrary to the above, on October 22, 2012, the licensee failed to notify the NRC until November 19, 2012, which was later than the next calendar day, that a medical event had occurred. Specifically, on October 22, 2012, the licensee had sufficient information to determine that the administration of byproduct material resulted in a dose to the prostate that differed from the prescribed dose by more than 0.5 Sievert (50 rem), and the total dose delivered differed from the prescribed dose by more than 20 percent.

This is a Severity Level IV violation (Section 6.9).

C. Title 10 CFR 35.3045(e) states, in part, that the licensee shall notify the individual who is the subject of the medical event no later than 24 hours after its discovery. The licensee is not required to notify the individual without first consulting the referring physician.

Contrary to the above, on November 27, 2012, the licensee failed to notify the individual who was the subject of the medical event no later than 24 hours after consulting with the referring physician. Specifically, the licensee consulted with the referring physician on November 26, 2012, and the licensee did not attempt to contact the patient until November 28, 2012.

This is a Severity Level IV violation (Section 6.9).

Pursuant to the provisions of 10 CFR 2.201, Oakwood Hospital and Medical 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" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or 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 was or 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 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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," 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.

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 27th day of February 2013.

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-02051
License No.:	21-04515-01
Report No.:	03002051/2012001(DNMS)
Licensee:	Oakwood Hospital and Medical Center
Location:	18101 Oakwood Boulevard Dearborn, Michigan
Dates of Inspection:	November 28-29, 2012, with continuing NRC in-office review through February 11, 2013
Exit Meeting:	February 11, 2013
Inspector:	Aaron T. McCraw, Senior Health Physicist
Reviewed By:	Tamara E. Bloomer, Chief Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Oakwood Hospital and Medical Center
Dearborn, Michigan
NRC Inspection Report No. 03002051/2012001(DNMS)

The U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection on November 28-29, 2012, to review the events and circumstances associated with a medical event that Oakwood Hospital and Medical Center (the licensee) reported to the NRC on November 19, 2012. The medical event occurred on September 18, 2012, because the iodine-125 (I-125) seeds were not placed in accordance with the treatment plan. Based on post-implant images, obtained on October 22, 2012, the seeds appeared to be up to one centimeter from the intended location, which prevented the base of the prostate from receiving the prescribed dose. The treatment dosimetry revealed that the prostate, as a whole, received 69.3 percent of the prescribed dose. Because the treatment resulted in a dose to the prostate 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 Title 10 Code of Federal Regulations (CFR) 35.2. The mispositioning of the sources also resulted in doses to tissues other than the treatment site (adjacent to the prostate) that exceeded the doses expected from the administration defined in the written directive. The licensee did not anticipate any long-term medical effects on the patient as a result of the medical event.

The inspector identified three violations in reviewing the facts and circumstances of this case. The first violation involved the licensee's failure to develop written procedures to provide high confidence that each administration was in accordance with the written directive, as required by 10 CFR 35.41(a). The second violation involved the licensee's failure to report the medical event to the NRC Headquarters Operations Center in a timely manner, as required by 10 CFR 35.3045(c). The third violation involved the licensee's failure to notify the patient of the medical event in a timely manner, as required by 10 CFR 35.3045(e).

To prevent recurrence of a similar medical event, the licensee implemented a change to its process for interstitial brachytherapy implants to require a verification of the needle positioning. The urologist and radiation oncologist, in consultation with each other, will use the longitudinal view of the ultrasound images obtained during the procedure to verify needle position and to help make certain that the tip of the needle is at the base of the prostate. This process change was documented in the licensee's written procedures for interstitial brachytherapy implants and communicated to all authorized users. The licensee completed the procedure revision and communication with the authorized users on February 7, 2013.

REPORT DETAILS

1 Program Scope and Inspection History

The NRC License Number, 21-04515-01, authorizes the licensee to use, in part, byproduct material for diagnostic and therapeutic administrations, which includes the permanent implantation of I-125 seeds, at its facility in Dearborn, Michigan. The licensee performs on average 5-10 interstitial brachytherapy implants per year for treatment of prostate cancers at its Dearborn facility.

During the NRC's last routine inspection conducted on March 23 and 24, 2011, with continued in-office review through April 5, 2011, the NRC issued a Severity Level IV violation for the licensee's failure to conduct physical inventories of all sealed sources in the licensee's possession every 6 months as required by the license.

During the previous routine inspection conducted on June 10, 2010, with continuing in-office review through June 25, 2010, the NRC issued a Severity Level III violation for the licensee's failure to fully implement security requirements.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspector interviewed the authorized user, the authorized medical physicist, the referring physician, the radiation safety officer for brachytherapy, and other licensee personnel to determine the sequence of events that resulted in the medical event. In addition, the inspector reviewed selected licensee records and procedures, and reviewed compliance with regulatory requirements relative to the implant procedure.

