**UNITED STATES**
**NUCLEAR REGULATORY COMMISSION**
Region III
2443 Warrenville Road, Suite 210
Lisle IL 60532-4352

January 31, 2013

EA-12-245

Joann Zeller, Manager
Radiation Oncology
Chancellor Center for Oncology
4055 Gateway Blvd
Newburgh, IN 47630-8947

SUBJECT: NOTICE OF VIOLATION – DEACONESS HOSPITAL;
NRC REACTIVE INSPECTION REPORT NO. 03001580/2012002(DNMS)

Dear Ms. Zeller:

This refers to a U.S. Nuclear Regulatory Commission (NRC) reactive inspection conducted on August 22, 2012, at the Chancellor Center for Oncology facility in Newburgh, Indiana, with continued NRC in-office review through November 28, 2012. During the inspection, an apparent violation of NRC requirements was identified. The significance of the issue and the need for lasting and effective corrective actions were discussed with you at a preliminary exit meeting on August 22, 2012, and at a final telephonic exit meeting on November 28, 2012. Details regarding the apparent violation were provided in NRC Inspection Report No. 03001580/2012002(DNMS) dated December 14, 2012.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report in one of three ways: (1) by providing a written response, (2) by requesting a pre-decisional enforcement conference, or (3) by verbally responding to the NRC that no additional information would be provided. On December 28, 2012, you verbally informed the NRC that you did not plan to provide any further response.

Based on the information developed during the inspection and the information that you provided in your 15-day report dated August 30, 2012, 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 our inspection report dated December 14, 2012. Specifically, the NRC determined that Deaconess Hospital's high dose-rate (HDR) remote afterloader brachytherapy procedures did not provide high confidence that administrations would occur in accordance with the written directives as required by Title 10 of the Code of Federal Regulations (10 CFR) Section 35.41(a)(2) and (b)(2).

The failure to have procedures that provide high confidence that administrations are in accordance with the written directive is of concern to the NRC because of the potential for a patient to receive a dose that is contrary to the prescribed dose. Furthermore, in this particular case, a patient actually received a radiation dose to an unintended location without anyone being aware of the incident until after all portions of the treatment had been completed, resulting in the patient having to undergo corrective surgery due to radiation trauma. In addition, there was the potential for the same error to occur on other patients due to the lack of procedures to

prevent the error from recurring. While the root cause of the medical event was human error, the underlying cause of the violation was that the procedures did not provide sufficient detail to ensure that there was a way to verify that the correct setup was being applied for the treatment being prescribed. Therefore, this violation has been categorized, in accordance with the NRC Enforcement Policy, at Severity Level III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $3500 is normally considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last two years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process described in Section 2.3.4 of the Enforcement Policy. The NRC determined that credit was warranted for the corrective actions taken. Your immediate corrective actions included, temporarily suspending your program until an external investigation could be completed. As long term corrective actions, you informed us that: (1) HDR treatment plans will be independently reviewed prior to delivery by a qualified third party for the first five plans provided by each physician or physicist, and for any physician or physicist with more than one year since the last treatment was performed, the first two plans will be independently reviewed; (2) appropriate training and Continuing Medical Education (CME) programs will be implemented for all staff participating in HDR procedures; (3) an independent check to verify the physical orientation of any channel (catheter) used in an HDR procedure will be required and documented in a customized independent checklist such that the physician will be able to readily verify the treatment plan orientation; and (4) the independent check will be included in the quality control procedures to address the geographic component for radiation therapy planning errors.

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, to not 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 that 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 correct the violation, and the date when full compliance was achieved, was adequately addressed on the docket in NRC Inspection Report No. 03001580/2012002(DNMS) dated December 14, 2012, and in your 15-day report dated August 30, 2012. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective action 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 you choose to provide one, 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, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary

information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). 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 C. Pederson for/***

Charles A. Casto
Regional Administrator

Docket No. 030-01580
License No. 13-00142-02

Enclosure:
Notice of Violation

cc w/encl: John Sutkowski, M.D.
Radiation Safety Officer
State of Indiana

NOTICE OF VIOLATION

Deaconess Hospital
Newburgh, IN

Docket No. 030-01580
License No. 13-00142-02
EA-12-245

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on August 22, 2012, with continuing in-office review through November 28, 2012, 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) Section 35.41(a)(2) requires, for any administration requiring a written directive, that the licensee develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.
>
> 10 CFR 35.41(b)(2) requires, in part, that, as a minimum, the procedures required by 10 CFR 35.41(a) address verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive.
>
> Contrary to the above, as of March 5, 2012, the licensee failed to have written procedures that provided high confidence that each administration was in accordance with the written directive. Specifically, the licensee administered a 34 Gray dose to a patient and the licensee's procedures did not require verifying that the administration was in accordance with the applicable treatment plan and the written directive.

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 the date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03001580/2012002(DNMS) dated December 14, 2012, and in your 15-day report dated August 30, 2012. 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-12-245," 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, 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 http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy, or proprietary, 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 of Violation within two working days of receipt.

Dated this 31st day of January, 2013

must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). 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 C. Pederson for/***

Charles A. Casto
Regional Administrator

Docket No. 030-01580
License No. 21-01190-05

Enclosure:
Notice of Violation

cc w/encl: John Sutkowski, M.D.
Radiation Safety Officer
State of Indiana

DISTRIBUTION:
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FILE NAME: G:\ORAIII\EICS\ENFORCEMENT\Cases\Enforcement Cases 2012\EA-12-245 Deaconess Hospital\EA-12-245 Deaconess Hospital draft final action.docx

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|---|---|---|---|---|---|---|
| NAME | Lougheed | Bloomer | Boland | Zimmerman[1] KDay for | Orth | Casto |
| DATE | 01/04/13 | 01/07/13 | 01/07/13 | 01/29/13 | 01/30/13 | 01/31/13 |

***OFFICIAL RECORD COPY***

1 OE concurrence received via e-mail from K. Day on January 29, 2013.

Letter to Joann Zeller from Charles A. Casto dated January 31, 2013

SUBJECT: NOTICE OF VIOLATION – DEACONESS HOSPITAL
NRC REACTIVE INSPECTION REPORT NO. 03001580/2012002(DNMS)

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