



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION IV  
611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TEXAS 76011-4005

October 13, 2006

Mr. John Nordwick, President and CEO  
Bozeman Deaconess Hospital  
915 Highland Blvd  
Bozeman, Montana 59715

SUBJECT: NRC INSPECTION REPORT 030-33305/06-001 AND NOTICE OF VIOLATION

Dear Mr. Nordwick:

This refers to the inspection conducted on May 16, 2006, at your facility in Bozeman, Montana. The inspection was conducted in response to a brachytherapy medical event that occurred at your facility on May 9, 2006, and reported to the NRC on May 10, 2006. Preliminary inspection findings were discussed with members of your staff at the conclusion of the onsite portion of the inspection. Additional review, including work by an NRC medical consultant, was conducted. A final exit briefing was conducted telephonically with you on August 31, 2006. The enclosed inspection report documents the NRC's review of this event.

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 selected examination of procedures and representative records, observation of activities and interviews with personnel.

Based on the results of this inspection, the NRC has determined one violation of NRC requirements occurred. This violation was evaluated in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy). The current Enforcement Policy is included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **What We Do, Enforcement**, then **Enforcement Policy**. 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. This violation involved the failure to have procedural requirements to verify that the administration is in accordance with the treatment plan and the written directive. This violation is being cited in the Notice because it was identified by the NRC, rather than being self-identified by the licensee. Additionally, a NRC medical consultant (physician who is experienced in radiation oncology) reviewed documents and conducted interviews related to the medical event. A report of the consultant's findings are attached to the NRC inspection report.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed on the docket in your letter dated May 17, 2006. 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, and its enclosures, and your response, if any, 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 <http://www.nrc.gov/reading-rm/adams.html>. 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.

Should you have any questions concerning this letter, please contact Mr. Larry Donovan at (817) 860-8140 or Ms. Vivian Campbell at (817) 860-8143.

Sincerely,

**/RA/**

Leonard D. Wert, Director  
Division of Nuclear Materials Safety

Docket No.: 030-33305  
License No.: 25-10994-04

Enclosures:

1. Notice of Violation
2. NRC Inspection Report 030-33305/06-001

cc w/enclosure:  
Montana Radiation Control Program Director

bcc w/enclosures (via E-Mail distribution):

- BMallett
- LWert
- VCampbell
- JEWhitten
- CLCain
- LDonovan
- KGardin
- NMIB
- RIV File (5<sup>th</sup> Floor)

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\*Previous Concurrence

**ENCLOSURE**

U.S. NUCLEAR REGULATORY COMMISSION  
REGION IV

Docket No.: 030-33305

License No.: 25-10994-04

Report No.: 030-33305/06-001

Licensee: Bozeman Deaconess Hospital

Location: Bozeman, Montana

Dates: May 16, 2006 - August 31, 2006

Inspector: Lawrence Donovan, M.S. Health Physicist  
Nuclear Materials Inspection Branch

Approved By: Vivian H. Campbell, Chief  
Nuclear Materials Inspection Branch

Attachment: 1. Supplemental Inspection Information  
2. NRC Medical Consultant's Report (Not publically available)

**ENCLOSURE 1**

NOTICE OF VIOLATION

Deaconess Bozeman Hospital  
Bozeman Montana

Docket No. 030-33305  
License No. 25-10994-04

During an NRC reactive inspection conducted on May 16, 2006, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions", the violation is listed below:

10 CFR 35.41(a) states that, in part, for any administration requiring a written directive, licensees are required to 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).

10 CFR 35.41(b) states, in part, that at a minimum, the procedures required by paragraph (a) must address verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive.

Contrary to the above, the licensee did not develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the licensee's procedures did not meet the requirements described in 10 CFR 35.41(b), in that the procedures did not require verification that the administration is in accordance with the treatment plan and the written directive.

This is a Severity Level IV violation (Supplement VI).

