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

June 23, 2015

EA-15-111
EN 50793
NMED No. 150083(Closed)

Ellen Talbott, RN, MSN, Vice President
Patient Care Services
McLaren Medical Center Bay Region
1900 Columbus Avenue
Bay City, MI 48708

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03013900/2015001(DNMS)
MCLAREN MEDICAL CENTER BAY REGION

Dear Ms. Talbott:

On February 11 through 13, 2015, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at McLaren Medical Center Bay Region, Bay City, Michigan, with continued in-office review through June 4, 2015. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for a medical event that occurred on February 6, 2015. The in-office review included a review of your written report and proposed corrective actions taken in response to the reported medical event. Our review also included the receipt and review of the NRC Medical Consultant's report. Ms. Deborah A. Piskura and Mr. Edward Harvey of my staff held a final exit meeting with you and members of your staff by telephone on June 4, 2015, to discuss the inspection findings.

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, one apparent violation of NRC requirements was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violation involved the licensee's failure to develop adequate written policies and procedures to provide high confidence that each iridium-192 high dose-rate remote afterloader brachytherapy treatment was in accordance with the physician authorized user's written directive and the applicable treatment plan, as required by Title 10 of the *Code of Federal Regulations* (CFR) Part 35.41(a)(2).

Because the NRC has not made a final determination in this matter, the NRC is not issuing a Notice of Violation for this inspection finding at this time. The circumstances surrounding this apparent violation, the significance of the issue, and the need for lasting and effective corrective action were discussed with you and members of your staff at the preliminary inspection exit meeting on February 13, 2015, and again at the final exit meeting on June 4, 2015.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond in writing to the apparent violation addressed in this inspection report within 30 days of the date of this letter; or (2) request a Predecisional Enforcement Conference (PEC). If a PEC is held, it will be open for public observation. The NRC will issue a press release to announce the time and date of the conference. **Please contact Mr. Aaron T. McCraw at 630-829-9650 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. 03013900/2015001(DNMS); EA-15-111," 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 was or will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in NRC 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 website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference 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.

As your facility has not been the subject of escalated enforcement action within the last two years or two inspections, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. In addition, based upon NRC's understanding of the facts and your corrective actions, it may not be necessary to conduct a PEC in order to enable the NRC to make a final enforcement decision. Our final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

In addition, please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and 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, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Deborah A. Piskura of my staff if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

Sincerely,

/RA/

Patrick L. Louden, Director
Division of Nuclear Materials Safety

Docket No. 030-13900
License No. 21-18585-01

Enclosure:
IR 03013900/2015001(DNMS)

cc w/encl: Tyre K. Jones, M.D., Radiation Safety Officer
Guy Boike, M.D., Referring Physician
State of Michigan

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/RA/

Patrick L. Louden, Director
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Enclosure:
IR 03013900/2015001(DNMS)

cc w/encl: Tyre K. Jones, M.D., Radiation Safety Officer
Guy Boike, M.D., Referring Physician
State of Michigan

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DATE	06/23/15							

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Letter to Ellen Talbott from Patrick Louden dated June 23, 2015

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03013900/2015001(DNMS)
MCLAREN MEDICAL CENTER BAY REGION

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Region III

Docket No.	030-13900
License No.	21-18585-01
Report No.	03013900/2015001(DNMS)
EA No./NMED No.	EA-15-111/150083
Licensee:	McLaren Medical Center Bay Region
Facilities:	1900 Columbus Avenue Bay City, Michigan Jeppesen Radiation Oncology Center 3180 East Midland Road Bay City, Michigan
Inspection Dates:	February 11 through 13, 2015, with continued in-office review through June 4, 2015
Exit Meeting Date:	June 4, 2015
Inspectors:	Deborah A. Piskura, Senior Health Physicist Edward F. Harvey, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

McLaren Medical Center Bay Region
NRC Inspection Report 03013900/2015001(DNMS)

The U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection on February 11 through 13, 2015, to review the events and circumstances associated with a medical event that McLaren Medical Center Bay Region (the licensee) reported to the NRC on February 6, 2015. The inspection also included a review of other routine aspects of the licensee's radiation safety program.

