February 17, 2011

EA-11-008
NMED No. 100290

Kurt A. Barwis
President and Chief Executive Officer
Bristol Hospital, Inc.
P.O. Box 977
Bristol, CT 06011-0977

SUBJECT: NOTICE OF VIOLATION - NRC Inspection Report No. 03001249/2010001

Dear Mr. Barwis:

This refers to the on-site inspection conducted on May 7 and September 15, 2010, at Bristol Hospital, Inc. (Bristol Hospital) in Bristol, Connecticut. The purpose of the inspection was to examine licensed activities as they relate to radiation safety and to compliance with NRC regulations and license conditions, as well as to review two medical events reported by Bristol Hospital on June 2, 2010, to the NRC Operations Center. In addition to conducting the onsite inspection, the NRC also performed in-office reviews of: (1) information Bristol Hospital provided the NRC on June 25 and December 9, 2010; and, (2) the findings of a medical consultant retained by the NRC to review this event, as documented in the consultant's report dated November 2, 2010. After concluding the in-office review, the results of the inspection were discussed with Dr. Banco, Chief Medical Officer, and other members of your organization on January 10, 2011. The findings were also described in the NRC Inspection Report 030012491/2010001 issued on January 10, 2011.

In a telephone conversation on February 1, 2011, Mr. Marc Ferdas of my staff informed you that three apparent violations of NRC requirements were identified during the inspection, one of which was being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. Mr. Ferdas also informed you that we had sufficient information regarding the apparent violations and your corrective actions to make an enforcement decision without the need for a predecisional enforcement conference (PEC) or a written response from you in regards to the apparent violation subject to escalated enforcement. In a followup electronic mail message dated February 3, 2011, you responded that Bristol Hospital did not intend to submit an additional written response or attend a PEC.

Therefore, based on the information developed during the inspection, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations involved the failures to: (1) notify the NRC Operations Center of two medical events, in accordance with 10 CFR 35.3045(c) (which require a report within the next calendar day of discovery); (2) properly implement procedures to provide high confidence that each medical administration of licensed material was in accordance with the written directive as required by 10 CFR 35.41(a)(2); and, (3) submit a written report for the medical events, within 15 days of the date of discovery, in accordance with 10 CFR 35.3045(d).

The two medical events involved patients receiving less than the intended prescribed dose during two different permanent prostrate brachytherapy seed implants on January 12, 2010. The events were the result of the failure of Bristol Hospital personnel to verify the designated seed loading prior to conducting the implants as required by Bristol Hospital's procedures. This resulted in displacement of some of the seeds from their intended locations due to improper delivery during the implantation. As of March 1, 2010, Bristol Hospital personnel had information available to determine that these medical events had occurred on January 12, 2010, and should have therefore reported the events by March 2, 2010. This did not occur. Rather, following NRC questioning of the circumstances during the inspection, Bristol Hospital evaluated the occurrences as medical events, and verbally reported the events to the NRC on June 2, 2010, and subsequently submitted a follow-up written report to the NRC on June 25, 2010.

The failure to inform the NRC of a medical event no later than the next calendar day, in accordance with 10 CFR 35.3045(c), impacts the NRC's ability to promptly assess the event circumstances and respond to ensure that Bristol Hospital had appropriate controls in place to ensure radiation safety during subsequent medical treatments. Therefore, in accordance with the NRC Enforcement Policy, this violation has been categorized at Severity Level (SL) III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $3,500 is considered for a SL III violation. Because your facility has not been the subject of an escalated enforcement action within the last two years or two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC determined that credit for corrective actions is warranted because your actions were prompt and comprehensive. These actions include providing training to all personnel involved in prostate brachytherapy in the definition and the reporting requirements (of medical events) found in 10 CFR Part 35, and updating Bristol Hospital's "Prostate Cancer Brachytherapy Quality Improvement Program" to include outcome limits that Bristol Hospital would utilize to initiate internal investigations to determine if an NRC reportable medical event occurred.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this SL III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The other two aforementioned violations have been classified at SLIV, and are cited in the enclosed Notice.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in this letter and in NRC Inspection Report No. 03001249/2010001. 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, its enclosure, and your response, if you choose to provide one, 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, 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. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at (http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/).

Sincerely,

/RA/

William M. Dean
Regional Administrator

Docket No. 03001249
License No. 06-02057-01

Enclosure: Notice of Violation

cc w/ Enclosure:
Dennis Ferguson, M.D., Radiation Safety Officer
Pat Caruso, Quality Consultant
State of Connecticut

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Sincerely,

/RA/

William M. Dean
Regional Administrator

Docket No. 03001249
License No. 06-02057-01

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Dennis Ferguson, M.D., Radiation Safety Officer
Pat Caruso, Quality Consultant
State of Connecticut

SUNSI Review Complete: ___AEP__

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NOTICE OF VIOLATION

Bristol Hospital, Inc.
Bristol, Connecticut

Docket No. 03001249
License No. 06-02057-01
EA-11-008

During an NRC inspection conducted on May 7 and September 15, 2010, for which a telephonic exit was conducted on January 10, 2011, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.3045(a)(1) requires, in part, that a licensee shall report any event where the administered dose differs from the prescribed dose 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, in part, that the NRC Operations Center be notified by telephone no later than the next calendar day after the discovery of a medical event.

   Contrary to the above, the licensee did not notify the NRC Operations Center by the next calendar day after discovering, during review of two post-treatment dosimetry plans on March 1, 2010, that two doses administered on January 12, 2010 differed from the prescribed doses by 50 rem to an organ or tissue, and the total doses differed by greater than 20 percent from the prescribed doses. This required notification to the NRC by March 2, 2010, but the licensee did not notify the NRC Operations Center until June 2, 2010.

   This is a Severity Level III violation (Enforcement Policy Section 6.9).

B. 10 CFR 35.3045(d) states, in part, that a written report be submitted to the appropriate Regional Office within 15 days after the discovery of a medical event.

   Contrary to the above, the licensee did not submit a written report within 15 days after notifying the NRC Operations Center on June 2, 2010 of the discovery of two medical events. Specifically, a written report describing the two medical events was not submitted to the NRC until June 25, 2010, a period greater than 15 days.

   This is a Severity Level IV violation (Enforcement Policy Section 6.9).

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

   Bristol Hospital 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.

   Contrary to the above, on January 12, 2010, during administration of brachytherapy seed implants to two patients, the licensee did not properly implement its written

procedure to provide high confidence that the administrations were in accordance with the written directive. Specifically, the Radiation Oncologist or his designee did not check the seed loading, and incorrectly assumed that the seeds were to be manually retracted during the procedure. This was not in accordance with the treatment plan, and resulted in displacement of some of the seeds from their intended locations.

This is a Severity Level IV violation (Enforcement Policy Section 6.3).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in the letter transmitting this Notice of Violation (Notice) and NRC Inspection Report No. 3001249/2010001. 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-2011-008], 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, within 30 days of the date of the letter transmitting this 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 17 day of February 2011