UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

September 28, 2015

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

Terry Murphy, FACHE
President and Chief Executive Officer
Bayhealth Medical Center
640 South State Street
Dover, DE 19901

SUBJECT: NRC INSPECTION REPORT NO. 03007565/2015001, BAYHEALTH MEDICAL CENTER, DOVER, DELAWARE

Dear Mr. Murphy:

On February 19, 2015, Janice Nguyen and Farrah Gaskins 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 to the NRC on February 10, 2015. Additional information provided in your correspondence dated February 23, March 3, and September 15, 2015, was also examined as part of the inspection. The findings of the inspection were discussed with your staff at the conclusion of the on-site inspection on February 19, 2015, and with Mr. John D. Shevock, Director of Operations, Oncology Services and several members of your organization on September 10, 2015. The enclosed report presents the results of this inspection.

The NRC in-office review included: (1) an assessment of your 15-day written medical event report; (2) a review of your written procedures in place in 2013; and (3) a review of your proposed corrective and preventative actions described in your letters dated February 23 and September 15, 2015. Based on the result of this inspection, two apparent violations of NRC requirements were identified.

The apparent violations involved:

1. The failure to implement procedures to provide high confidence that each administration was in accordance with the written directive as required by 10 CFR 35.41(a)(2); and

2. The failure to notify the NRC Operations Center of a medical event no later than the next calendar day, as required by 10 CFR 35.3045(c).

A more detailed description of the apparent violations and the circumstances surrounding the apparent violations may be found in the enclosed inspection report.

Because the NRC has not made a final determination in this matter with respect to the apparent violations, a Notice of Violation for these findings is not being issued at this time. You will be advised by separate correspondence when a final determination has been made.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Regulations, Guidance and Communications.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents;** then **Enforcement Policy (Under 'Related Information').** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

No reply to this letter is required. Please contact Janice Nguyen at 610-337-5006 if you have any questions regarding this matter.

Sincerely,

/RA/

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 03007565/2015001

cc w/Encl: Adam M. Henry, Radiation Safety Officer
State of Delaware

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No reply to this letter is required. Please contact Janice Nguyen at 610-337-5006 if you have any questions regarding this matter.

Sincerely,

/RA/

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 03007565/2015001

cc w/Encl: Adam M. Henry, Radiation Safety Officer
State of Delaware

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OFFICE	DNMS/RI	N	DNMS/RI	N	DNMS/RI			
NAME	JNguyen/tlw f/		FGaskins/fcg		JDwyer/jpd			
DATE	09/28/15		09/28/15		09/28/15			

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03007565/2015001
Docket No.	03007565
License No.	07-14850-01
NMED Item No.	150090
Licensee:	Bayhealth Medical Center
Location:	640 South State Street Dover, Delaware 19901
Inspection Dates:	February 19, 2015 September 10, 2015 (telephonic exit)
Date Follow-up Information Received:	February 24, March 3, and September 15, 2015

Inspectors:

/RA Tara L. Weidner for/ ***09/28/15***

Janice Nguyen, Senior Health Physicist — date
Medical Branch
Division of Nuclear Materials Safety

/RA/ ***09/28/15***

Farrah C. Gaskins, Health Physicist — date
Medical Branch
Division of Nuclear Materials Safety

Approved By:

/RA/ ***09/28/15***

James P. Dwyer, Chief — date
Medical Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Bayhealth Medical Center
NRC Inspection Report No. 03007565/2015001

An announced, special inspection was conducted on February 19, 2015, at Bayhealth Medical Center in Dover, Delaware to review the circumstances surrounding a medical event reported on February 10, 2015 (NMED Item Number 150090). The medical event was identified by the licensee when the Radiation Safety Officer and authorized medical physicist were conducting a routine audit of brachytherapy patient records on February 9, 2015. Additional information provided by Bayhealth Medical Center on February 24, March 3, and September 15, 2015, was also reviewed. The inspection consisted of a review of licensed activities associated with the prostate brachytherapy program at Bayhealth Medical Center. The last routine inspection of the facility was performed on April 9-10, 2013, and no violations were identified at that time. The medical event occurred on July 24, 2013, and was the only manual brachytherapy patient treatment that had been performed since the last inspection. The inspectors determined that a medical consultant was not necessary in this case because it was an underdose to the prostate gland. In-office evaluation of the medical event, the brachytherapy program, and Bayhealth Medical Center's corrective actions continued through September 2, 2015. An exit was conducted with the license on September 10, 2015, and the licensee submitted additional corrective and preventative actions on September 15, 2015.