The NRC has concluded that 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 was achieved is already adequately addressed on the docket in your letter dated May 17, 2006. 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," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region IV, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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 document 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.

Dated this 13<sup>th</sup> day of October 2006.

## EXECUTIVE SUMMARY

Bozeman Deaconess Hospital, Bozeman, Montana  
NRC Inspection Report 030-33305/06-001

This was a reactive, announced inspection of licensed activities involving the telephonic notification of a medical event that occurred on May 9, 2006. The medical event involved the use of iodine-125 (I-125) brachytherapy sources that resulted in a radiation dose to an unintended site. The treatment plan called for a brachytherapy dose of 145 Gy (14500 rads) utilizing 82 I-125 sealed sources contained in "seeds." Instead of the prescribed dose, only 10 seeds were implanted in the correct location of the prostate. As a result, the patient received 8.6 Gy (860 rads), a dose of only 6 percent of the prescribed dose to the treatment site. The inspection was limited to a review of the medical event with particular focus on the direct, contributing and root cause(s) of the medical event, and the licensee's brachytherapy program.

### Direct Causes

The direct cause of the medical event was attributed to human error. Specifically, the urologist incorrectly positioned 69 I-125 implant seeds at the base of the penile bulb site instead of implanting the seeds in the prostate. Only 10 seeds were implanted in the prostate and there were also 3 loose seeds found (Section 4.2).

### Contributing Causes

The lack of verification that the administration was performed in accordance with the treatment plan and written directive and the inexperience of the brachytherapy team were identified as contributing causes of the medical event (Section 4.2).

### Root Causes

The urologist's lack of experience led to the misidentification between the penile bulb and prostate combined with insufficient didactic training was identified as the root cause of the medical event (Section 4.2).

### Notifications and Reports

The licensee fulfilled the regulatory requirements pertaining to patient, referring physician and NRC notifications (Section 5.2).

### Corrective Actions

The licensee instituted corrective actions that appear adequate to prevent similar types of medical events from recurring (Section 6.2).

### Regulatory Issues

The inspector identified one violation of NRC requirements to have in place and implement procedural controls to verify that the administration was in accordance with the written directive (Section 7.2).

## Report Details

### **1 Program Overview (87132, 87103)**

#### **1.1 Inspection Scope**

The inspectors interviewed licensee personnel, reviewed the license application, supporting documentation, brachytherapy procedures and other records maintained by the licensee.

#### **1.2 Observations and Findings**

Bozeman Deaconess Hospital (BDH) is authorized under NRC License 25-33305-04 to use byproduct material in unsealed and sealed forms for use in medical diagnosis and therapeutic treatments as defined in 10 CFR 35.100-400. The majority of therapeutic treatments performed under the NRC license at BDH utilize iodine-125 (I-125) and palladium-103 (Pd-103) contained in sealed sources. The sealed sources are used for various intercavitary, interstitial, and interluminal treatment modalities. At the time of the inspection, the oncology staff was comprised of a radiation oncologist authorized user (AU), a medical physicist, one dosimetrist and one staff urologist. All brachytherapy procedures performed at BDH were under the supervision and direction of the AU.

#### **1.3 Conclusion**

The licensee is authorized to perform therapeutic medical brachytherapy procedures utilizing sealed sources as specified in 10 CFR 35.400, specifically, I-125 and Pd-103. BDH had performed six interstitial implant brachytherapy treatments under the supervision of the AU.