2.2 Observations and Findings

On September 18, 2012, the licensee performed a permanent interstitial brachytherapy implant for the treatment of a patient diagnosed with prostate cancer. Per the written directive, dated August 14, 2012, and treatment pre-plan, dated August 22, 2012, the licensee was to permanently implant 72 I-125 seeds – each with an activity of 0.365 millicuries – for a total implanted activity of 26.28 millicuries. The treatment plan called for the seeds to deliver the prescribed dose of 160 Gray (Gy) to the target volume (prostate).

On October 22, 2012, the patient returned to the licensee's facility for post-implant imaging and treatment evaluation. The licensee performed the post-implant imaging in accordance with industry standards using computerized tomography (CT). The post-implant images revealed that all 72 seeds were accounted for; however, during the treatment evaluation – more specifically, during the contouring of the prostate on the CT images – the licensee noted that the seeds were up to one centimeter toward the apex of the prostate from their intended locations. As a result, several of the seeds were outside of the contoured target volume, and the dose delivered to the prostate was approximately 70 percent of the prescribed dose. The authorized medical physicist, who performed the initial contour and dose evaluation, identified the treatment as a potential

medical event per NRC's definition in 10 CFR 35.2 and brought it to the attention of the authorized user, who performed a more detailed analysis of the images to contour the critical organs and tissues. The authorized user's analysis was completed on November 15, 2012.

The authorized user's analysis confirmed that the prostate received a fraction of the prescribed dose. The final post-plan analysis of the treatment indicated that the dose to 90 percent of the target volume, or D90, was 69.3 percent of the prescribed dose, or 110.91 Gy. Based on the dosimetric evaluation, the administration of the I-125 seeds resulted in a medical event as defined in 10 CFR 35.2. Per the criteria in 10 CFR 35.3045(a)(1), the administration resulted in doses that differed from the prescribed doses by more than 0.5 Sievert (50 rem)[1] to an organ or tissue; and the total dose delivered to the treatment site differed from the prescribed dose by 20 percent or more. The licensee reported the occurrence of the medical event to the NRC Headquarters Operations Center by telephone on November 19, 2012.

In response to the report of a medical event, the NRC dispatched an inspector to conduct a reactive inspection at the licensee's facility on November 28-29, 2012. Based on information from the personnel interviewed and the files review, the inspector confirmed the licensee's determination that the cause of the medical event appeared to be the misplacement of the seeds by up to one centimeter. The exact cause is difficult to ascertain retroactively. Two scenarios are the most probable factors leading to the medical event: (1) the base of the prostate was mistakenly identified approximately one centimeter from the actual base of the prostate and all seeds were placed with respect to the mistakenly identified base or (2) an error was made in measuring the length of needle that was not inserted in order to gauge the depth and subsequent needles were placed with respect to the first needle and strand of seeds that were inserted and placed in the prostate. The inspector determined that the licensee's procedures for interstitial brachytherapy lacked a means of secondary verification to ensure the proper placement of the needles; therefore, the procedures could not provide high confidence that the administration was in accordance with the written directive, as required by 10 CFR 35.41(a).

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. The written procedures must also meet the requirements described in 10 CFR 35.41(b). The licensee's failure to develop an adequate procedure to provide high confidence that the I-125 seeds were implanted in accordance with the written directive is a violation of 10 CFR 35.41(a).

Based on a review of written directives and treatment plans for other interstitial brachytherapy implants using I-125 seeds, the inspector determined that the medical event was isolated. All other administrations reviewed were in accordance with their respective written directives and treatment plans. The inspector determined that the licensee maintained an experienced staff that performs the implants and that the

[1] The Sievert is a unit of dose equivalent, or effective dose, and the Gray is a unit of absorbed dose. For purposes of this report, one Gray from iodine-125 is equivalent to one Sievert.

licensee had consistently implemented its written procedures for conducting interstitial brachytherapy implants. Because of this the inspector concluded that there were no programmatic weaknesses in the licensee's performance of interstitial brachytherapy implants. The licensee's lack of a means of secondary verification of the placement of the needles is an isolated gap in its written procedures that could have minimized the likelihood of occurrence of this medical event.

As a result of the medical event, tissues adjacent to the prostate received higher than expected doses. To evaluate the potential consequences of the medical event, the licensee conducted an initial dosimetric analysis of the treatment on November 19, 2012, and then performed a more in-depth dosimetric analysis of organs and tissues adjacent to the prostate on December 18, 2012. The licensee determined that no organ or tissue outside of the prostate received a significant difference in dose between what was expected and what was received. Exact doses to these tissues are difficult to determine due to the differences in imaging technology and imaging quality between the pre-treatment plan and the post-treatment plan. The pre-treatment plan is based on ultrasound images, while the post-treatment plan and evaluation are based on CT images. The same anatomical structures cannot always be easily differentiated when comparing the two types of images. The tissues that received the additional, unintended dose were composed of muscle, connective tissue, vascular tissue, and neural tissue, all of which are more resistant to effects from radiation exposure. The licensee did not anticipate any long-term radiological consequences as a result of the additional, unintended doses to the tissues adjacent to the prostate. The referring physician saw the patient during a followup appointment at his office on November 30, 2012. The patient did not present any complications from the procedure at that time.