Based on the results of this inspection, the inspectors identified two apparent violations:

- Bayhealth Medical Center did not implement procedures to provide high confidence that each administration was in accordance with the written directive as required by 10 CFR 35.41(a)(2). Specifically, Bayhealth Medical Center's written procedures for radiation therapy treatment variance stated that, "deviations in brachytherapy exceeding plus or minus 20% from the prescribed dose of radiation to a patient should be reported to the Medical Director – Radiation Oncology, chief radiation physicist, clinical manager – radiation oncology, and the Bayhealth Radiation Safety Officer (RSO) so that all necessary corrective actions can be taken to eliminate injury to the patient and to be in compliance with State of Delaware and NRC regulations (10 CFR 35.3045)." However, on July 24, 2013, a patient was implanted with 70 prostate seeds and 20 of the prostate seeds, 29% of the total prescribed, were subsequently removed through cystoscopy. Bayhealth Medical Center did not make an assessment to determine if the delivered dose was within 20% of the prescribed dose. As a result, a medical event was not identified by Bayhealth Medical Center until an audit was performed on February 9, 2015.

- Bayhealth Medical Center did not notify the NRC Operations Center no later than the next calendar day after discovery of the medical event in accordance with 10 CFR 35.3045(c). Specifically, Bayhealth Medical Center had adequate information on July 24, 2013, the date of the implant, to determine that a medical event had occurred. However, the NRC Operations Center was not notified until February 10, 2015.

REPORT DETAILS

I. Organization and Scope of the Program

a. Inspection Scope

An announced, special inspection was conducted on February 19, 2015, at Bayhealth Medical Center in Dover, Delaware to review the circumstances surrounding a medical event reported on February 10, 2015 (NMED Item Number 150090). Additional information provided by Bayhealth Medical Center on February 24, March 3, and September 15, 2015, was also reviewed. The inspection was performed in accordance with NRC Inspection Procedure 87132 and Management Directive 8.10, and consisted of a review of licensed activities associated with the manual brachytherapy program, license commitments, and the details of the reported medical event.

The medical event occurred on July 24, 2013, and was the only manual brachytherapy implant that had been performed since the last routine inspection on April 9-10, 2013. The prostate brachytherapy program is currently inactive.

b. Observations and Findings

Bayhealth Medical Center (BMC) is a medical institution authorized for the possession and use of radionuclides permitted by 10 CFR 35.100, 35.200, 35.300, 35.400, and 35.600. The Radiation Safety Officer (RSO) is a consultant health physicist who is on-site at least monthly and is responsible for auditing the radiation safety program.

BMC performed only one prostate brachytherapy procedure since the last routine inspection on April 9-10, 2013.

Event Chronology

7/16/13 Prior to treatment, the authorized user (AU) obtained ultrasound images of the patient's prostate gland and assessed the prostate volume to be 50 cubic centimeters (cc). The written directive was prepared and signed by the authorized user for a prescribed dose of 145 Gray (Gy) to the prostate gland.

7/18/13 The medical physicist ordered 70 iodine-125 (I-125) seeds from Best Medical International. The seeds contained 0.4 millicuries (mCi) of I-125 each for a total of 28 mCi.

7/22/13 The seeds were received. The medical physicist verified that the seed loading was in accordance with the computer dosimetry plan and the written directive.

