



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

March 1, 2017

EA-16-066
NMED No. 140443 (closed)

Mr. David Gaffney
Vice President, Imaging Services
Botsford General Hospital
28050 Grand River Avenue
Farmington Hills, MI 48336-5933

SUBJECT: NOTICE OF VIOLATION - NRC REACTIVE INSPECTION REPORT NO.
03002077/2014001(DNMS) AND INVESTIGATION REPORT 3-2015-011
BOTSFORD GENERAL HOSPITAL

Dear Mr. Gaffney:

The U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at your facility in Farmington Hills, Michigan, on August 28 and 29, 2014, with continued in-office review through May 12, 2016. The inspection was conducted to review the circumstances surrounding a medical event, and the details of the inspection were documented in NRC Inspection Report No. 03002077/2014001(DNMS). The inspection report is available electronically in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML16288A190. The NRC Office of Investigations began an investigation on April 30, 2015, and the investigation report was issued on March 18, 2016. The purpose of the investigation was to determine whether a medical physicist falsified a medical treatment report. Based on the results of the inspection and investigation, the NRC identified an apparent violation involving the failure to develop a written procedure for high dose rate remote afterloader administrations that provide high confidence that each administration is in accordance with the written directive, as required by Title 10 of the *Code of Federal Regulations* (CFR) 35.41(a)(2).

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report by: (1) attending a predecisional enforcement conference, (2) providing a written response, or (3) attending an alternative dispute resolution session before we made our final enforcement decision. In a letter, dated November 10, 2016, you provided a response to the apparent violation. In your response, you disputed the NRC's characterization of the violation. You believed the violation was more appropriately characterized as a failure to follow the procedure rather than a failure to have an adequate procedure as characterized by the NRC. You believed that the requirement to carefully check the High Dose Rate Afterloader (HDR) pre-treatment report against the printed HDR plan report is sufficient to ensure that the proper plans have been loaded for execution. You stated in your response that in this case you believed the physicist failed to follow the policy.

We considered the information provided in your response dated November 10, 2016. Based on the information gathered during the inspection and investigation, the NRC determined that even if the plan had been checked by the physicist, the written procedure was not detailed enough to provide sufficient guidance to ensure that the proper treatment plan was loaded into the treatment system prior to administration. Contributing factors included a lack of a standard naming convention for treatment plans and not removing previous plans from the folder on a network drive where they were available for import to the treatment console.

Based on the information developed during the inspection and investigation and the information that you provided in your response, dated November 10, 2016, the NRC continues to find that a violation of 10 CFR 35.41(a)(2) 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. The failure to develop a written procedure with sufficient guidance to ensure, with high confidence, that the correct treatment plan is loaded into the treatment system is a significant safety concern because using the incorrect treatment plan could provide a dose that is significantly greater, less, or to an area other than the treatment site. 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 \$7,000 is considered for a Severity Level III violation.

Because your facility has not been the subject of escalated enforcement actions within the last 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 determined that *Corrective Action* credit was warranted due to implementing the following corrective actions: (1) modifying the HDR procedure to have a second individual verify that the correct plan is loaded into the treatment system; (2) moving treatment plan files to a backup directory rather than leaving them in the main directory to reduce the likelihood of re-importing a previous plan; and (3) establishing a standard naming convention for treatment to clearly identify plans.

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 also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

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 Inspection Report No. 03002077/2014001(DNMS) and your November 10, 2016, letter. 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 enclosure, and your response, if any, will be made available electronically for public inspection

D. Gaffney

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in the NRC Public Document Room and in the NRC's ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response, if you choose to provide one, should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Sincerely,

/RA by Darrell J. Roberts acting for/

Cynthia D. Pederson
Regional Administrator

Docket No. 030-02077
License No. 21-08892-01

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

Letter to David Gaffney from Cynthia D. Pederson dated March 1, 2017

SUBJECT: NOTICE OF VIOLATION - NRC REACTIVE INSPECTION REPORT NO. 03002077/2014001(DNMS) AND INVESTIGATION REPORT 3-2015-011 - BOTSFORD GENERAL HOSPITAL

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DATE	1/3/17	1/5/17	1/9/17	02/15/17	02/15/17	03/01/17

OFFICIAL RECORD COPY

¹ OE/OGC/NMSS Concurrence received by Kerstun Norman email dated February 15, 2017.

NOTICE OF VIOLATION

Botsford General Hospital
Farmington Hills, Michigan

Docket No. 030-02077
License No. 21-08892-01
EA-16-066

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on August 28 and 29, 2014, with continued in-office review through May 12, 2016, and an NRC investigation completed on March 18, 2016, 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) requires, in part, that for any administration requiring a written directive, the licensee 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 July 10, 2014, the licensee failed to develop a written procedure for high dose rate remote afterloader administrations that provided high confidence that each administration is in accordance with the written directive. Specifically, the licensee's written procedure for such administrations did not contain sufficient guidance to ensure that the proper treatment plan is loaded into the treatment system prior to administration.

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. 03002077/2014001(DNMS) and the licensee's letter, dated November 10, 2016. 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-16-066)," 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, 2443 Warrenville Road, Lisle, IL 60532 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 1st day of March 2017

Enclosure