U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001249/2010001
Docket No.	030-01249
License No.	06-02057-01
NMED No.	100290
Licensee:	Bristol Hospital, Inc.
Address:	P.O. Box 977 Newell and Brewster Roads Bristol, Connecticut 06011-0977
Location Inspected:	Newell and Brewster Roads Bristol, Connecticut 03011-0977
Inspection Dates:	May 7, 2010, September 15, 2010 and January 10, 2011 (telephonic exit meeting)
Follow-up Information Received/Dated:	June 25, 2010, and December 9, 2010

Inspector: **/RA/** 1/10/2011
Lester Tripp date
Health Physicist

Approved By: **/RA/** 1/10/11
Marc S. Ferdas, Chief date
Medical Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Bristol Hospital, Inc.
NRC Inspection Report No. 03001249/2010001

A routine, unannounced inspection was conducted on May 7 and September 15, 2010 at Bristol Hospital, Inc. (Bristol Hospital) in Bristol, Connecticut. Additional information provided by Bristol Hospital in a facsimile received on June 25, 2010, and a letter dated December 9, 2010 was also reviewed. The inspection consisted of a review of licensed activities associated with the use of radioactive material in the Nuclear Medicine and Radiation Oncology Departments. The inspector also identified and reviewed two medical events which involved permanent prostate brachytherapy implants that occurred on January 12, 2010 and reported by Bristol Hospital to the NRC Operations Center on June 2, 2010 (NRC Event Notification No. 45973). The inspector conducted interviews, observed day-to-day operations, and reviewed documents and procedures. In addition, the inspector performed an in-office review to evaluate the medical events, the medical consultant's report, and Bristol Hospital's corrective actions.

Bristol Hospital's 15-day report concluded that the two medical events were attributed to unexpected displacement of the brachytherapy seeds in the inferior (caudal) direction. In their letter dated December 9, 2010, Bristol Hospital further clarified the cause of the medical events and concluded that a miscommunication occurred between the implant team members. Specifically, information concerning the seed loading for the implants on January 12, 2010 (first implants of the program) was not communicated to all implant team members prior to treatment. The seeds used during the implants were base loaded but manually retracted during the implant, which resulted in displacement of the seeds by approximately 2 to 3 millimeters.

A medical consultant was retained by the NRC to review the reported medical events. The NRC medical consultant completed his review on November 2, 2010, and concluded that neither patient would likely be harmed from receiving a dose lower than intended to treat their prostate cancer.

Based on the results of this inspection, the inspector identified the following three apparent violations:

- Bristol Hospital 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, Bristol Hospital's written procedures required that seed loading be check by the AU or his designee prior to the implant. The seed loading was not verified prior to the prostate brachytherapy treatments on January 12, 2010 and resulted in displacement of the seeds and two medical events

- Bristol Hospital did not notify the NRC Operations Center of two medical events in accordance with 10 CFR 35.3045(c). Specifically, Bristol Hospital did not notify by telephone the NRC Operations Center no later than the next calendar day after discovery of two medical events on March 1, 2010. Bristol Hospital subsequently notified the NRC Operations Center on June 2, 2010.

- Bristol Hospital did not submit a written report in accordance with the time constraints specified 10 CFR 35.3045(d). Specifically, Bristol Hospital did not submit a written report within 15 days after discovery of a medical event. A written report was required to be submitted by June 17, 2010 but was not submitted until June 25, 2010, a period greater than 15 days.

REPORT DETAILS

a. Inspection Scope

A routine, unannounced inspection was conducted on May 7 and September 15, 2010 at Bristol Hospital, Inc. (Bristol Hospital) in Bristol, Connecticut. Additional information provided by Bristol Hospital in a facsimile received on June 25, 2010, and a letter dated December 9, 2010 was also reviewed. The inspection was performed in accordance with NRC Inspection Procedure 87131 and 87132 and consisted of a review of licensed activities associated with the use of radioactive material in the Nuclear Medicine and Radiation Oncology Departments. The following focus areas were reviewed during the inspection: security and control of licensed material; shielding of licensed material; comprehensive safety measures; radiation dosimetry program; radiation instrumentation and surveys; radiation safety training and practices; and management oversight.

