

September 2, 2011

EA-11-165
NMED NO. 110087 (Closed)

Frank Sottile, M.D.
Chief Medical Officer
Crittenton Hospital
1101 West University
Rochester, MI 48307

SUBJECT: NOTICE OF VIOLATION – CRITTENTON HOSPITAL
NRC REACTIVE INSPECTION REPORT NO. 03002157/2011-001(DNMS)

Dear Dr. Sottile:

This refers to a U.S. Nuclear Regulatory Commission (NRC) reactive inspection conducted on February 22 and 23, 2011, at your Rochester Hills, Michigan, facility with continued NRC in-office review through June 28, 2011. The purpose of this inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for 11 reported medical events that occurred from September 2009 through January 2011. During the inspection, an apparent violation was identified. The significance of the issue, and the need for lasting and effective corrective actions were discussed with you at the February 23, 2011, preliminary exit meeting and during the July 18, 2011, telephonic exit meeting. Details regarding the apparent violation were provided in NRC Inspection Report No. 03002157/2011-001(DNMS) dated July 22, 2011.

In our July 22, 2011, 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 August 8, 2011, you provided a response to the apparent violation.

Based on the information developed during the inspection and the information provided in your August 8, 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 high dose rate (HDR) remote afterloader 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 written procedure, your staff did not consider that it would need to specifically require verification of the step size on the HDR device's control unit. A contributing cause was that the HDR device's control unit used a default step size without requiring the user to enter or verify the value used. The violation is of concern to the NRC because it resulted in patients receiving lower than intended radiation doses to the treatment area as well as larger than intended radiation doses to areas outside of the treatment area.

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 corrective actions which included, but were not limited to, revision of the policy for HDR treatments to address the manual entry of treatment data and the use of a checklist to check step size, dwell positions and all treatment parameters before actual treatment delivery. You stated that a verbal verification of treatment parameters would also occur before each treatment. Additionally, you educated your staff about the revised policy, the need for verbal and visual confirmation of treatment parameters before each treatment, and the need for a "time out" to review the checklist before treatment delivery to ensure that your staff is sensitive to the potential for error with manual entry of data.

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. 03002157/2011-001(DNMS) and in your response submitted on August 8, 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

F. Sottile

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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 by Cynthia D. Pederson Acting for/

Mark A. Satorius
Regional Administrator

Docket No. 030-02157
License No. 21-13562-01

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

F. Sottile

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Enclosure:
Notice of Violation

cc w/encl: State of Michigan

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See next page

*See previous concurrence

FILE NAME: G:\ORAI\IICS\ENFORCEMENT\Enforcement Cases 2011\EA-11-165 Crittenton Hospital HDR Step Size\EA-11-165 Crittenton Hospital draft Final Action.docx

Publicly Available, non-sensitive

OFFICE	RIII	RIII	RIII	OE	RIII	RIII
NAME	Lougheed*	Bloomer*	Louden for Boland*	Day for Zimmerman ¹	Orth	Pederson for Satorius
DATE	08/24/11	08/24/11	08/26/11	09/02/11	09/02/11	09/02/11

OFFICIAL RECORD COPY

¹ OE concurrence received via e-mail from K. Day on September 02, 2011.

Letter to Frank Sottile from Mark A. Satorius, dated September 2, 2011

SUBJECT: NOTICE OF VIOLATION – CRITTENTON HOSPITAL
NRC REACTIVE INSPECTION REPORT NO. 03002157/2011001(DNMS)

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NOTICE OF VIOLATION

Crittenton Hospital
Rochester, Michigan

Docket No. 030-02157
License No. 21-13562-01
EA-11-165

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on February 22 and 23, 2011, with continued in-office review through June 28, 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, from September 2009 until January 2011, the licensee's written procedure for identifying patients and confirming prescriptions before treatment, which includes treatments performed on the high dose rate (HDR) remote afterloader unit, did not provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee failed to address in its written procedure the need to verify that the step size used in the treatment plan was correctly translated into the HDR unit. This resulted in 11 medical events where the HDR device's control unit default step size of 2.5 mm was used vice the 5 mm used in the treatment planning system.

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 NRC Inspection Report No. 03002157/2011-001(DNMS) and in your response dated August 8, 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-11-165," 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

ENCLOSURE

Notice of Violation

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<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 2nd day of September 2011

ENCLOSURE