2.3 Conclusions

The inspector identified a violation of 10 CFR 35.41(a) concerning the licensee's failure to develop a procedure to provide high confidence that interstitial brachytherapy implants are performed in accordance with the respective written directives and treatment plans.

3 Notifications and Reports

3.1 Inspection Scope

The inspector interviewed the radiation safety officer for brachytherapy, the authorized medical physicist, the authorized user, and the referring physician to determine what event notifications had been made. The inspector reviewed the licensee's telephonic event notification to the NRC Headquarters Operations Center on November 19, 2012, and the licensee's written report received by the NRC on December 3, 2012. 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 ML13010A358.

3.2 Observations and Findings

The medical event occurred on September 18, 2012; however, as is standard with interstitial brachytherapy implants, the determination of the placement of the seeds and

the dosimetric evaluation cannot occur until the post-implant imaging occurs up to 4-6 weeks after the implant. The licensee performed the post-implant imaging and initial dosimetric evaluation on October 22, 2012. The licensee reported the medical event to the NRC Headquarters Operations Center on November 19, 2012, after the authorized user had concluded his review of the post-implants images and discussed the treatment with other colleagues. Title 10 CFR 35.3045(c) requires, in part, that licensees notify by telephone the NRC Headquarters Operations Center no later than the next calendar day after discovery of the medical event. The inspector determined that the licensee had sufficient information, as early as October 22, 2012, to determine that the interstitial brachytherapy implant that took place at the licensee's facility on September 18, 2012, met the criteria for a medical event, as codified in 10 CFR 35.3045(a)(1). Based on this, the licensee was required to report the medical event to the NRC Headquarters Operations Center by telephone no later than October 23, 2012. The licensee's failure to report this medical event in a timely manner is a violation of 10 CFR 35.3045(c).

The NRC received the licensee's written report, dated November 19, 2012, on December 3, 2012. The written report contained all required information.

The inspector also reviewed the licensee's compliance with the required notifications to the referring physician and patient, as required by 10 CFR 35.3045(e). Title 10 CFR 35.3045(e) requires, in part, that the licensee notify the referring physician and the individual who is the subject of the medical event no later than 24 hours after discovery of the medical event. This regulation allows some flexibility in the notification to the patient as it permits consultation with the referring physician prior notifying the patient. The referring physician was notified of the medical event on November 26, 2012. There was a delay in notifying the referring physician due to the referring physician's being out of the office because of illness. The patient was notified of the medical event on November 28, 2012. The licensee did not make any attempts to notify the patient until November 28, 2012, a period greater than 24 hours after consulting with the referring physician. The licensee's failure to notify the patient of the medical event in a timely manner is a violation of 10 CFR 35.3045(e).

3.3 Conclusions

The inspector identified two violations of NRC requirements concerning the timely reporting of the medical event to the NRC Headquarters Operations Center and the patient, as required by 10 CFR 35.3045(c) and (e), respectively.

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 received by the NRC on December 3, 2012.

4.2 Observations and Findings

To prevent recurrence of a similar medical event, the licensee implemented a change to its process for interstitial brachytherapy implants to require a verification of the needle

positioning. The urologist and radiation oncologist, in consultation with each other, will use the longitudinal view of the ultrasound images obtained during the procedure to verify needle position and to help make certain that the tip of the needle is at the base of the prostate. This process change was documented in the licensee's written procedures for interstitial brachytherapy implants and communicated to all authorized users. The licensee completed the procedure revision and communication with the authorized users on February 7, 2013.

4.3 Conclusions

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

5 Exit Meeting Summary

The inspector discussed the conclusions described in this report with the licensee during a preliminary debrief at the licensee's facility on November 28, 2010. The licensee did not identify any information provided to the inspector during this inspection as proprietary in nature. A final exit meeting was conducted on February 11, 2013.

LIST OF PERSONS CONTACTED

+^ Zubin Bharucha, Physicist
+^ Andre A. Konski, M.D., Chairman, Radiation Oncology
+^ Christine Kupovits, Assistant Director, Cancer Center
Choon K. Lee, M.D., Radiation Oncologist
+^ Sharon Menzel, Director, Quality
+^ Taljit Sandhu, Ph.D., Chief Physicist
+^ Susan Stellini, Director, Cancer Center
Jorge R. Torriglia, M.D., Urologist

+ Participated in the preliminary debrief on November 29, 2012
^ Participated in the final exit meeting on February 11, 2013