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

August 27, 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: NOTICE OF VIOLATION – MCLAREN MEDICAL CENTER BAY REGION
NRC REACTIVE INSPECTION REPORT NO. 03013900/2015001(DNMS)

Dear Ms. Talbott:

This letter refers to the reactive inspection conducted February 11–13, 2015, at your facility in 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 medical event as well as a review of the U.S. Nuclear Regulatory Commission (NRC) Medical Consultant's report. During the inspection, an apparent violation of NRC requirements was identified. The significance of the issue and the need for lasting and effective corrective actions were discussed with you and members of your staff during the telephonic exit meeting that was held on June 4, 2015. Details regarding the apparent violation were provided in NRC Inspection Report No. 03013900/2015001(DNMS) dated June 23, 2015.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report by either providing a written response or requesting a predecisional enforcement conference. In a letter dated August 4, 2015, you provided a response to the apparent violation.

Based on the information developed during the inspection, the information you provided in your written report dated February 19, 2015, and in your response dated August 4, 2015, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. Specifically, the NRC identified that your staff failed to develop written procedures to provide high confidence that each iridium-192 high-dose rate (HDR) remote afterloader brachytherapy treatment was performed in accordance with the physician authorized user's written directive, as required by Title 10 of the *Code of Federal Regulations* (CFR) 35.41(a)(2). As a result, a medical event occurred where the patient received an unintended dose of approximately 2.6 Gray (260 rad) to the skin of the right thigh.

The root cause of the violation included human error in the positioning of a close-ended catheter. A contributing cause was the lack of specific steps in the procedure to verify the

positioning of the catheter within the applicator. This violation is of concern to the NRC because of the actual and potential consequences to patients. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $3,500 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last 2 years or two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC considered the information that you provided to the inspector at the time of the inspection, the information you provided in your written report, and your response dated August 4, 2015. The corrective actions for your HDR program included: (1) a review of all past treatments involving close-ended transfer tube catheters since inception of the program; (2) utilization and documentation of computed tomography (CT) radiographs with radio-opaque markers verifying the catheter position within the applicator; (3) verification of the catheter position by an authorized user; (4) and instituting a secondary time-out check prior to commencing treatment to verify treatment parameters. As a long-term corrective action, you revised your policy and the procedure to reflect the above and provided training to staff. On the basis of these corrective actions, the NRC determined that *Corrective Action credit* is warranted.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in the inspection report, in your written report dated February 19, 2015, and in your response dated August 4, 2015. Therefore, you are not required to respond to this letter unless the description therein 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 enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and in the NRC’s Agencywide

Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. The NRC also includes significant enforcement actions on its Web site at http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions.

Sincerely,

/RA/

Cynthia D. Pederson
Regional Administrator

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

Enclosure:
Notice of Violation

cc: State of Michigan
Tyre K. Jones, M.D.
Radiation Safety Officer

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Sincerely,

/RA/

Cynthia D. Pederson
Regional Administrator

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

Enclosure:
Notice of Violation

cc: State of Michigan
Tyre K. Jones, M.D.
Radiation Safety Officer

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DATE	08/13/15	08/14/15	08/14/15	08/25/15	08/26/15	08/27/15

OFFICIAL RECORD COPY

1 OE concurrence provided via e-mail from Kerstun Norman on August 25, 2015.

NOTICE OF VIOLATION

McLaren Medical Center Bay Region
Bay City, MI

Docket No. 030-13900
License No. 21-18585-01
EA-15-111

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted February 11–13, 2015, with continued in-office review through June 4, 2015, a 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* (10 CFR) 35.41(a)(2) states, in part, that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.
>
> Contrary to the above, as of February 6, 2015, the licensee failed to develop, implement, and maintain a written procedure to provide high confidence that each iridium-192 high dose-rate (HDR) brachytherapy administration was in accordance with the written directive. Specifically, the licensee failed to include specific steps in its procedure to verify the positioning of a close-ended catheter within the applicator in order to ensure that the administration was in accordance with the written directive.

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

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03013900/2015001(DNMS) dated June 23, 2015, in your written report dated February 19, 2015, and in your response dated August 4, 2015. 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, EA-15-111" 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 of Violation (Notice).

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, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site 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.

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 August, 2015.