### **2 Background (87103)**

The patient was first interviewed by the urologist and treated for bladder stones in 2001. A transurethral resection procedure (TURP) was recommended and subsequently performed later that year. During the routine follow up in October 2005, the patient was found to have carcinoma of the prostate. The patient was identified as a good candidate for interstitial brachytherapy treatment. On May 9, 2006 the patient underwent the prescribed brachytherapy treatment using I-125 seed implants in the form of 82 seeds. The brachytherapy team consisted of the urologist, radiation oncologist, medical physicist, dosimetrist, and other ancillary staff. The physician-prescribed brachytherapy treatment required the implanting of 82 I-125 seeds into the prostate of a male patient. The treatment plan called for a brachytherapy dose of 145 Gy (14500 rads). At the completion of the procedure, the urologist noted that three loose seeds were recovered following implant and two rapid strands containing 5 seeds each were protruding out of the perineum. Intraoperative fluoroscopy procedure was performed and revealed that 69 of the implanted seeds were placed inferior to the prostate region. The two protruding strands were removed and re-implanted into the correct position in the prostate. Post implant CT revealed that the two strands containing 10 seeds were

implanted in the prostate but the other 69 seeds were implanted in the soft tissues of the penile bulb and base of the penis. The corresponding dose to the prostate was 8.6 Gy (860 rads) representing a gross under dose while the soft tissue of the penile bulb and base of penis received an estimated 130 Gy (13,000 rads). This error occurred because the urologist misidentified the prostate and implanted the 69 seeds into the area of the penile bulb. Additionally, three seeds were found outside the patient that either fell out of the patient or were dislodged, thus leaving a total of 79 seeds implanted in the patient.

The radiation oncologist, urologist, and medical physicist recognized the error and notified the RSO who, in turn, immediately contacted the NRC Operations Center on May 10, 2006 to report the medical event.

After contacting the NRC Operations Center, the licensee notified the patient. The licensee, based on the dose received, expected that the patient would not incur adverse health effects as a result of the medical event. The only possible complications could be impotence and problems in urination which would possibly manifest in the summer of 2006. However, patient follow up during the summer of 2006 revealed none of these adverse effects.

### **3 Event Chronology (87103)**

#### **3.1 Inspection Scope**

The inspector interviewed licensee personnel, reviewed procedures and corresponding documentation and inspected equipment associated with the medical event to reconstruct the sequence of events.

#### **3.2 Observations and Findings**

The following is a chronological sequence of events that led to the medical event and subsequent licensee identification:

- On February, 2001, the patient met the urologist to discuss treatment for bladder stones.
- The urologist performed a transurethral resection procedure (TURP) in the latter part of 2001.
- Routine followup of patient by urologist in October 2005 showed elevated Prostate Specific Antigen (PSA) levels and diagnosis of prostate carcinoma. Patient desired treatment and was referred to BDH for radiation therapy. A treatment plan was developed which included either external beam fractional radiation therapy or brachytherapy implant therapy. The patient agreed to brachytherapy implant procedure.
- Brachytherapy procedure commenced on May 9, 2006, utilizing the written directive which called for 82 iodine-125 seeds to be implanted in the prostate

under ultrasound guidance with the intention of delivering 145 Gray (14,500 rads).

- Preoperative procedures began at 7:30 A.M. MST. The patient was given anesthesia. Ultrasound was turned on and verification of calibration was performed. Ultrasound was calibrated a week earlier in accordance with the standard protocols so a recalibration was performed in order to obtain a current calibration.
- Urologist commenced the procedure by insertion of ultrasound probe into the rectum. Template was placed in front of the perineum which corresponds to a grid on ultrasound. Dosimetrist called out each grid location. Implanting procedure was done visually in the X/Y plane. Seeds were then moved to the Z axis position (sagittal) before dropping the seeds. The radiation oncologist confirmed the Z axis position before the seeds were implanted.
- Intraoperative fluoroscopy was performed towards the end of the procedure and revealed 69 implanted seeds were placed inferior to the prostate region. Three loose seeds were recovered after the procedure.
- Two protruding strands containing 10 seeds were removed from the perineum and reimplanted into the correct position in the prostate using ultrasound guidance.
- Post implant computed tomography (CT) performed later in the day revealed that the 10 seeds contained in the 2 strands were in the correct position in the prostate and the other 69 seeds that were first implanted were found to be in the soft tissues of the penile bulb and base of the penis.
- Post implant CT dosimetry revealed that the prostate had received 8.6 Gy (860 rads) (6 percent of prescribed dose) representing a gross under dosing; the volume equivalent dose to the penile bulb was estimated at 130 Gy (13,000 rads).
- Urologist, radiation oncologist and medical physicist contacted the Radiation Safety Officer (RSO).
- Licensee contacted two experts from Seattle, Washington, and Scottsdale, Arizona, to seek guidance on subsequent patient follow up.
- Discussions between experts and licensee determined that the best approach was to observe the patient and then consider re-treatment at a later date. Possible complications identified from the 69 improperly implanted seeds were problems in urination and impotence which the licensee determined could manifest in the summer 2006.
- On May 10, 2006, RSO notified HQ NRC Operations Center.
- An NRC inspector was dispatched to licensee's facility on May 16, 2006.