The inspector also identified and reviewed two medical events which involved permanent prostate brachytherapy implants that occurred on January 12, 2010 that were reported by Bristol Hospital to the NRC Operations Center on June 2, 2010 (NRC Event Notification No. 45973). The review of the medical events was performed in accordance with NRC Management Directive 8.10.

The inspector conducted interviews with Bristol Hospital personnel, observed day-to-day operations, toured Bristol Hospital facilities, and reviewed documents and procedures. In addition, an in-office review to evaluate the event, the medical consultant's report, and Bristol Hospital's corrective actions continued through January 10, 2011.

b. Observations and Findings

Bristol Hospital is a medical institution authorized for the possession and use of radionuclides permitted by 10 CFR 35.100, 35.200, 35.300 and 35.400.

Nuclear Medicine

The Bristol Hospital nuclear medicine program includes a full range of diagnostic procedures in accordance with 10 CFR 35.100, 35.200, and 35.300. Iodine 131 (I-131) is used for treatment of hyperthyroidism. Hyperthyroid treatments are performed on an outpatient patient basis and patients are released pursuant to 10 CFR 35.75. Bristol Hospital is not authorized for the use of I-131 for the treatment of thyroid carcinoma. The majority of the diagnostic studies performed at the facility are stress tests. The radioisotopes used at the facility are Technetium 99m (Tc-99m) and I-131. The inspector determined that doses are measured in a dose calibrator prior to use. The nuclear medicine department has two gamma cameras and one treadmill. The licensee's nuclear medicine consultant performs audits quarterly and performs the required source inventory and leak testing. The consultant also performs dose calibrator quality assurance (QA) checks, staff training, and reviews the dosimetry records. During the inspection, the inspector reviewed dose calibrator records, package receipt records, dosimetry records, patient dose administration records, and survey meter calibration documentation.

Prostate Brachytherapy Program

The radiation oncology program at Bristol Hospital is limited to permanent prostate brachytherapy implantation for the treatment of prostate cancer in accordance with 10 CFR 35.400. Bristol Hospital began this program in January 2010. The radiation oncology department consists of three authorized users (AU). Medical physics support is provided by a medical physicist consulting group. The first implants were performed on January 12, 2010. As of the first onsite inspection activity, Bristol Hospital had performed 10 prostate brachytherapy procedures using Cesium-131 (Cs-131) and/or Iodine 125 (I-125) seeds. Prostate brachytherapy implant patients are released in accordance with 10 CFR 35.75 and return approximately one month after surgery for post-plan computerized tomography (CT) imaging used in developing post-plan dosimetric evaluation of the implants.

In general, Bristol Hospital utilizes the following process to perform prostate brachytherapy treatments. Prior to treatment the urologist obtains ultrasound images of the patient's prostate gland to assess the prostate volume; and the AU specifies margins around the prostate to define a planning treatment volume (PTV). The consultant medical physicist develops a computerized treatment plan (pre-treatment plan) based on the information received by the urologist and the AU. The pre-treatment plan is signed by the AU and the written directive is prepared and signed by the AU. The written directive for the implant designates the implant site, intended radioisotope, number of seeds, and activity of seeds, prescribed dose and seed placement within the PTV. The brachytherapy seeds are then ordered from an authorized vendor by the AU or person designated by AU to order seeds.

During the implant procedure, the implant team (consisting of AU, the referring urologist, an ultrasound technologist, and a consultant medical physicist) utilizes ultrasound imaging to visualize the implantation of the seeds into the prostate PTV in accordance with the pre-treatment plan. The implant team can also utilize the ultrasound images to modify the pre-treatment plan during the implant if necessary, in accordance with Bristol Hospital's procedures for prostate brachytherapy.

The consultant medical physicist provides physics and radiation safety support during and immediately after the implant. The medical physicist is responsible for generating the post-implant dosimetry (post-treatment plans) using the CT data obtained approximately one month after the implant and based on the prostate contours from the AU. The post-treatment plan yields the dosimetric parameters of the treatment. This information is provided to the AU and the radiation safety officer for their evaluation.

