



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

August 9, 2006

Docket No. 03007565

License No. 07-14850-01

Dennis Klima
President/CEO
Bayhealth Medical Center
640 South State Street
Dover, DE 19901

SUBJECT: INSPECTION 03007565/2006001, BAYHEALTH MEDICAL CENTER, DOVER,
DELAWARE SITE AND NOTICE OF VIOLATION

Dear Mr. Klima:

On June 16, 2006, Sandy Gabriel and Michelle Simmons of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was limited to a review of a medical event reported by your staff to the NRC Operations Center on June 12, 2006. The inspection was continued in the Region I office to review: (1) followup information provided by your staff through July 21, 2006, and (2) a report by a medical consultant retained by the NRC to review this event. Preliminary findings of the inspection were discussed with Ms. Deborah Watson, Vice President, and other members of your staff at the conclusion of the onsite portion of the inspection. A final exit meeting was conducted telephonically with Ms. Donna Stinson, Dr. John Lahaniatis, Dr. Raji Subramanyan, Ms. Cheryl Rogers, and Ms. JoAnn Davis of your staff on July 27, 2006. The enclosed report provides the results of this inspection. Also enclosed is a copy of the medical consultant's report.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes the violation by severity level. 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. 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.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Toolkit Index Page**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **What We Do, Enforcement**, then **Enforcement Policy**. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

D. Klima
Bayhealth Medical Center

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Thank you for your cooperation.

Sincerely,

Original signed by Pamela J. Henderson

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosures:

1. Notice of Violation
2. Inspection Report No. 03007565/2006001
3. Medical Consultant's Report [not released to public]

cc:

John Lahaniatis, M.D., Department of Radiation Oncology
State of Delaware

D. Klima
Bayhealth Medical Center

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NOTICE OF VIOLATION

Bayhealth Medical Center
Dover, DE

Docket No. 03007565
License No. 07-14850-01

During an NRC inspection conducted on June 16, 2006, and following the review of additional information provided through July 21, 2006, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below

10 CFR 35.41 (a)(2) requires, that for any administration requiring a written directive, the license shall develop, implement, and maintain written procedures to provide high confidence that each administration is performed in accordance with the written directive.

Contrary to the above, the license did not consistently implement written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, on June 12, 2006, a prostate implant was performed for which the licensee did not confirm the accuracy of the source activity in comparison with the treatment plan. The implant was performed using 100 iodine-125 sources with activity of 0.34 millicuries per seed, however the treatment plan was calculated using a source activity of 0.268 millicuries per seed.

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 will be achieved is already adequately addressed on the docket. 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, D.C. 20555 with a copy to the Regional Administrator, Region I, 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 to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated This 9th day of August 2006

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No. 03007565/2006001
Docket No. 03007565
License No. 07-14850-01
NMED No. 060382
Licensee: Bayhealth Medical Center, Kent General Hospital
Location: 640 South State Street
Dover, Delaware 19901
Inspection Date: June 16, 2006
Dates Followup
Information Received: June 23, 27, and 30, 2006; July 17 and 21, 2006
Exit Meeting Date: July 27, 2006 (by telephone)

	Original Signed by:	August 9, 2006
Inspectors:	_____	_____
	Sandra Gabriel Senior Health Physicist	date
	Original Signed by:	August 8, 2006
	S. Gabriel for M. Simmons	
	_____	_____
	Michelle R. Simmons Health Physicist	date
	Original signed by	August 9, 2006
	Pamela J. Henderson	
Approved By:	_____	_____
	Pamela J. Henderson, Chief Medical Branch Division of Nuclear Materials Safety	date

EXECUTIVE SUMMARY

Bayhealth Medical Center, Kent General Hospital
NRC Inspection Report No. 03007565/2006001

An announced, special inspection was conducted to review the circumstances surrounding a medical event that occurred on June 12, 2006 and was reported to the NRC on the same day. The medical event involved a permanent prostate implant performed using iodine- 125 brachytherapy sources of activity 0.34 millicuries per seed. The source activity entered into the treatment planning computer system was 0.34 U (0.268 millicuries) per seed, which is 27% lower in activity than the implanted sources. Consequently, the total implanted activity was 27% higher than the intended activity stated in the computerized treatment plan.

Although the implanted source activity was 27% higher than intended, post-implant dosimetry showed a D90 value (minimum dose received by 90% of the prostate volume) of 104% of the prescribed dose.

An NRC medical consultant concluded that “no significant adverse effect is expected.”

Within the scope of this inspection, one violation of NRC regulations was identified. The licensee failed to consistently implement procedures to provide high confidence that each brachytherapy treatment is delivered in accordance with the written directive.