## **4 Causes of the Medical Event (87103)**

### **4.1 Inspection Scope**

The inspector conducted interviews with licensee personnel, evaluated the equipment used for the brachytherapy administration, and reviewed the brachytherapy procedures and records to determine the direct, contributing, and root causes of the medical event.

### **4.2 Direct, Contributing and Root Causes**

#### **4.2.1 Direct Causes**

The inspectors determined that the direct cause was human error by the urologist and radiation oncologist. The urologist, under ultrasound guidance, improperly positioned 69 seeds at the base of the penile bulb instead of implanting the seeds in the prostate. Only 10 seeds were properly implanted in the prostate and the remaining seeds were implanted in the vicinity of the penile bulb. The urologist failed to confirm that the image seen under ultrasound guidance, was indeed the prostate. Instead, he imaged an area that mimicked the prostate-bladder interface.

#### **4.2.2 Contributing Causes**

The licensee received authorization to conduct brachytherapy implantation in December 2005. The urologist had 18 years of urology experience, with graduate didactic studies in seed implantation plus 2 courses in implantation methodology combined with 12 years of work experience at BDH. The radiation oncologist was certified by the American Board of Radiology in Radiation Oncology, had 13 years experience with 3 and half years of working experience at BDH. The licensee had conducted only five such brachytherapy procedures previously and was relatively inexperienced. In the first two brachytherapy procedures performed by the licensee, a renowned radiation oncologist from Seattle Washington who had experience in performing this type of procedure was present to proctor the procedure. The third through fifth procedure were conducted by the brachytherapy team without a proctor. These brachytherapy procedures were conducted in accordance with the written directive and delivered the specified dose. The urologist and radiation oncologist, who performed the previous five procedures as require by the written directive were the same physicians who performed the brachytherapy procedure addressed in this report. These previous five procedures were all uneventful.

The brachytherapy team also failed to resolve a question concerning the appearance of the ultrasound images relative to a pre-procedure ultrasound prostate volume study. No real time in-progress verification using fluoroscopy was performed during the procedure to ensure proper seed placement. The lack of verification that the administration was performed in accordance with the treatment plan and written directive and the inexperience of the brachytherapy team were identified as contributing causes of the medical event.

#### 4.2.3 Root Causes

The urologist failed to properly visualize the correct location of the prostate. Instead, he visualized a location that mimicked the prostate bladder interface which was the soft tissues of the penile bulb and the base of the penis. The urologist's relative inexperience with this type of procedure combined with the failure to properly visualize the prostate was identified as the root cause of the medical event.

#### 4.3 Conclusions

The direct cause of the medical event was human error by the urologist and radiation oncologist. The following were identified as contributing causes: (1) the lack of verification that the administration was performed in accordance with the treatment plan and written directive and (2) the inexperience of the brachytherapy team were identified as contributing causes of the medical event. The urologist's relative inexperience with this type of procedure combined with the failure to properly visualize the prostate was identified as the root cause of the medical event.

### **5 Notifications and Reports (87103)**

#### 5.1 Inspection Scope

The inspector interviewed BDH personnel and reviewed licensee records and documentation relative to the patient, referring physician, and NRC notification requirements.

