September 17, 2009

EA-09-182

Bernie Albertini
Assistant Administrator
Ohio Valley Medical Center
2000 Eoff Street
Wheeling, WV 26003-3870

SUBJECT: NOTICE OF VIOLATION - NRC Inspection Report 03012498/2009001

Dear Mr. Albertini:

This refers to the NRC inspection conducted between June 17 and August 4, 2009. The inspection took place onsite at your Wheeling, West Virginia, facility on June 17, and continued in-office through August 4, to review information obtained in your correspondence dated June 22, July 1, July 17, and August 4, 2009. The inspection also included telephone conversations on June 26, June 29, July 9, July 30, and August 4, 2009, between staff members of your organization and this office. The purpose of the inspection was to examine your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and your license conditions. An exit meeting was conducted with you, by telephone, on August 5, 2009, and the inspection report related to this action was issued on August 24, 2009.

Based on the results of this inspection, four apparent violations were identified. In the telephone conversation on August 5, 2009, Dr. Sandra Gabriel informed you that the NRC was considering escalated enforcement for one of the apparent violations involving the failure to meet the physical presence requirements for high dose rate remote afterloader (HDR) units, and offered Ohio Valley Medical Center (OVMC) the opportunity to attend a predecisional enforcement conference (PEC) or provide additional information. Dr. Gabriel also informed you that the NRC has sufficient information regarding the apparent violation and your corrective actions to make an enforcement decision without the need for a PEC, or an additional written response from you. You indicated that the OVMC did not desire to participate in a PEC or provide any additional information.

Therefore, based on the information developed during the inspection and the information that OVMC provided in its correspondences noted above, the NRC has determined that violations of NRC requirements occurred, one of which is subject to escalated enforcement. The escalated violation is cited in the enclosed Notice of Violation (Notice) in Section I, and the circumstances surrounding it are described in detail in the subject inspection report. This violation involved the failure to have an authorized medical physicist (AMP) and either an authorized user (AU) or a physician, under the supervision of an AU, who has been trained in the operation and emergency response for the HDR unit, to be physically present during continuation of all patient treatments involving the unit. Specifically, on June 17, 2009 and other occasions prior to that date, neither an AU nor a physician under the supervision of an AU and trained in the operation and emergency response for the unit, were physically present during continuation of HDR

treatments. This violation occurred due to OVMC's misinterpretation of the regulations pertinent to an AU, in that the AU and the AMP believed that the physical presence requirements only required the AU to be present at the treatment console during initiation of the treatment, and that during continuation of the treatment, as long as the AU was readily available (e.g., within the department), the physical presence requirements were met. However, the NRC considers the term "physically present" to be as defined in Section V, "Summary of Changes," of the 2002 revised Part 35, as published in the *Federal Register* on April 24, 2002 (67 FR 20355), stating, "As used in this provision, physically present means to be within hearing distance of normal voice." NRC Regulatory Issue Summary (RIS) 2005-23, "Clarification of the Physical Presence Requirements during Gamma Stereotactic Radiosurgery Treatments," also states, "as long as the AU and the authorized medical physicist were able to hear each other without raising their voices, then the physical presence requirement would be met."

In this case, the NRC considered that the AU failed to be physically present during continuation of HDR treatments on multiple occasions, in that the AU was often not within "hearing distance of normal voice" during the continuation of HDR treatment. Therefore, this violation 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 in the amount of $7,000 is considered for a SL III violation. Because your facility has not been the subject of escalated enforcement actions within the last two 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. The NRC determined that corrective action credit is warranted, because OVMC's actions were considered to have been prompt and comprehensive. These actions included providing the NRC documentation that staff was retrained on the physical presence requirements, and updating written procedures to require the AU and the AMP to be physically present during the entire HDR treatment, at a distance of no more than 10 feet from the treatment console. 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.

Three additional violations, documented in Section II of the Notice, have been categorized in accordance with the NRC Enforcement Policy as SL IV. The circumstances surrounding these violations are documented in detail in the above-referenced inspection report.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 030-12498/2009001, and in the OVMC correspondences referenced above. 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. 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 www.nrc.gov; select **What We Do**, **Enforcement**, then **Significant Enforcement Actions**.

Sincerely,

/***RA***/

Samuel J. Collins
Regional Administrator

Docket No. 030-12498
License No. 47-17282-01

Enclosure: Notice of Violation

cc: State of West Virginia

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Sincerely,

/RA/

Samuel J. Collins
Regional Administrator

Docket No. 030-12498
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cc: State of West Virginia
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NOTICE OF VIOLATION

Ohio Valley Medical Center
Wheeling, West Virginia

Docket No. 030-12498
License No. 47-17282-01
EA-09-182

During an NRC inspection conducted between June 17 and August 4, 2009, for which an exit was conducted on August 5, 2009, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

I. VIOLATION SUBJECT TO ESCALATED ENFORCEMENT

10 CFR 35.615(f)(2) requires for high dose rate remote afterloader (HDR) units that an authorized medical physicist (AMP) and either an authorized user (AU) or a physician, under the supervision of an AU, who has been trained in the operation and emergency response for the unit, be physically present during continuation of all patient treatments involving the unit.

Contrary to the above, on June 17, 2009 and occasions prior to that date, either an AU or a trained physician under the supervision of an AU, was not physically present during continuation of a patient treatment. Specifically, the AU was outside of the Radiation Oncology Department during continuation of an HDR treatment. In addition, on other occasions, the AU was not physically present during the continuation of HDR treatments.

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

II. NON-ESCALATED VIOLATIONS

A. 10 CFR 35.40(a) requires that a written directive be dated and signed by an AU before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (uCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

Contrary to the above, on six instances in 2007 and 2008, written directives were signed by physicians to administer I-131 sodium iodide patient dosages ranging from 3 millicuries (mCi) to 15 mCi, and these physicians were not authorized for this use.

This is a Severity Level IV violation.

B. 10 CFR 35.67(g) requires, in part, that a licensee in possession of sealed sources or brachytherapy sources, shall conduct a semi-annual physical inventory of all such sources in its possession.

Contrary to the above, during the past nine months prior to June 17, 2009, a sealed source, a Strontium-90 ophthalmic eye applicator, was in the licensee's possession in storage and had not been inventoried.

This is a Severity Level IV violation.

C. 10 CFR 35. 633(b)(5) requires that full calibration measurements of a remote afterloader unit for medical use include determination of timer accuracy and linearity over the typical range of use.

Contrary to the above, the full calibration measurements of a remote afterloader unit for medical use did not include a determination of timer linearity over the typical range of use. Specifically, from 2007 until June 17, 2009, timer linearity was routinely performed over a range of two minutes, with one test performed out to five minutes, even though the licensee primarily performs mammosite treatments with treatment times of five to ten minutes.

This is a Severity Level IV violation.

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 Inspection Report No. 030-12498/2009001, and in the Ohio Valley Medical Center (OVMC) correspondences dated June 22, July 1, July 17, and August 4, 2009. Therefore, OVMC is not required to respond to this Notice of Violation (Notice). However, OVMC is required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect OVMC's corrective actions or position. In that case, or if OVMC chooses to respond, clearly mark the response as a "Reply to a Notice of Violation, EA-09-182," 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, 475 Allendale Rd., King of Prussia, PA, 19406, within 30 days of the date of the letter transmitting this Notice.

If OVMC chooses to respond, the 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, OVMC may be required to post this Notice within two working days.

Dated this 17th day of September 2009