7/24/13 The patient was taken to the operating room and placed under general anesthesia. A transrectal biplanar ultrasound probe was used to verify the position of seminal vesicles, prostate, urethra, and rectum. Prostate volume was recorded as 51.32 cc. Seed model number and dose were verified. Real-time treatment planning was performed with the VariSeed treatment planning software. Trocar and seed location was adjusted to obtain a good dose distribution. Using a template and coordinates, the 70 radioactive seeds were deposited into the prostate gland according to the intraoperative plan. Fluoroscopy was performed and dose distribution appeared adequate within the prostate. Immediately following the implant, the urologist performed a cystoscopy and removed 20 of the 70 implanted seeds (29%) and numerous spacers from the bladder. It was noted that a very large median lobe was protruding into the bladder lumen, which may have caused issues with seed placement. Based on the removal of 20 seeds from the bladder, the physicians noted that the implant appeared to be suboptimal and that the patient may require additional treatments in the form of external beam therapy. The AU noted on the written directive that 70 seeds were implanted into the prostate for a total activity of 28 mCi, and that 20 seeds were retrieved from the bladder.

8/21/13 The patient returned for a post-implant CT scan. Post implant dosimetry was performed by a medical physicist. The D90 value (the dose to 90% of the target volume) was calculated to be 32.58 Gy (22% of the prescribed dose).

9/16/13 The AU informed the patient of the suboptimal implant and offered him treatment with image guided intensity modulated radiation therapy. The patient declined additional treatment and indicated he was moving to Florida that week. The AU offered him a referral.

2/9/15 The RSO and an authorized medical physicist (AMP) were conducting an audit of the Radiation Oncology program, and identified that the only manual brachytherapy case since the last NRC inspection had resulted in a medical event. The RSO and AMP reassessed the post implant dosimetry and determined the prostate volume at the time was 61.53 cc (larger because of swelling from the therapy.) The RSO and AMP calculated a D90 value of 42.92 Gy (29.60% of the prescribed dose).

2/10/15 The RSO notified the NRC Operations Center (Event Number 50804) and the Region I office of the medical event that occurred on July 24, 2013.

2/24/15 The 15 day report was received by the NRC Region I office.

10 CFR 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, in part, each administration is in accordance with the written directive. BMC's procedure entitled, "Radiation Therapy Treatment Variance" indicates that, "Deviations in brachytherapy exceeding plus or minus 20% from the prescribed dose of radiation to a patient should be reported to the Medical Director – Radiation Oncology, chief radiation physicist, clinical manager – radiation oncology, and the Bayhealth Radiation Safety Officer (RSO) so that all necessary corrective actions can be taken to eliminate injury to the patient and to be in compliance with State of Delaware and NRC regulations (10 CFR 35.3045)." However, Bayhealth Medical Center did not make an assessment to determine if the delivered dose was within 20% of prescribed dose. As a result, a medical event was not identified by Bayhealth Medical Center until February 9, 2015, during a routine audit by the RSO and AMP. Failure of the licensee to make assessments to determine if the delivered dose is within 20 percent of the prescribed dose is an apparent violation of 10 CFR 35.41(a)(2).

Medical Event Reporting

During a routine audit of manual brachytherapy records on February 9, 2015, the RSO and AMP identified a medical event that had occurred on July 24, 2013.

10 CFR 35.3045(a) requires, in part, that a licensee shall report any event in which the administration of radiation from byproduct materials results in a dose that differs from the prescribed dose by more than 5 rem effective dose equivalent or 50 rem to an organ or tissue and the total dose delivered differs from the prescribed dose by 20 percent or more. 10 CFR 35.3045(c) requires the licensee to notify, by telephone, the NRC Operations Center no later than the next calendar day after the discovery of the medical event. The inspectors concluded that the implant performed on July 24, 2013, which resulted in the removal of 20 of the 70 implanted seeds through cystoscopy, provided the licensee with the information needed to determine that a medical event occurred. Still, the licensee did not make the required notification to the NRC Operations Center until February 10, 2015. This is an apparent violation of 10 CFR 35.3045(c).

A 15-day report was received by NRC on February 24, 2015. Bayhealth Medical Center concluded in the 15-day report that the cause of the medical event was an irregular prostate interface at the bladder (an enlarged median lobe of prostate protruding into the bladder) which resulted in 20 of the 70 seeds being mistakenly implanted into the bladder.