The inspector reviewed documentation for all 10 prostate brachytherapy implant cases. During the review of the post-treatment plans the inspector noted that, in two of the cases, Bristol Hospital calculated a delivered dose greater than 20% different from prescribed dose for treatments conducted on January 12, 2010. Post- treatment plans, dated February 22, 2010, and signed by the AU on March 1, 2010, evaluated the treatments by using the calculated D90 (minimum dose received by 90% of prostate volume) and V100 (i.e., percent of prostate volume receiving at least 100% of prescribed dose) values.

The inspector noted for the two cases indicated above, that the D90 values were 58% and 59%; suggesting that the administered treatments were not in accordance with

Bristol Hospital's acceptance criteria and medical event reporting requirements in 10 CFR 35.3045. The inspector discussed these cases with Bristol Hospital personnel who stated that a treatment was found acceptable if the D90 value was equal to or greater than 80% of prescribed dose.

Based on the inspector's observations, Bristol Hospital performed a detailed review of these two cases to determine if they were performed in accordance with the written directives and pre-treatment plan; and assessed the cases against the medical event reporting requirements. Upon completion of their review, Bristol Hospital confirmed on June 1, 2010, that two medical events occurred during prostate brachytherapy treatments performed on January 12, 2010. Specifically, they concluded that the D90 values were less than their criteria value of 80% and, therefore, met the NRC notification requirements for failure to deliver the prescribed dose within 20% of that intended.

On June 2, 2010, Bristol Hospital reported two medical events to the NRC Headquarters Operations Center on June 2, 2010 (NRC Event Notification No. 45973). The report contained the following information concerning the medical events:

- Patient 1 was implanted with 60 I-125 seeds with a total activity of 20.4 millicuries to deliver a prescribed dose of 14,500 centigray (rads). On March 1, 2010, post-implant dosimetry calculations indicated a D90 dose of 8,400 centigray (rads).

- Patient 2 was implanted with 66 Cs-131 seeds with a total activity of 186 millicuries. The pre-treatment plan prescribed a dose of 11,000 centigray (rads). On March 1, 2010, post-implant dosimetry calculations indicated a D90 dose of 6,500 centigray (rads).

The inspector determined that on March 1, 2010, Bristol Hospital personnel had information available to determine that two medical events had occurred on January 12, 2010. Therefore, Bristol Hospital should have notified the NRC Operation Center by March 2, 2010.

Medical Event Reporting & Follow-up

Bristol Hospital reported two medical events to the NRC Headquarters Operations Center on June 2, 2010. Bristol Hospital notified the patient and their referring physician. Bristol Hospital also submitted a 15-day written report to the NRC on June 25, 2010. The inspector noted that the written report was not submitted within 15 days of Bristol Hospital reporting that two medical events had occurred, and that it should have been submitted by June 17, 2010.

Bristol Hospital stated in their 15-day written report that Patient 1 did not receive adequate coverage of the involved portion the prostate and would require additional treatment via external beam radiation therapy (XRT). Patient 2 received adequate coverage of involved prostate and additional treatment was not required. The report concluded that the two medical events were attributed to unexpected displacement of the seeds in the inferior (caudal) direction. Bristol Hospital further stated that this could be due to: (1) patient movement during the implant procedure; (2) inattention to implant needle placement in the "Z" axis during the treatment; (3) diminished attention to "slow" needle withdrawal from the prostate; and/or (4) unusual swelling/bleeding in the prostate base region.

In their letter dated December 9, 2010, Bristol Hospital further clarified the cause of the medical events and concluded that a miscommunication occurred between the implant team members. Specifically, information concerning the seed loading for the implants on January 12, 2010 was not communicated to all members of the implant team prior to Bristol Hospital stated that the seeds were based loaded but manually retracted when implanted. The retraction resulted in a displacement of some seeds by approximately 2 to 3 millimeters from the intended pre-treatment plan. They further stated that comparisons of the radiographs of the strands supplied with the shipment from the manufacture and the treatment plan would have shown that the implant was planned with base loading, with no retractions.

The inspector noted that Bristol Hospital's policy 305.596, "Brachytherapy Treatment Policy," requires that prior to implant the seeds activity and loading are checked and verified by the Radiation Oncologist or designee. Based on discussions with Bristol Hospital personnel and a review of documents associated with the two treatments the inspector determined that Bristol Hospital did not properly implement their written procedures for brachytherapy treatments. This resulted in the misplacement of seeds from their intended location due to improper delivery.

