May 17, 2011

EA-11-037
NMED No. 100448 (CLOSED)

Michael Wiemann, Ph.D.
Chief Executive Officer
Providence Hospital
16001 West Nine Mile Road
Southfield, Michigan 48037

SUBJECT: NOTICE OF VIOLATION – PROVIDENCE HOSPITAL
NRC INSPECTION REPORT NO. 030-02022/2010-001(DNMS)

Dear Dr. Wiemann:

This refers to a U.S. Nuclear Regulatory Commission (NRC) reactive inspection conducted on September 16, 2010, at Providence Hospital facilities in Novi, Michigan, and Southfield, Michigan, with continued in-office review through March 17, 2011. The purpose of this inspection was to review the circumstances, root cause, contributing factors, and proposed corrective actions for a medical event that was discovered on August 30, 2010. The significance of the issues, and the need for lasting and effective corrective action were discussed with you at the inspection exit meeting on March 18, 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 April 8, 2011, you provided a response to the apparent violation.

Based on the information developed during the inspection, and the information provided in your April 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 brachytherapy treatment was in accordance with the written directive. Specifically, on August 30, 2010, an authorized user performed a palliative medical treatment involving implantation of iodine-125 seeds into and around a rectal tumor. The procedure used by the authorized user did not prescribe sufficient verification steps to ensure that the seeds were placed at the correct depth. As described in Inspection Report No. 030-02022/2010-001(DNMS), this resulted in the seeds actually being implanted superior to the treatment site, resulting in an underdose to the treatment site that differed from the prescribed dose by more than 50 rem to an organ or tissue and the total dose delivered differed from the prescribed dose by 20 percent. Additionally, the mispositioning

of the radioactive seeds resulted in doses to tissues other than the treatment site that exceeded 50 rem and 50 percent of the doses expected from the administration defined in 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 for additional procedural requirements to ensure that seeds were properly placed for any interstitial procedure that only used fluoroscopy. The misplacement of the radioactive seeds resulted in a medical event and required additional medical procedures to remove some of the seeds from within and surrounding the bladder. 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) modifying interstitial procedures to require that the use of fluoroscopy alone will be done with the use of markers to confirm source placement; (2) modifying interstitial procedures that use fluoroscopy alone to require a needle depth check, using two different methods for verification during treatments; and (3) providing training to all appropriate authorized users on the new requirements.

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. 030-02022/2010-001(DNMS) and in your response submitted on April 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 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. 030-02022
License No. 21-02802-03

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. 030-02022
License No. 21-02802-03

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

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*See previous concurrence
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OFFICE	RIII	RIII	RIII	OE	RIII	RIII
NAME	Pelke for Lougheed*	Piskura for Bloomer*	Boland	Day for Zimmerman[1]*	Orth	Pederson for Satorius
DATE	04/21/11	04/22/11	04/22/11	05/09/11	05/16/11	05/17/11

OFFICIAL RECORD COPY

[1] OE concurrence received via e-mail from K. Day on May 9, 2011.

Letter to Michael Wiemann from Mark A. Satorius dated May 17, 2011

SUBJECT: NOTICE OF VIOLATION – PROVIDENCE HOSPITAL
NRC INSPECTION REPORT NO. 030-02022/2010-001(DNMS)

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NOTICE OF VIOLATION

Providence Hospital
Southfield, Michigan

Docket No. 030-02022
License No. 21-02802-03
EA-11-037

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on September 16, 2010, with continued in-office review through March 17, 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 (10 CFR) 35.41(a) states 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. Procedures must meet the applicable requirements described in 10 CFR 35.41(b).
>
> Contrary to the above, as of August 30, 2010, the licensee failed to develop written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee's interstitial brachytherapy procedure did not provide high confidence that the needles would be inserted to the right depth, because the licensee did not require the use of available means, such as biological or needle markers, to minimize the occurrence of a medical event. This resulted in a patient receiving a larger than planned radiation dose 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. 030-02022/2010-001(DNMS) and in your response dated April 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-11-037," 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 17th day of May 2011

ENCLOSURE