On February 6, 2015, the licensee administered a patient treatment for endometrial cancer using its high dose-rate remote afterloader (HDR) unit with a vaginal cylinder. The physician authorized user prescribed a dose of 22 Gray (2,200 rad) in four fractions at 5.5 Gray (550 rad) per fraction. After completion of the second fraction, the oncology staff disconnected the HDR treatment catheter from the vaginal cylinder and immediately recognized that the treatment catheter was not fully inserted within the applicator to the prescribed treatment position. The inserted length of the treatment catheter within the vaginal cylinder was placed 15 centimeters from the prescribed treatment position, resulting in no dose delivered to the treatment site and an unintended dose to the patient's right thigh. The licensee estimated that the HDR source irradiated the medial aspect of the patient's right thigh (approximately 1 cm area of tissue) and assigned a dose of 2.6 Gray (260 rad) to the skin.

The root cause of the medical event was human error by the medical physicist who mispositioned the treatment catheter within the vaginal cylinder. This resulted in the HDR source traveling outside of the cylinder. The mispositioning of the iridium source during the treatment resulted in no dose delivered to the treatment site and differed from the prescribed dose by more than 50 rem. The total dose delivered to the treatment site during the second fraction differed from the prescribed fractionated dose by more than 50 percent. In addition, the medical event resulted in a dose to localized area of the skin of the patient's inner right thigh that exceeded 50 rem and was greater than 50 percent of the dose expected from the administration defined in the written directive. The licensee concluded that the medical event would not result in adverse health consequences for the patient. The NRC's medical consultant determined that no significant adverse effect had occurred or was expected to occur as a result of the unintended dose to the patient's thigh.

The inspectors identified an apparent violation of 10 CFR 35.41(a)(2) involving the licensee's failure to develop, implement and maintain written procedures to provide high confidence that administrations requiring a written directive, were performed in accordance with the written directive. Specifically, the licensee's written procedures for iridium-192 HDR treatments did not specify how the licensee verified the positioning of the treatment catheter within the applicator at the treatment point identified in the treatment plan implementing the written directive.

As a corrective action to prevent recurrence of a medical event and to address the apparent violation, the licensee revised its policies for administering HDR vaginal cylinder treatments by directing the licensee staff to verify the catheter positioning by using radio-opaque markers. The licensee committed to incorporate a "time out" process in their procedures to verify all dose administration parameters during HDR administrations.

REPORT DETAILS

1 Program Overview

The NRC License Number 21-18585-01 authorizes McLaren Medical Center Bay Region to use byproduct material for diagnostic and therapeutic nuclear medicine, prostate seed implants, microspheres administrations, and iridium-192 high dose rate (HDR) remote afterloading brachytherapy treatments for gynecological cancers.

A routine safety inspection was initiated on October 27-28, 2011, with continued in-office review through February 21, 2012. One Severity Level IV violation of NRC requirements was identified involving the failure to revise its procedures to provide high confidence that each manual brachytherapy administration was performed in accordance with the written directive, as required by Title 10 of the *Code of Federal Regulations* (CFR) Part 35.41(a). No violations were identified during the previous routine inspection conducted on April 29, 2008.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspectors reviewed the licensee's investigation of the medical event. The inspectors also interviewed selected licensee personnel, and observed related equipment and facilities.

2.2 Observations and Findings

On the morning of February 3, 2015, the physician authorized user prepared a written directive for an iridium-192 high dose rate (HDR) brachytherapy treatment of endometrial cancer for a 50 year old female. The physician authorized user prescribed a dose of 22 Gray (2,200 rad) in four fractions, 5.5 Gray (550 rad) per fraction, using a single channel vaginal cylinder. The vaginal cylinder was connected to the HDR unit using a closed-end treatment catheter; the coupler connected to the tandem of the cylinder and allowed the treatment catheter position to be adjusted to the treatment position within the applicator. According to the licensee staff, the first fraction was administered in accordance with the written directive.

On February 6, 2015, the licensee prepared the patient for the second treatment fraction. The licensee imaged the patient using computerized tomography (CT) with radio-opaque markers to verify the positioning of the vaginal cylinder within the patient. The licensee also collected CT images with the treatment catheter inserted within the vaginal cylinder; the staff did not use radio-opaque markers or other indicators to verify the catheter position within the vaginal cylinder. The staff proceeded to administer the second treatment fraction. After completion of the treatment, the oncology staff disconnected the HDR treatment catheter from the vaginal cylinder and immediately recognized that the treatment catheter was not fully inserted within the applicator to the prescribed treatment position. The inserted length of the treatment catheter within the vaginal cylinder was placed 15 centimeters from the prescribed treatment position, resulting in no dose delivered to the treatment site and an unintended dose to the patient’s right thigh. Based on the patient’s position during the treatment, the licensee

estimated that the HDR source irradiated the medial aspect of the patient's right thigh (approximately one centimeter area of tissue) and assigned a dose of 2.6 Gray (260 rad) to the skin.

