

June 8, 2011

EA-11-094

F. Remington Sprague, M.D.
Vice President and Chief Medical Officer
Mercy Hospital
1500 East Sherman Blvd.
Muskegon, Michigan 49444

SUBJECT: NOTICE OF VIOLATION – MERCY HOSPITAL
NRC INSPECTION REPORT NO. 030-02016/2011-001(DNMS)

Dear Dr. Sprague:

This refers to a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on February 24 and 25, 2011, at Mercy Hospital facilities in Muskegon, Michigan, with continued in-office review through April 8, 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 actions were discussed with you at the February 25, 2011, site exit meeting and during the April 8, 2011, telephonic exit meeting. Details regarding the apparent violation were provided in NRC Inspection Report No. 030-02016/2011-001(DNMS) dated April 29, 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 May 16, 2011, you provided a response to the apparent violation.

Based on the information developed during the inspection, and the information provided in your May 16, 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 the licensee did not recognize the need to provide written procedures when the ability to perform high dose-rate remote (HDR) treatments was added to the NRC license in 2008. The violation is of concern to the NRC because the lack of a written procedure could have resulted in a patient receiving a radiation dose different from that prescribed by the written directive. 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 \$3,500 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: (1) preparing written procedures that addressed the requirements of 10 CFR 35.41(b); and (2) providing training to authorized users on the new procedures.

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. 030-02016/2011-001(DNMS) and in your response dated May 16, 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. 030-02016
License No. 21-02187-01

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

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Sincerely,

/RA/

Mark A. Satorius
Regional Administrator

Docket No. 030-02016
License No. 21-02187-01

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

DISTRIBUTION:
See next page

*See previous concurrence
FILE NAME: G:\ORAI\IICS\ENFORCEMENT\Enforcement Cases 2011\EA-11-094 Mercy Hospital\EA-11-094 Mercy Hospital Final Action.docx
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OFFICE	RIII	RIII	RIII	OE	RIII	RIII
NAME	Lougheed*	Bloomer*	Boland*	Day for Zimmerman ¹	Heller for Orth	Satorius
DATE	06/01/11	06/01/11	06/03/11	06/07/11	06/07/11	06/08/11

OFFICIAL RECORD COPY

¹ OE concurrence received via e-mail from K. Day on June 7, 2011.

Letter to F. Remington Sprague from Mark A. Satorius, dated June 8, 2011

SUBJECT: NOTICE OF VIOLATION – MERCY HOSPITAL
NRC INSPECTION REPORT NO. 030-02016/2011-001(DNMS)

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NOTICE OF VIOLATION

Mercy Hospital
Muskegon, Michigan

Docket No. 030-02016
License No. 21-02187-01
EA-11-094

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on February 24 and 25, 2011, with continued in-office review through April 8, 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: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive.

Title 10 CFR 35.40(a) requires, in part, that a written directive be dated and signed before the administration of any therapeutic dose of radiation from byproduct material.

Contrary to the above, between June 18, 2008, and February 23, 2011, the licensee performed approximately 200 high dose-rate remote (HDR) afterloader administrations requiring written directives, and failed to develop written procedures to provide high confidence that each HDR afterloader administration was in accordance with the written directive. Specifically, HDR afterloaders provide therapeutic doses of radiation from byproduct material which require completion of a written directive, per 10 CFR 35.40(a). This in turn requires development of written procedures, per 10 CFR 35.41(a). The licensee had not developed any written procedures.

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. 030-02016/2011-001(DNMS) and in your response dated May 16, 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-11-094," 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.

ENCLOSURE

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 8th day of June 2011