October 10, 2008

EA-08-234
NMED No. 080337

Kevin W. Barr
Executive Vice President
Bon Secours Virginia Health Source
7229 Forest Avenue
Suite 208
Richmond, VA 23226

SUBJECT: NOTICE OF VIOLATION - NRC Inspection Report No. 03032638/2008001

Dear Mr. Barr:

This refers to the inspection conducted on June 13, 2008 at your Richmond, Virginia facility. The purpose of the inspection was to review the circumstances surrounding a medical event which occurred on May 1, 2008, and was reported to the NRC on June 6, 2008. Additional information examined as part of the inspection included the 15-day written report required by 10 CFR 35.3045(d), which was provided in a letter dated June 20, 2008. Also examined as part of the inspection was an electronic mail message, with attachments, dated July 31, 2008; and an electronic mail message dated August 7, 2008. The final inspection findings were discussed with Teresa Crist of your staff by telephone on August 8, 2008. The subject inspection report was issued as an enclosure to our letter dated September 3, 2008.

As noted in our September 3, 2008 letter, on August 20, 2008, Dr. Gabriel of my staff informed Ms. Crist that the NRC was considering escalated enforcement for apparent violations at your Richmond facility involving the failures to: (1) verify whether a high dose rate remote afterloader (HDR) treatment was administered in accordance with the treatment plan and written directive; (2) have an authorized user (AU) physician physically present during the initiation of an HDR patient treatment, and have an AU, or physician working under the supervision of an AU, physically present during continuation of the treatment; and, (3) report to the NRC a medical event. Dr. Gabriel also informed Ms. Crist that the NRC had sufficient information regarding the apparent violations and your corrective actions to make an enforcement decision without the need for a predecisional enforcement conference or a written response from you. Ms. Crist indicated that Bon Secours Virginia Health Source (BSVHS) chose not to request a predecisional enforcement conference or submit a written response.

Based on the information developed during the inspection and the additional information provided in your correspondence dated June 20, July 31, and August 7, 2008, the NRC has determined that three violations of NRC requirements occurred. These 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 were associated with a medical event which occurred on May 1, 2008 wherein an Authorized Medical Physicist (AMP) did not take appropriate action in response to an error

message from the HDR device indicating friction or obstruction in the HDR catheter. The AMP did not investigate the cause of the error message and attempted to resolve the apparent friction/obstruction problem by incorrectly changing the catheter length value at the treatment console by 20 millimeters instead of the intended two millimeters. This parameter change was initiated without any supervision of the AMP by the AU, who was in a nearby room working with another patient at the time, and without a written directive procedure in use that included steps to be taken if an HDR device error message was received. The modification to the treatment by the AMP caused a portion of the target volume to receive a fractionated dose that differed from the prescribed dose by greater than 50%. In addition, a small volume of skin outside the target volume received a dose that exceeded the expected dose from that described in the written directive by greater than 50%. Although BSVHS discovered the event on May 1, 2008, immediately after completing a treatment fraction, BSVHS did not report the event to the NRC until June 6, 2008, about 35 days after the event, instead of making a verbal report within one day and a written report within 15 days, as required.

Although an NRC medical consultant concluded that no significant adverse health effect to the patient is expected from this medical event, the first violation is of concern because the failure to have adequate procedures to verify that the HDR administration is in accordance with the treatment plan and written directive could result in clinically significant adverse health effects. The second violation is of concern, because the AU physician responsible for this treatment did not participate in the evaluation and resolution of the device error message that impacted the accuracy of the treatment. While the second violation indicates a single date, the Director of Radiation Oncology indicated that the AU physician was not physically present at the HDR console on other occasions as well. This fact contributed to our assessment of the severity of this violation. The third violation is of concern because the delay in reporting the medical event to the NRC resulted in a delay in identifying and correcting weaknesses in procedures to verify that each HDR administration is in accordance with the treatment plan and written directive. Therefore, each of these violations has been categorized in accordance with the NRC Enforcement Policy at Severity Level (SL) III.

