

June 24, 2011

EA-11-088

Gary M. Beaulac, Executive Vice President
and Chief Operating Officer
Henry Ford Macomb Hospital
15855 Nineteen Mile Road
Clinton Township, MI 48038

SUBJECT: NOTICE OF VIOLATION – HENRY FORD MACOMB HOSPITAL
NRC REACTIVE INSPECTION REPORT NO. 030-02106/2010-001(DNMS)

Dear Mr. Beaulac:

This refers to a U.S. Nuclear Regulatory Commission (NRC) reactive inspection conducted on December 14 and 15, 2010, at your Clinton Township, Michigan, facility, with continued in-office review through April 14, 2011. The purpose of this inspection was to examine activities conducted under your license as they relate to safety and compliance with the NRC's rules and regulations and with the conditions in your license. During the inspection, an apparent violation was identified. The significance of the issue, and the need for lasting and effective corrective action were discussed with you at the December 15, 2010, site exit meeting and during the April 21, 2011, telephonic exit meeting. Details regarding the apparent violation were provided in NRC Inspection Report No. 030-02106/2010-001(DNMS) dated May 13, 2011.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report by either attending a Predecisional Enforcement Conference or by providing a written response before we made an enforcement decision. In a letter dated June 7, 2011, you provided a response to the apparent violation.

Based on the information developed during the inspection, and the information provided in your June 7, 2011, response, 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. The violation involved the failure to develop written procedures to provide high confidence that each brachytherapy treatment was in accordance with the written directive. The failure to develop written procedures to provide high confidence that the treatment was in accordance with the written directive is contrary to the requirements of Title 10 of the Code of Federal Regulations (10 CFR) 35.41(a).

The root cause of the violation was that, when preparing the procedures, your staff did not consider that there were two lengths of transfer tubes available. Therefore, the procedures did not contain sufficient steps to verify that the treatment plan length was the same as the Computed Tomography (CT) simulation setup sheet. The violation was of concern to the NRC because it resulted in patients receiving larger than intended radiation doses to areas not being treated which resulted in several patients having erythema.

Therefore, the violation has been categorized in accordance with the NRC Enforcement Policy as a Severity Level III violation.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3500 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement action 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. Credit was warranted for your comprehensive corrective actions which included, but were not limited to: (1) adding steps to measure and verify the catheter length at the time of CT simulation, at the time of treatment planning, as part of the physics check and finally in the treatment room; (2) storing the transfer guide tubes in clearly labeled cases that are separated by length; (3) training the radiation oncology staff on the changes made to the high dose-rate remote (HDR) program and performing quarterly "just-in-time" training; (4) performing a detailed review of all HDR procedures to ensure consistency across the Henry Ford Health System and quarterly review of the Quality Assurance policies and procedures associated with the HDR program; and (5) performing an external review of all HDR procedures by an independent, authorized medical physicist.

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, which may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to be taken 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. 030-02106/2010-001(DNMS) and in your response submitted on June 7, 2011. 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 any, will be made 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 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/

Mark A. Satorius
Regional Administrator

Docket No. 030-02106
License No. 21-11850-01

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

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 in the NRC Public Document Room or from 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/

Mark A. Satorius
Regional Administrator

Docket No. 030-02106
License No. 21-11850-01

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

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OFFICE	RIII	RIII	RIII	OE	RIII	RIII
NAME	Lougheed	Bloomer	Louden for Boland	Day for Zimmerman ¹	Orth	Satorius
DATE	06/17/11	06/21/11	06/21/11	06/22/11	06/22/11	06/24/11

OFFICIAL RECORD COPY

¹ OE concurrence received via e-mail from K. Day on June 22, 2011.

Letter to Gary M. Beaulac from Mark A. Satorius, dated June 24, 2011

SUBJECT: NOTICE OF VIOLATION – HENRY FORD MACOMB HOSPITAL
NRC REACTIVE INSPECTION REPORT NO. 030-02106/2010-001(DNMS)

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NOTICE OF VIOLATION

Henry Ford Macomb Hospital
Clinton Township, Michigan

Docket No. 030-02106
License No. 21-11850-01
EA-11-088

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on December 14 and 15, 2010, with continued in-office review through April 14, 2011, 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 (CFR) 35.41(a) requires, 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 December 9, 2010, the licensee did not develop written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee's procedure did not include steps to verify the transfer tube assembly length used at the time of the administration was in accordance with the transfer tube assembly length identified in the treatment plan implementing the written directive. This resulted in four patients receiving radiation doses to areas which were not included within the planned treatment area.

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 be taken 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. 030-02106/2010-001(DNMS) and in your response dated June 7, 2011. 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-11-088," 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 and the Enforcement Officer, Region III, 2443 Warrenville Road, Suite 210, 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, U.S. 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 from 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 24th day of June 2011

ENCLOSURE