The medical physicist immediately informed the physician authorized user of the error. The physician authorized user notified the patient and added a fraction to the patient's treatment course to compensate for the treatment error. The licensee determined that the error met the criteria for a reportable medical event and then notified the NRC Headquarters Operations Center of the medical event. On February 11 through 13, 2015, two inspectors from the NRC conducted a reactive inspection. During the inspection, the inspectors identified one apparent violation of NRC regulations.

Title 10 CFR Section 35.41(a)(2) requires, for any administration requiring a written directive that the licensee develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Title 10 CFR 35.41(b)(2) requires, in part, that, as a minimum, the procedures required by 10 CFR 35.41(a) address verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive. As of February 6, 2015, the licensee failed to have written procedures that provided high confidence that each administration was in accordance with the written directive. Specifically, on February 6, 2015, the licensee administered an HDR treatment to a patient, and the licensee's procedures did not require verifying that the administration was in accordance with the applicable treatment plan and written directive. The licensee's procedures did not meet the requirements described in 10 CFR 35.41(b), in that, the procedures did not require explicit verification of the positioning of the treatment catheter within a vaginal cylinder applicator were in accordance with the respective treatment plan and the written directive. Accordingly, the treatment plan and written directive were not followed to ensure that the proper dose was delivered to the treatment site. The licensee's failure to have written procedures that provided high confidence that each administration was in accordance with the written directive is an apparent violation of 10 CFR 35.41(a)(2).

The licensee attributed the root cause of the medical event to human error in mispositioning of the treatment catheter within the vaginal cylinder prior the patient treatment; the inspectors agreed with the licensee's determination of the root cause. The inspectors also noted that the licensee's policies and procedures instructed the staff to verify the positioning of the applicator and treatment catheter, however, the procedure lacked specific steps on how to verify positioning of treatment catheter within the vaginal cylinder. The inspectors identified the procedures as a contributing cause of the medical event because the pre-treatment imaging process failed to include a means to verify the positioning of the treatment catheter within the vaginal cylinder.

Based on the licensee's calculations, the patient received an unintended dose to the skin of the right thigh of approximately 2.6 Gy, equivalent to 260 rad. None of the prescribed dose was delivered to the treatment site for the second fraction. The unintended dose to the skin of the patient's thigh exceeded 0.5 Sv, equivalent to 50 rem and 50 percent or more of the dose expected from the administration defined in the written directive. The licensee continues to examine this patient periodically; no adverse skin reactions had been observed to date. To evaluate the extent of condition of the error, the licensee reviewed all other patient medical records involving vaginal cylinder treatments; the review was completed on February 8, 2015. No additional instances of the error were identified.

2.3 Conclusions

A medical event occurred as a result of human error by a member of the licensee staff. The medical physicist mispositioned the treatment catheter within the vaginal cylinder applicator. No other members of the team verified the treatment catheter positioning. The inspectors identified an apparent violation of 10 CFR 35.41(a) involving the licensee's failure to develop, implement and maintain written procedures to provide high confidence that administrations requiring a written directive, were performed in accordance with the written directive.

3 Licensee Corrective Actions

3.1 Inspection Scope

The inspectors reviewed the licensee's proposed corrective actions to prevent similar events. The review included the licensee's written report dated February 19, 2015, regarding the medical event, and the licensee's revised policies and procedures. The inspectors also interviewed selected licensee personnel.

3.2 Observations and Findings

The licensee took immediate remedial actions which included administering an additional HDR treatment fraction to the patient. The licensee investigated the root cause of the medical event and its procedures for administering HDR brachytherapy treatments. The licensee reviewed all of its HDR brachytherapy administrations since 2010 and identified no additional medical events. The licensee developed the following corrective actions in response to the medical event:

- revising its policies and procedures to require the use of radio-opaque markers to visualize and verify the treatment catheter position during CT imaging;
- saving the CT image showing the radio-opaque markers verifying the catheter position within the applicator in the patient's chart; and
- instituting a "time out" prior to the treatment to confirm the treatment parameters, including the catheter position within the applicator.

The licensee committed to provide training to all staff directly involved in HDR administrations on its corrective actions and revisions to its policies and procedures.

3.3 Conclusions

The inspectors determined that the licensee implemented adequate corrective actions to address the root cause of the medical event.

4 Notifications and Reports

4.1 Inspection Scope

The inspectors reviewed the licensee's notifications to the NRC Headquarters Operations Center, the referring physician, and the patient. In addition, the inspectors reviewed the licensee's written report describing the medical event.