#### 5.2 Observations and Findings

The inspector determined that the medical event was reported by the authorized user to the patient on May 9, 2006. The medical event was reported to NRC on May 10, 2006. On May 11, 2006 the urologist and radiation oncologist met to discuss the event in more detail. On May 25, 2006, NRC Region IV received the written report of the medical event from the licensee dated May 17, 2006, as required by 10 CFR 35.3045.

#### 5.3 Conclusions

The licensee properly identified and reported the brachytherapy medical event to the patient, referring physician and NRC.

### **6 Licensee Evaluation and Corrective Actions (87103)**

#### 6.1 Inspection Scope

The inspector interviewed licensee personnel, reviewed the licensee's proposed corrective actions, and reviewed the licensee's written report submitted to the NRC in accordance with 10 CFR 35.3045.

## 6.2 Observations and Findings

As discussed during the onsite portion of the inspection on May 16, 2006, and as noted in the licensee's written report, the following corrective actions will be implemented:

- Procedures will be changed to prevent recurrence. A fluoroscopic examination will be done early in the implant procedure to ensure that the seeds are being placed in the prostate.
- Any question concerning differences in appearance of the ultrasound images obtained in the operating room and images obtained during a prior volume study will be resolved prior to commencing with the implant.
- Patients requiring implants since this event, are referred to other local institutions. Additional training, including proctoring on site, will be obtained before performing another implant at BDH.

## 6.3 Conclusions

The licensee has instituted corrective actions that appear adequate to address the causes of the medical event and avoid another incident.

## **7 Regulatory Issues (87103)**

### 7.1 Inspection Scope

The inspector also reviewed the regulatory requirements, the license commitments, the licensee's brachytherapy written directive procedures and the records and reports related to the medical event.

### 7.2 Observations and Findings

Although there were several issues identified that contributed to the medical event, the licensee failed to perform verification of the written directive as required by 10 CFR 35.41. 10 CFR 35.41(a) states, in part, that for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration will be conducted in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b). 10 CFR 35.41(b) states, in part, that at a minimum, the procedures required by paragraph (a) must address verifying that the administration was done in accordance with the treatment plan, if applicable, and the written directive. The licensee had not developed or implemented written procedures to provide a high confidence that each administration would be in accordance with the written directive. Specifically, the licensee's procedures did not meet the requirements described in 10 CFR 35.41(b), in that the procedures did not require verification that the administration was conducted in accordance with the treatment plan and the written directive.

### 7.3 Conclusions

One violation was identified during the inspection. The violation involved the licensee's failure to develop, maintain and implement procedures to require verifications of the prescribed dose as specified in 10 CFR 35.41(b)(2). Specifically, the licensee failed to verify that the administration was conducted in accordance with the treatment plan and the written directive. This failure to conduct verification was identified as a violation of 10 CFR 35.41(b).

**ATTACHMENT 1**

**LIST OF PERSONS CONTACTED**

Licensee

- \*#John Nordwick, President and CEO
- \*#James Brewer, Ph.D., Medical Physicist
- \* Ronald W. Tharp MD, RSO

- # Present at entrance
- \* Present at exit

**INSPECTION PROCEDURES USED**

87103 Inspection of Material Licensees Involved In An Incident or Bankruptcy Filing  
87132 Brachytherapy Programs

**ITEMS OPENED, CLOSED AND DISCUSSED**

Opened

030-33305/2006-001	VIO	The failure to verify the accuracy of the intended treatment site to ensure that the final treatment plan was in accordance with the written directive.
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Closed

None

Discussed

None

**List of Acronyms Used**

ABR	American Board of Radiology
I-125	Iodine-125
NRC	Nuclear Regulatory Commission
Pd-103	Palladium-103
PSA	Prostate Specific Antigen
RSO	Radiation Safety Officer
TURP	Trans Urethral Resection Procedure

**ATTACHMENT 2**

**MEDICAL CONSULTANT'S REPORT**