Bristol Hospital implemented the following corrective actions:

- Developed a "Brachytherapy Pre-Implant Checklist" to be utilized in conjunction with Policy 305.596. The checklist provides required items that need to be reviewed prior to treatment, including reviewing the manufacturer's radiographs of the strands and performing a comparison with the treatment plan by the Radiation Oncologist. The checklist requires that any discrepancies be resolved prior to start of the treatment.

- Provided additional training/instructions to implant team members (AUs and anesthesiologist) concerning seed implantation techniques and immobilization of the patient.

- Provided training to all personnel involved in prostate brachytherapy in the definition and the reporting requirements (of medical events) found in 10 CFR Part 35.

- Initiated a "Prostate Cancer Brachytherapy Quality Improvement Program" that provides a formal, on-going process, to evaluate all implants using objective measures to monitor and evaluate its brachytherapy program. The program also includes outcome limits that Bristol Hospital would utilize to initiate internal investigations to determine if an NRC reportable medical event occurred.

On June 10, 2010, an NRC medical consultant was retained to review the two medical events. The NRC medical consultant completed their review on November 2, 2010, and concluded that neither patient would likely be harmed from receiving a dose lower than intended to treat their prostate cancer, except for possible recurrence of the disease. The medical consultant noted in their report that the AU for the patients did determine that Patient 2 did not require further supplemental treatment; and that Patient 1 was provided supplemental external beam radiotherapy treatment approximately two months

after the brachytherapy implant. The medical consultant further stated that he did not believe that either patient would suffer from deterministic effects from the potential increased exposure to their bladder or rectum.

c. Conclusions

The inspector concluded that the evaluation performed by Bristol Hospital was adequate and identified the likely causes of the medical events. The corrective actions developed and implemented by Bristol Hospital appear reasonable.

Based on the results of this inspection, three apparent violations of NRC requirements were identified:

- Bristol Hospital 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, Bristol Hospital's written procedures required that seed loading be checked by the AU or his designee prior to the implant. The seed loading was not verified prior to the prostate brachytherapy treatments on January 12, 2010 and resulted in displacement of the seeds and two medical events.

- Bristol Hospital did not notify the NRC Operations Center of two medical events in accordance with 10 CFR 35.3045(c). Specifically, Bristol Hospital did not notify by telephone the NRC Operations Center no later than the next calendar day after discovery of two medical events on March 1, 2010. Bristol Hospital subsequently notified the NRC Operations Center on June 2, 2010.

- Bristol Hospital did not submit a written report in accordance with the time constraints specified 10 CFR 35.3045(d). Specifically, Bristol Hospital did not submit a written report within 15 days after discovery of a medical event to NRC Region I Office. A written report was required to be submitted by June 17, 2010 but was not submitted until June 25, 2010, a period greater than 15 days.

Exit Meeting

A preliminary exit meeting was conducted on May 7, 2010 to discuss the scope of the inspection and the inspectors' initial observations. On January 10, 2011 an exit meeting was held by telephone with Dr. Banco, Chief Medical Officer, and other members of Bristol Hospital's staff, to discuss the results of this inspection and the medical consultant's report.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

+Len Banco, M.D., Chief Medical Officer
+Joseph Ravalese, M.D., Authorized User
Bernard Percarpio, M.D., Authorized User Radiation Oncologist (via telephone)
+Dennis Ferguson, M.D., Radiation Safety Officer
*Jack Sloan, Consultant Medical Physicist (via telephone)
*+Marie Marciano, MBA, Director of Diagnostic Services
+*Lynne Ramer, RN, Operations Director, Perioperative Services
*Pat Caruso, RN, Quality Consultant
Peter D'Addario, M.D., Referring Urologist
Curt Barvis, President and CEO
*Marc Edelman
*Tina Loarte-Rodriguez, Clinical Coordinator, OR
*Anna Vincencio, CNMT
*Barbara Nawroki, Director, Cancer Care Center
+*Diane Bouffard, Director, Quality Impovement
+*Abby Smith, Risk Management Assistant

* Present at preliminary exit meeting on May 7, 2010.
+ Participated in telephonic exit meeting conducted on January 10, 2011.