



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**  
REGION IV  
1600 E. LAMAR BLVD.  
ARLINGTON, TX 76011-4511

June 17, 2014

Elizabeth Lewis, Chief Operating Officer  
Bozeman Deaconess Hospital  
915 Highland Boulevard  
Bozeman, Montana 59715

SUBJECT: NRC INSPECTION REPORT 030-33305/2013-001 AND NOTICE OF VIOLATION

Dear Ms. Lewis:

This letter refers to the inspection conducted on December 18-19, 2013, at your facility in Bozeman, Montana. This inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of examination of records and selected procedures, observations of licensed activities, and interviews with personnel. Preliminary inspection findings were discussed with you at the conclusion of the onsite inspection on December 19, 2013. Over the next few months, Bozeman Deaconess Hospital submitted additional information to the NRC regarding this inspection, to include information describing the use of written directives for prostate brachytherapy and possible medical events that occurred in 2008. A final exit briefing was conducted telephonically with you and members of your staff on June 4, 2014.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of the NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy included on the NRC's Web site at [www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html](http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html). The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the Notice. The violation is being cited in the Notice because it was identified by the NRC during the inspection. The violation involved the failure to perform a radiation survey of a patient after an HDR treatment.

You are required to respond to this letter and must follow the instructions specified in the enclosed Notice when preparing your response. Information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be (was) achieved should be addressed. The NRC will use your response to determine whether further enforcement action is necessary to ensure your compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and 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's Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not

include any personal privacy, proprietary, or information so that it can be made available to the Public without redaction.

Should you have any questions regarding this letter or the enclosed Notice, please contact James Thompson at 817-200-1538 or myself at 817-200-1130.

Sincerely,

*/RA/*

G. Michael Vasquez, Chief  
Nuclear Material Safety Branch A  
Division of Nuclear Materials Safety

Docket: 030-33305  
License: 25-10994-04

Enclosures:  
Notice of Violation (Notice)

cc w/enclosure:

Roy Kemp  
Deputy Administrator  
Division of Quality Assurance  
Department of Public Health and  
Human Services  
2401 Colonial Drive  
P.O. Box 202953  
Helena, MT 59620-2953

include any personal privacy, proprietary, or information so that it can be made available to the Public without redaction.

Should you have any questions regarding this letter or the enclosed Notice, please contact James Thompson at 817-200-1538 or myself at 817-200-1130.

Sincerely,

***/RA/for/ADGaines***

G. Michael Vasquez, Chief  
Nuclear Material Safety Branch A  
Division of Nuclear Materials Safety

Docket: 030-33305  
License: 25-10994-04  
Enclosure:  
Notice of Violation (Notice)

cc w/encl:

Roy Kemp  
Deputy Administrator Division of Quality Assurance  
Department of Public Health and  
Human Services  
2401 Colonial Drive  
P.O. Box 202953  
Helena, MT 59620-2953

**DISTRIBUTION w/encl:**

L. Howell  
J. Whitten  
M. Herrera  
R4DNMS\_MS-A

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By: <b>JLT</b>							
OFFICE	DNMS/NMSB-A	C:NMSB-A					
NAME	JLThompson	GMVasquez					
SIGNATURE	<b><i>/RA/</i></b>	<b><i>/RA/for ADGaines</i></b>					
DATE	06/17/14	06/17/14					

**OFFICIAL RECORD COPY**

## NOTICE OF VIOLATION

Bozeman Deaconess Hospital  
Bozeman, Montana

Docket: 030-33305  
License: 25-10994-04

During the U.S. Nuclear Regulatory Commission (NRC) inspection conducted on December 18-19, 2013, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.604 requires, in part, that before releasing a patient from licensee control, the licensee shall survey the patient and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source has been removed from the patient and returned to the safe shielded position.

Contrary to the above, on October 1 and 8, 2013, the licensee failed to survey the patient and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source had been removed from the patient and returned to the safe shielded position. Specifically, the licensee failed to perform this required survey on the same patient after two HDR treatments as described above.

This is a Severity Level IV violation. (Section 6.3(d))

Pursuant to the provisions of 10 CFR 2.201, Bozeman Deaconess Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region IV, 1600 E. Lamar Blvd., Arlington, Texas, 76011, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at [www.nrc.gov/reading-rm/pdr.html](http://www.nrc.gov/reading-rm/pdr.html) or [www.nrc.gov/reading-rm/adams.html](http://www.nrc.gov/reading-rm/adams.html), to the extent possible, it 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, then 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 material, 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). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11(a)(4), you may be required to post this Notice to workers within two working days.

Dated this 17 day of June 2014