



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

November 13, 2015

Docket No. 03007565
EA-15-200

License No. 07-14850-01

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

**SUBJECT: BAYHEALTH MEDICAL CENTER, NOTICE OF VIOLATION - NRC
INSPECTION REPORT NO. 03007565/2015001**

Dear Mr. Murphy:

This letter provides you with the U.S. Nuclear Regulatory Commission's (NRC) enforcement decision for the apparent violations identified during an announced, on-site special inspection conducted by Ms. Janice Nguyen of my staff on February 19, 2015, at Bayhealth Medical Center (Bayhealth), Dover, Delaware. The special inspection was limited to a review of a medical event reported to the NRC Operations Center on February 10, 2015 (Event Notification 50804). An in-office review continued through September 2, 2015, and included: (1) an assessment of your 15-day written medical event report; (2) a review of your written procedures in place prior to July 2013; and (3) a review of your proposed corrective and preventative actions described in your letters dated February 23, and September 15, 2015. At the conclusion of the in-office review, Ms. Nguyen discussed the results of the inspection with Mr. John D. Shevock, Director of Operations, Oncology Services, and several members of your organization during a telephonic final exit meeting on September 10, 2015. The NRC Inspection Report and letter dated September 28, 2015, (ML15271A268)¹, described two apparent violations.

Based on the information developed during the inspection, the NRC has determined that two violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them were described in detail in the September 28, 2015 letter and in the subject inspection report. The 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).

The NRC notes that Bayhealth took corrective actions to address the violations. Specifically, Bayhealth: (1) developed an intra-operative procedure checklist to assess if a change in the written directive is necessary prior to completion of implant procedure; (2) developed a post-implant procedure checklist, including review of the written directive, to include follow-up on

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Unless otherwise noted, documents referenced in this letter are publicly available using the accession number in ADAMS.

external beam radiation (if necessary); (3) committed to quarterly review by the Radiation Safety Officer (RSO) of brachytherapy procedures as a secondary check of actual dose and written directive documentation; (4) updated the appropriate policies and procedures to include items #1 through #3; (5) committed to education by the Chief Physicist and the RSO of the entire prostate seed implant team on the appropriate policies and procedures prior to the next scheduled brachytherapy case and annually thereafter (if cases are performed); (6) revised the implant checklist to include the number of seeds planned for implant versus the number of seeds implanted so that variances of greater than 20 percent in the number of seeds would be identified; (7) completed education of the radiation oncology staff on medical event criteria and reporting in accordance with 10 CFR 35.3045; and (8) added medical event criteria and reporting of medical events in accordance with 10 CFR 35.3045 to the annual radiation safety competency for radiation oncology staff. The NRC has concluded that information regarding: (1) the reasons for the violations; (2) the actions planned or already taken to correct the violations and prevent recurrence; and, (3) the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03007565/2015001 and in this letter. 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 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>. To the extent possible, your response, if you choose to provide one, should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

T. Murphy

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We appreciate your cooperation.

Sincerely,

/RA/

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

Enclosure:
Notice of Violation

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

T. Murphy

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We appreciate your cooperation.

Sincerely,

/RA/

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

Enclosure:
Notice of Violation

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

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NOTICE OF VIOLATION

Bayhealth Medical Center
Dover, DE

Docket No. 03007565
License No. 07-14850-01
EA-15-200

During an NRC inspection conducted on February 19, 2015, with continued in-office review through September 2, 2015, for which a final exit meeting was conducted on September 10, 2015, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

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

Bayhealth Medical Center's written procedure entitled, "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).

Contrary to the above, on July 24, 2013, Bayhealth Medical Center did not implement their written procedures to provide high confidence that an administration was performed in accordance with the written directive. Specifically, a patient was implanted with 70 iodine-125 seeds to deliver a dose of 145 Gy. Although twenty of the seeds were removed through cystoscopy immediately following the implant, the licensee did not determine that the delivered dose differed from the prescribed dose by greater than 20% and report the variance to the required personnel 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) until a routine audit of the program was conducted on February 9, 2015, by the Radiation Safety Officer and Authorized Medical Physicist.

This is a Severity Level IV violation (Enforcement Policy Example 6.3.d.1.).

- B. 10 CFR 35.3045(a)(1) requires, in part, that a licensee report any event, except for an event that results from patient intervention, in which the administration of byproduct material results in a dose that differs from the prescribed dosage by more than 0.5 Sv (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 that the licensee notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the medical event.

Contrary to the above, Bayhealth Medical Center did not notify by telephone the NRC Operations Center no later than the next calendar day after removing 20 of the 70 implanted seeds from the bladder through cystoscopy, that a dose administered on July 24, 2013, differed from the prescribed dose by more than 0.5 Sv (50 rem) to an organ or tissue and the total dose delivered differed from the prescribed dose by 20 percent or more. This required notification by July 25, 2013, but the licensee did not notify the NRC Operations Center until February 10, 2015.

This is a Severity Level IV violation (Enforcement Policy Example 6.9.d.7.).

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the actions planned or already taken to correct the violations and prevent recurrence; and (3) the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03007565/2015001 and in the letter transmitting this Notice. Therefore, you are not required to respond to this Notice. 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-15-200," 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, Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406, 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.

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

Dated This 13 day of November 2015