September 2, 2011

EA-11-163
NMED No. 110193 (CLOSED)

Ms. Kay Beauregard, R.N., M.S.A.
Vice President
William Beaumont Hospital
3601 West Thirteen Mile Road
Royal Oak, MI 48073-6769

SUBJECT: NOTICE OF VIOLATION – WILLIAM BEAUMONT HOSPITAL
NRC REACTIVE INSPECTION REPORT NO. 03002006/2011-001(DNMS)

Dear Ms. Beauregard:

This refers to a U.S. Nuclear Regulatory Commission (NRC) reactive inspection conducted on May 2 through 5, 2011, at the William Beaumont Hospital with continued NRC in-office review through July 7, 2011. The purpose of this inspection was to review the circumstances, root and contributing causes, and propose corrective actions for a medical event that occurred on April 27, 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 May 5, 2011, preliminary exit meeting and during the July 7, 2011, telephonic exit meeting. Details regarding the apparent violation were provided in NRC Inspection Report No. 03002006/2011-001(DNMS) dated July 21, 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 July 29, 2011, you provided a response to the apparent violation. Your response indicated that our inspection report accurately reflected the root cause of the violation and your corrective actions. In addition, you provided a correction to your submitted event report concerning the size of the microcatheter involved in the treatment.

Based on the information developed during the inspection, and the information provided in your July 29, 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 involving microspheres of yttrium-90 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 recognize the potential for microcatheters to become blocked when the administration involved a high concentration of microspheres. Therefore, the procedure did not contain instructions on how to ensure that the authorized user would be able to add enough water to suspend the microspheres in a concentration dilute enough to permit flow of the mircrospheres through the microcatheters. As a result of not having instructions, the microcatheter became blocked when your staff administered a dose with a high concentration of microspheres. The violation is of concern to the NRC because the patient only received approximately 20 percent of the prescribed dose.

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 revising your policies and procedures for microsphere administrations to: (1) limit the catheter size to be used; (2) direct the authorized user to consider dividing any dose in excess of two gigabecquerels to ensure the suspension is dilute enough to pass through the microcatheter; and (3) incorporate a “time out” process when difficulties are encountered during microsphere administrations.

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. 03002006/2011-001(DNMS) and in your response dated July 29, 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 by Cynthia D. Pederson Acting for/

Mark A. Satorius
Regional Administrator

Docket No. 030-02006
License No. 21-01333-01

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 by Cynthia D. Pederson Acting for/

Mark A. Satorius
Regional Administrator

Docket No. 03002006
License No. 21-01333-01

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	Pederson for Satorius
DATE	08/23/11	08/24/11	08/24/11	09/01/11	09/01/11	09/02/11

OFFICIAL RECORD COPY

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

Letter to Kay Beauregard from Mark A. Satorius, dated September 2, 2011

SUBJECT: NOTICE OF VIOLATION – WILLIAM BEAUMONT HOSPITAL
NRC REACTIVE INSPECTION REPORT NO. 03002006/2011001(DNMS)

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NOTICE OF VIOLATION

William Beaumont Hospital
Royal Oak, Michigan

Docket No. 030-02006
License No. 21-01333-01
EA-11-163

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted from May 2 through May 5, 2011, with continued in-office review through July 7, 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 May 5, 2011, the licensee did not develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee's written procedures for yttrium-90 treatments did not specify how personnel should administer a dose of microspheres using a fine bore catheter and a high concentration of microspheres in order to prevent blockage within the catheter.

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. 03002006/2011-001(DNMS) and in your response dated July 29, 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-11-163," 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 2nd day of September 2011