

April 20, 2011

EA-11-016
NMED No. 100506 (CLOSED)

Mr. Joseph C. Heckman
Vice President
Cancer Care Services
Community Health Network
1500 N. Ritter Avenue
Indianapolis, Indiana 46219

SUBJECT: NOTICE OF VIOLATION – COMMUNITY HOSPITALS OF INDIANA
NRC INSPECTION REPORT NO. 030-01625/2010-003(DNMS)

Dear Mr. Heckman:

This refers to a U.S. Nuclear Regulatory Commission (NRC) reactive inspection conducted on October 18 to 20, 2010, at your Community Hospital East Indianapolis, Indiana facility, with continued in-office review through January 18, 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 October 6, 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 February 3, 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 March 18, 2011, you provided a response to the apparent violation.

Based on the information developed during the inspection, and the information provided in your response dated March 18, 2011, 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 fully implement licensee procedures to provide high confidence that a high dose-rate remote afterloader brachytherapy treatment was in accordance with the written directive. Specifically, on September 30, 2010, an authorized medical physicist missed a step in the procedure that established the starting position for the high dose remote afterloader brachytherapy treatment. The failure to implement this step resulted in the iridium-192 source being positioned incorrectly within the patient's body such that the patient received doses that differed from the prescribed doses by more than 20 percent. The failure to implement the procedure as written is contrary to the requirements of Title 10 of the Code of Federal Regulations (10 CFR) 35.41(a).

The NRC determined that the direct cause of the violation was human error by the authorized medical physicist in failing to select the correct starting position for the treatment. Contributing factors were that: (1) the starting positions for this type of treatment were different from the computer default positions as well as from other type treatments; (2) it was difficult to identify that the correct starting position was selected; and (3) there were no checks in the procedure to verify that the correct starting position was selected. However, the failure to fully implement licensee procedures to provide high confidence that the brachytherapy treatment is in accordance with the written directive is of significant regulatory concern because the patient received a larger than expected radiation dose to areas not being treated. 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) adding a step to the procedure to verify that the applicator is properly oriented in the three-dimensional image; (2) adding a check box to the written directive form to verify that the correct starting position was selected; and (3) reviewing the written directive forms and treatment planning process for other procedures to identify other treatments requiring a change to the default starting position.

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 problem constitutes escalated enforcement action, which may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 030-01625/2010-003(DNMS) and in your response submitted on March 18, 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.

J. Heckman

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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. 030-01625
License No. 13-06009-01

Enclosure:
Notice of Violation

cc w/encl: State of Indiana

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. 030-01625
License No. 13-06009-01

Enclosure:
Notice of Violation

cc w/encl: State of Indiana

DISTRIBUTION:
See next page

*See previous concurrence

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OFFICE	RIII	RIII	RIII	OE	RIII	RIII
NAME	Lougheed*	Bloomer*	Boland*	Day for Zimmerman ¹	Orth	Pederson for Satorius
DATE	04/8/11	04/08/11	04/12/11	04/18/11	04/20/11	04/20/11

OFFICIAL RECORD COPY

¹ OE concurrence received via e-mail from K. Day on April 18, 2011.

Letter to Joseph C. Heckman from Mark A. Satorius, dated April 20, 2011

SUBJECT: NOTICE OF VIOLATION – COMMUNITY HOSPITALS OF INDIANA
NRC INSPECTION REPORT NO. 030-01625/2010-003(DNMS)

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NOTICE OF VIOLATION

Community Hospitals of Indiana
Indianapolis, Indiana

Docket No. 030-01625
License No. 13-06009-01
EA-11-016

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted from October 18 to 20, 2010, with continued in-office review through January 18, 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.

Contrary to the above, on September 30, 2010, the licensee failed to implement its "Accelerated Partial Breast Irradiation Multiple Lumen HDR Procedure" during the development of the treatment plan for a high dose-rate remote afterloader (HDR) brachytherapy treatment such that the administration was not in accordance with the written directive. Specifically, the licensee missed Step 5 of the "Treatment Planning" section of the procedure which required the user to choose the "tip end" when reconstructing catheters for breast HDR treatments. As a result of the missed step, areas which were not included within the planned treatment area received a larger than planned radiation dose.

This is a Severity Level III violation (Section 6.3).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 030-01625/2010-001(DNMS) and in your response dated March 18, 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-11-016," 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 20th day of April 2011

ENCLOSURE