REPORT DETAILS

I. Event Description

a. Inspection Scope

This inspection was limited to a review of the circumstances surrounding the reported prostate implant medical event that occurred on June 12, 2006. The inspection of the event consisted of observations by the inspectors, interviews with the radiation oncologist, physicists, and nurse who were present during the implant operative procedure, and a selected examination of records describing the event and followup actions.

b. Observations and Findings

Prostate Implant Program

The licensee began its manual brachytherapy prostate implant program approximately 6 years ago. Implants are performed using both iodine-125 and State-licensed palladium-103. The same team performs prostate implants at two Bayhealth Medical Center locations: Kent General Hospital (KGH), which operates under NRC license 07-14850-01, and Milford Memorial Hospital (MMH), which operates under NRC license 07-14900-01. In the past year, the licensee performed 16 prostate implants, 15 at KGH and 1 at MMH, using iodine-125 in 14 cases and palladium-103 in 2 cases. The licensee currently does ultrasound-based, real-time intraoperative treatment planning using Variseed software version 7.1. Following treatment planning, a physicist uses the geometric pattern of needles and sources developed in the treatment plan to pre-load the sterilized seeds into sterilized needles. These are then implanted into the patient.

Event Chronology

June 12 Licensee personnel prepared for the implant procedure by bringing to the operating room pre-sterilized seeds, needles, and spacers and setting them up on a table with an L-block shield. The sources ordered for this patient were Best Model 2301, with source activity of 0.34 millicuries per seed, confirmed by the source calibration certificate. The prescribed dose was 145 Gray.

Physicist A set up the laptop computer used to run the Variseed software and entered data including patient identifiers, prescription information, and source descriptors, including manufacturer, model number, source activity, and units of source activity. Source activity was entered as 0.34 U per seed¹. This was the second time that Physicist A entered this information into the Variseed software for real-time, intraoperative

¹ U is the symbol for air-kerma strength, denoting the combination of units $\mu\text{Gy m}^2 \text{h}^{-1}$. A conversion factor for iodine-125 of 1 mCi=1.27 U is recommended by the AAPM Radiation Therapy Subcommittee on Low-Energy Brachytherapy Source Dosimetry.

treatment planning, though she had done this many times for post implant dosimetry.

At approximately 2:00 p.m., the patient was anesthetized and the ultrasound prostate volume study was performed. The authorized user radiation oncologist contoured the prostate volume on the ultrasound images and determined the volume to be approximately 42 cubic centimeters. Physicist B and the authorized user developed a treatment plan using the Variseed software. Physicist B used the printout of the Variseed seed loading information to load the seeds into needles. The nurse doublechecked the loading as each needle was loaded. Trocars were inserted into the implant template according to the needle pattern in the treatment plan. For each needle, the authorized user checked to assure accurate seed loading, then implanted the sources into the patient. Following implantation of all sources and removal of all trocars, x-ray imaging showed good seed placement and cystoscopy showed no sources in the bladder.

The authorized user began to write the post-operative note and asked Physicist A to verify the source information. At this point, licensee personnel identified the discrepancy between the implanted source activity of 0.34 millicuries per seed and the value entered into the treatment planning computer system of 0.34 U, which equals 0.268 millicuries per seed.

The authorized user notified the patient's wife and hospital administration of the error.

At 5:20 p.m., a licensee staff member called the NRC Operations Center to report a medical event, in accordance with 10 CFR 35.3045.

June 14 The patient returned for a post-implant dosimetry CT scan. The resulting calculations showed a D90 (minimum dose received by 90% of the prostate volume) of 150.77 Gray, which is 104% of the prescribed dose of 145 Gray.

June 15 In response to a request from the NRC, the licensee began to perform an audit of recent prostate implant cases to confirm that the source activity used in each Variseed calculation was accurate. The licensee identified that an error also occurred for a palladium-103 implant performed at MMH on May 30, 2006. In that case, Physicist A entered the source descriptors into the Variseed software, using a value of 1.1 U (0.851 millicuries) instead of 1.1 millicuries. This was the first time that Physicist A entered the source descriptors into the Variseed software for real-time, intraoperative treatment planning. This event occurred under MMH's State of Delaware radioactive materials license. Upon identification, the licensee reported this event to the State of Delaware.

Notification of the Event

As noted above, the licensee made a telephone report to the NRC Operations Center on the day of the event. The authorized user notified the patient's wife and urologist (referring physician) immediately upon identification of the event (while the patient was recovering from anesthesia) and later discussed the event with the patient. The authorized user then made a written report to the patient on June 16, 2006. The licensee also submitted a 15-day written report, which was received in Region I on June 27, 2006.