In accordance with the NRC Enforcement Policy, a base civil penalty is considered for a SL III violation. Because your facility has not been the subject of escalated enforcement action within the last 2 years or the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Credit for corrective actions is warranted, because the NRC considered that BSVHS' actions were prompt and comprehensive. The corrective actions include: (1) updating the procedures to define steps to be taken to resolve HDR device error messages; (2) updating procedures to require the AU to be present at the HDR control console and in direct line of sight, paying full attention to the patient's treatment; (3) reporting the medical event to the Headquarters Operations Center, albeit late; and, (4) updating procedures for medical event reporting, including appropriate additional review and discussions if there is any question that a medical event may have 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 these SL III violations constitutes escalated enforcement action that may subject you to increased inspection effort.

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 dates when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03032638/2008001 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's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. If you choose to provide a response, to the extent possible, your response 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/ *Original Signed by Marc L. Dapas for*

Samuel J. Collins
Regional Administrator

Docket No. 03032638
License No. 45-25187-01

Enclosure: Notice of Violation

cc: Commonwealth of Virginia

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 dates when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03032638/2008001 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.

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Sincerely,

***/RA/** Original Signed by Marc L. Dapas for*

Samuel J. Collins
Regional Administrator

Docket No. 03032638
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cc: Commonwealth of Virginia

SUNSI Review Complete: _____ (Reviewer's Initials)

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NOTICE OF VIOLATION

Bon Secours Virginia Health Source
Richmond, Virginia

Docket No. 03032638
License No. 45-25187-01
EA-08-234

During an NRC inspection conducted on June 13, 2008, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.41(a) states, in part, that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b). 10 CFR 35.41(b)(2) requires that the licensee's procedures for administration of licensed material requiring a written directive include verification that the administration is in accordance with the treatment plan and written directive.

Contrary to the above, as of May 1, 2008, the licensee's procedures did not meet the requirements described in 10 CFR 35.41(b)(2). Specifically, the licensee did not develop and implement written procedures to provide high confidence that each administration is in accordance with the written directive, in that the procedures did not address response to HDR device error messages.

This is a Severity Level III violation (Supplement VI).

B. 10 CFR 35.615(f)(2) requires for high dose rate remote afterloader (HDR) units, that an authorized user (AU) and an authorized medical physicist (AMP) be physically present during the initiation of all patient treatments involving the unit, and that the AMP and an AU, or a physician under the supervision of the AU, be physically present during continuation of patient treatment.

Contrary to the above, on May 1, 2008, during initiation of a patient treatment, an AU was not physically present, and during continuation of the patient treatment, neither the AU, nor a physician under the supervision of an AU, was physically present. Specifically, the AU was working with another patient in another room and was not involved in the investigation and resolution of an HDR device error message that was received during the patient treatment.

This is a Severity Level III violation (Supplement VI).

C. 10 CFR 35.3045(a)(1)(iii) requires, in part, that the licensee report any event, except for an event that results from patient intervention, in which the administration of radiation from byproduct material results in a dose that differs from the prescribed dose by more than 50 rem to an organ or tissue and the fractionated dose differs from the prescribed dose, for a single fraction, by 50% or more. 10 CFR 35.3045(a)(3) requires, in part, that the licensee report an event, except for an event that results from patient intervention, in which dose to the skin or an organ or tissue other than the treatment site exceeds by 50 rem and 50 percent or more of the dose expected from the administration defined in the written directive. 10 CFR 35.3045(c) requires that the licensee notify the NRC Operations Center by telephone no later than the next calendar day of the discovery of

the medical event. 10 CFR 35.3045(d) requires, in part, that the licensee submit a written report within 15 days after discovery of the medical event.

Contrary to the above, the licensee did not report by telephone within the next calendar day or in writing within 15 days, an event that met the reporting criteria of 10 CFR 35.3045(a)(1)(iii) and 35.3045(a)(3). Specifically, for an HDR fractional treatment that resulted in a dose delivered to a portion of the treatment site which differed from the prescribed dose by more than 50 rem, and the fractionated dose differed from the prescribed dose, for a single fraction, by more than 50%; and for which the dose to an area of skin other than the treatment site exceeded by 50 rem and more than 50% of the dose expected from the administration defined in the written directive, licensee personnel did not provide a verbal report to the NRC until June 6, 2008 and did not provide a written report until June 20, 2008, even though the event was discovered on May 1, 2008.

This is a Severity Level III violation (Supplement VI).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violations and prevent recurrence, and the dates when full compliance was achieved, is already adequately addressed on the docket in the letter transmitting this Notice and in Inspection Report No. 03032638/2008001. 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-08-234," 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.

Dated this 10th day of October 2008.