Because the patient received an underdose to the prostate gland, it was determined that a medical consultant was not necessary to review this case.

Corrective and Preventative Actions

As a result of the inspection, Bayhealth Medical Center implemented the following corrective and preventive actions as documented in their letters dated February 23 and September 15, 2015:

- Developed an intra-operative procedure checklist to assess if a change in written directive is necessary prior to completion of implant procedure.
- Developed a post-implant procedure checklist, including review of written directive, to include follow-up external beam radiation (if necessary).
- Quarterly review by the Radiation Safety Officer of brachytherapy procedures as secondary check of actual dose and written directive documentation.
- Appropriate policy and procedure will be updated to include items above.
- Education of entire prostate seed implant team of policy and procedure by chief physicist and radiation safety officer prior to the next scheduled LDR case and annually thereafter (if cases are performed).
- Revised the implant checklist to include planned versus implanted seeds to identify greater than or less than 20% variance of number of seeds.
- Completed education of radiation oncology staff on identification and reporting of medical event criteria in accordance with 10 CFR 35.3045 on September 15, 2015.
- Addition of identification and reporting of medical event criteria in accordance with 10 CFR 35.3045 to the annual radiation safety competency for radiation oncology staff.

c. Conclusions

On July 27, 2013, the licensee performed a prostate implant in which 20 of 70 seeds were removed by cystoscopy, resulting in a D90 value of 29.6% of the prescribed dose to the prostate.

Based on the inspectors' observations, two apparent violations of NRC requirements were identified. Specifically:

1. Bayhealth Medical Center did not implement procedures to provide high confidence that each administration was in accordance with the written directive as required by 10 CFR 35.41(a)(2). Specifically, Bayhealth Medical Center's written procedures for radiation therapy treatment variance stated that, "deviations in brachytherapy exceeding plus or minus 20% from the prescribed dose of radiation to a patient

should be reported to the Medical Director – Radiation Oncology, chief radiation physicist, clinical manager – radiation oncology, and the Bayhealth Radiation Safety Officer (RSO) so that all necessary corrective actions can be taken to eliminate injury to the patient and to be in compliance with State of Delaware and NRC regulations (10 CFR 35.3045)." However, on July 24, 2013, a patient was implanted with 70 prostate seeds and 20 of the 70 implanted seeds (29%) were subsequently removed through cystoscopy. Bayhealth Medical Center did not make an assessment to determine if the delivered dose was within 20% of the prescribed dose. As a result, a medical event was not identified by Bayhealth Medical Center until an audit was performed on February 9, 2015.

2. Bayhealth Medical Center did not notify the NRC Operations Center no later than the next calendar day after discovery of the medical event in accordance with 10 CFR 35.3045(c). Specifically, Bayhealth Medical Center had adequate information on July 24, 2013, the date of the implant, to determine that a medical event had occurred. However, the NRC Operations Center was not notified until February 10, 2015.

II. Exit Meeting

A preliminary exit meeting was conducted on February 19, 2015, to discuss the scope of the inspection and the inspectors' initial observations. On September 10, 2015, an exit meeting was held by telephone with Mr. John D. Shevock, Director of Operations, Oncology Services, and other members of Bayhealth Medical Center's staff, to discuss the results of the inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

*Deborah Watson, FACHE, FACMPE, Senior Vice President and Chief Operating Officer
*+John D. Shevock, FACHE, CMPE, Director of Operations, Oncology Services
*Donna Stinson, FACHE, Executive Director, Bayhealth Cancer Institute
*+Laura Ryan, RTT (R,T), Clinical Manager, Radiation Oncology/Oncology Services
*+John E. Lahaniatis, M.D., Authorized User, Radiation Oncology
*+Wenzheng Feng, M.S., DABR, Chief Radiation Physicist, Oncology Services
*+Adam M. Henry, Radiation Safety Officer
+John Desiderio, FACHE, MBA, Administrative Director of Operations

*Present at preliminary exit meeting on February 19, 2015
+Participated in telephonic exit meeting conducted on September 10, 2015