July 22, 2011

EA-11-109

Mr. David Feess
Acting Chief Executive Officer
Liberty Hospital
2525 Glenn W. Hendren Drive
Liberty, MO 64069

SUBJECT: NOTICE OF VIOLATION – LIBERTY HOSPITAL; NRC REACTIVE INSPECTION REPORT NO. 030-10532/2010-001(DNMS)

Dear Mr. Feess:

This refers to a U.S. Nuclear Regulatory Commission (NRC) reactive inspection conducted on October 13 and 14, 2010, at your Liberty, Missouri, facility, with continued in-office review through May 17, 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 during the May 17, 2011, telephonic exit meeting. Details regarding the apparent violation were provided in NRC Inspection Report No. 030-10532/2010-001(DNMS) dated June 8, 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 June 22, 2011, you provided a response to the apparent violation.

Based on the information developed during the inspection, and the information provided in your June 22, 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, implement, and maintain written procedures to provide high confidence that each brachytherapy treatment was in accordance with the written directive. This resulted in a patient receiving approximately 13 percent of the prescribed treatment dose. The failure to develop, implement, and maintain written procedures to provide high confidence that the administration is 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, the licensee did not specify that the position of the prostate be verified before beginning treatment. The medical condition of the patient contributed to the event; however, the procedures lacked steps to ensure the proper placement of the seeds. The violation is of concern to the NRC because it resulted in the patient receiving significantly less radiation dose to the intended treatment site than what was 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 $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, but were not limited to modifying your procedure to: (1) obtain an ultrasound image of the prostate just prior to treatment to verify the dimensions of the prostate and determine if they match the pre-plan image; (2) obtain a side (sagittal) view of the prostate or a fluoroscopic image of the pelvic area after the insertion of each seed strand to verify seed position in the patient; (3) verify and document the depth of insertion of the needles in relationship to the balloon on the Foley catheter in the bladder by both the urologist and radiation oncologist present; (4) document the placement of seeds by ultrasound image of the central seed in each row of needles and verifying the depth of needle placement by noting the distance from the edge of the brachytherapy template to the hub of the needle using the markings on the side of the implant needles; and (5) verify the stability of the source strands when the needle is retracted using the sagittal ultrasound images in real time.

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 NRC Inspection Report No. 030-10532/2010-001(DNMS) and in your response dated June 22, 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. 030-10532
License No. 24-16178-01

Enclosure:
Notice of Violation

cc w/encl: State of Missouri

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. 030-10532
License No. 24-16178-01

Enclosure:
Notice of Violation

cc w/encl: State of Missouri

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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	07/18/11	07/18/11	07/19/11	07/21/11	07/22/11	07/22/11

OFFICIAL RECORD COPY

[1] OE concurrence received via e-mail from K. Day on July 21, 2011.

Letter to David Feess from Mark A. Satorius, dated July 22, 2011

SUBJECT: NOTICE OF VIOLATION – LIBERTY HOSPITAL; NRC REACTIVE INSPECTION REPORT NO. 030-10532/2010-001(DNMS)

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NOTICE OF VIOLATION

Liberty Hospital
Liberty, Missouri

Docket No. 030-10532
License No. 24-16178-01
EA-11-109

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 13 and 14, 2010, with continued in-office review through May 17, 2011, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> Title 10 CFR 35.41(a)(2) requires, in part, that for any administration requiring a written directive, licensees must develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).
>
> Title 10 CFR 35.41(b), requires, in part, that the procedures required by 10 CFR 35.41(a) must address methods for verifying that the administration of byproduct material is in accordance with the treatment plan, if applicable, and the written directive.
>
> Contrary to the above, as of October 6, 2010, the licensee's procedure for prostate seed implants did not provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee's procedure did not require that the licensee verify the position of the patient's prostate before seed placement. This resulted in an underdose to the patient's prostate, with the prostate receiving only 16.9 Gray (Gy), more than 20 percent below the prescribed dose of 125 Gy.

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 NRC Inspection Report No. 030-10532/2010-001(DNMS) and in your response dated June 22, 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-11-109," 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 22nd day of July 2011