Licensee's Corrective and Preventive Actions

During the inspection conducted on June 16, 2006 and in subsequent correspondence, the licensee indicated that it took the following corrective and preventive actions:

1. Instituted a root cause analysis.
2. Asked the Seattle Prostate Institute to review the records of the patient affected by the medical event.
3. Revised prostate implant procedures to include two "time outs." The first time out will take place after a physicist enters the initial data into the Variseed software. At this point the Radiation Oncology nurse will verify the accuracy of the entered data including source descriptors. The second time out will take place after completion of the Variseed treatment plan and prior to source implantation. At this point the authorized user will verify against the vendor's source calibration certificate the source type, model number, units of activity, and activity per seed entered into the Variseed software.
4. Conducted an audit of all prostate implant cases performed at KGH and MMH since the beginning of 2005 to confirm the accuracy of the source activity used in each pre-implant and post-implant Variseed calculation. This audit identified no inaccurate implants other than those performed on May 30, and June 12, 2006.

c. Conclusions

The inspectors concluded the following:

1. The licensee performed a prostate implant in which the source activity entered into the treatment planning software was 27% lower than the implanted source activity. As a result, the implanted source activity was 27% higher than intended. Despite this error, post-implant dosimetry showed that the minimum dose received by 90% of the prostate volume was only 4% higher than the prescribed dose.
2. The licensee's notification to the NRC, referring physician, and patient, and 15-day report to the NRC were in compliance with the requirements of 10 CFR 35.3045.

3. The root cause of the event was human error involving the licensee's failure to verify that the correct source activity was used in the real-time intraoperative dosimetry calculations. Possible contributing factors were a) the inexperience of Physicist A, and b) the inherent difficulty of performing careful doublechecks in the demanding intraoperative setting.
4. The licensee's corrective actions directly address the cause of the medical event and appear to be adequate to prevent recurrence.

II. Written Directive Procedures

a. Inspection Scope

The inspectors reviewed the licensee's procedures for administrations requiring a written directive to assess compliance with 10 CFR 35.41. The review focused on the implementation and adequacy of the procedures for the prostate implant program. The inspectors interviewed licensee personnel and examined selected records documenting the program and its implementation for the June 12, 2006 implant that resulted in a medical event.

b. Observations and Findings

10 CFR 35.41 requires, in part, that the licensee develop, implement, and maintain written procedures to provide high confidence that licensed material or radiation from licensed material will be administered as directed by the authorized user.

The licensee's procedures to meet the objectives of 10 CFR 35.41 for brachytherapy require:

- (i) written directives
- (ii) verification of patient identity
- (iii) before implanting the radioactive material, verification of the planned brachytherapy loading, including confirmation of the radionuclide, the number of sources, the source strength, and the loading sequence
- (iv) verification of brachytherapy source position
- (v) record of brachytherapy source implantation
- (vi) verification of dose calculations before the total dose has been administered

The inspectors confirmed that the licensee followed these procedures, except that, before implanting the radioactive material, the licensee did not confirm the accuracy of the source strength in comparison with the treatment plan. The medical event might have been averted if, before implanting the radioactive material, the licensee compared the source strength in the treatment plan with the source strength ordered and supplied by the vendor.

c. Conclusions

The inspectors identified a violation of 10 CFR 35.41(a)(2), in that the licensee did not consistently implement written procedures to provide high confidence that each administration is in accordance with the written directive.

III. Medical Consultant's Report

The NRC contracted a medical consultant to review this event, its effect on the patient, and the licensee's corrective actions taken to prevent recurrence of similar events. The medical consultant's report was received on July 3, 2006. The consultant concluded that "no significant adverse effect is expected since the excess dose was minimal and patient treatment was not compromised."

IV. Exit Meeting

A preliminary exit meeting was conducted on June 16, 2006 to discuss the scope of the inspection and the inspectors' initial observations. On July 27, 2006, at the conclusion of the inspection, an exit meeting was held by telephone to discuss the inspectors' observations, the medical consultant's report, and the violation of 10 CFR 35.41(a)(2).

PARTIAL LIST OF PERSONS CONTACTED

Licensee

- *# Raji Subramanyam, Ph.D., Radiation Physicist
- *# Donna Stinson, Administrative Director, Oncology Service Line
- *# John Lahaniatis, M.D., Radiation Oncologist
- Sapna Paramale, Radiation Physicist
- Janet Messina, R.N., Radiation Oncology Nurse
- *# Cheryl Rogers, Director of Accreditation Services
- *# Jo Ann Davis, Director, Risk Management
- * Rachel Taylor, M.D., Radiation Safety Officer
- * Deborah Watson, Vice President

- * Attended preliminary Exit Meeting on June 16, 2006
- # Participated in Exit Meeting by telephone on July 27, 2006

Medical Consultant

Subir Nag, M.D.