4.2 Observations and Findings

On February 6, 2015, the day of the administration, the licensee notified the NRC Operations Center of the medical event (Event Number 50793). The licensee notified the patient and the patient's referring physician. In addition, the licensee provided the referring physician and the patient a copy of its written report on the medical event. The licensee provided its written report of the medical event to the NRC in a report dated February 19, 2015, detailing its corrective actions. The report included the information required by 10 CFR 35.3045(d)(1).

4.3 Conclusions

The licensee made all of the notifications and reports as required by 10 CFR 35.3045 within the specified time period. The inspectors determined that the licensee's written report included all of the required information.

5 Independent Patient Dose Assessment

5.1 Inspection Scope

The NRC contracted a medical expert consultant to assess probable deterministic effects of the radiation exposure to the patient as of result of the medical event. The inspectors reviewed the medical consultant's report dated May 25, 2015.

5.2 Observations and Findings

The physician consultant noted that the no significant adverse effects have occurred (nor should be expected to occur) on the thigh. An additional treatment fraction was given subsequently so that the total dose and the patient treatment were not compromised.

5.3 Conclusions

The medical consultant agreed with the licensee's assessment. The medical consultant determined that the overall impact on the patient from the unintended dose to the skin was minimal.

6 Other Areas Inspected

6.1 Inspection Scope

The inspectors reviewed other aspects of the licensee's radiation protection program, which included, security of licensed material, personnel monitoring, training, labeling of containers, and postings. The inspectors interviewed selected individuals, toured the icensee's facilities, examined the licensee's containers and reviewed selected records.

6.2 Observations and Findings

The inspectors observed the administration of several diagnostic nuclear medicine procedures. The inspection included observations of dose calibrator checks, security of

byproduct material, use of personnel monitoring, package receipts, and patient surveys. The inspectors reviewed a sampling of written directives for radiopharmaceutical therapies, manual low dose brachytherapy implants and HDR treatments.

The inspectors observed the administration of an HDR brachytherapy treatment. The inspectors reviewed the written directive and the treatment plan, and interviewed the authorized user and the medical physicist. The inspection included observations of operability of treatment room safety equipment, security of byproduct material, use of personnel monitoring, and patient surveys.

The inspectors examined a sampling of sealed sources, including the iridium-192 HDR, in the licensee's possession. Each source container was noted to bear a clearly visible label identifying the radionuclides and source activities. The inspectors observed that the licensee posted copies of NRC Form 3. The inspectors also observed that the areas where licensed material was used and stored were appropriately posted with "CAUTION-RADIOACTIVE MATERIALS" and "CAUTION-RADIATION AREA" signs. The nuclear medicine hot lab was also posted with emergency/decontamination procedures and an approved dosage chart. The HDR console was posted with emergency procedures and contacts.

6.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspectors determined that no violations of NRC requirements were identified.

7 Exit Meeting Summary

The NRC inspectors presented preliminary inspection findings following the onsite inspection on February 13, 2015. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary. The licensee acknowledged the findings presented. The final exit meeting was subsequently conducted via telephone on June 4, 2015, and included a discussion of the apparent violation and the licensee's corrective actions.

LIST OF PERSONNEL CONTACTED

*#+Matthew Buczek, M.S., Authorized Medical Physicist
+Chris Cossin, Director of Imaging Services
*#Steven M. Gerhardt, CNMT, Lead Technologist
Victor Hosfeld, M.S., Authorized Medical Physicist
*#+Tyre K, Jones, M.D., Radiation Safety Officer
+Sue Lang, Supervisor, Jeppesen Radiation Oncology
Paul G. Kocheril, M.D., Radiation Oncologist
#Julie R. Laskowski, Manager, Diagnostic Imaging
Ian Reineck, M.S., Authorized Medical Physicist
*#Willa Roussea, Interim Director, Diagnostic Imaging
*Courtney Szeleski, RT(R)(T), Radiation Oncology Manager
#+Ellen Talbott, RN, MSN, Vice President, Patient Care Services

Several nuclear medicine technologists were also contacted during this inspection

*Individuals present for entrance meeting
#Individuals present for exit meeting
+Individuals contacted by phone on June 4, 2015, for telephonic exit meeting

INSPECTION PROCEDURES (IP) USED

IP 87103, “Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing”
IP 87130, “Nuclear Medicine Programs, Written Directive Not Required”
IP 87131, “Nuclear Medicine Programs, Written Directive Required”
IP 87132, “Brachytherapy Programs”