

October 21, 2009

EA-09-212
NMED No. 090395

Barry Graf
Vice President of Operations
Virtua Health System - West Jersey Hospital
101 Carnie Boulevard
Voorhees, NJ 08043

SUBJECT: NOTICE OF VIOLATION - NRC INSPECTION REPORT NO. 03002443/2009001

Dear Mr. Graf:

This letter refers to the NRC special inspection conducted between March 20 and August 26, 2009 at Virtua Health System – West Jersey Hospital (Virtua) in Marlton, New Jersey. In addition to an on-site review of licensee activities, the NRC staff also reviewed supplemental information submitted to the NRC by Virtua in correspondences dated March 25, April 3 and 20, May 15 and 18, and August 5, 2009. The special inspection reviewed the circumstances surrounding a medical event involving a permanent prostate implant performed on January 19, 2009. During the conduct of post-implant dosimetry calculations on March 19, 2009, Virtua identified that a medical event had occurred, and reported it by telephone to the NRC Operations Center on the same day. Pamela Henderson and Michelle Simmons of the NRC conducted an inspection exit meeting with Debra Grigiani and Daniel Januseski, of the Virtua staff, and you, by telephone, on August 26, 2009. The NRC issued the inspection report related to this action on September 8, 2009.

In a telephone conversation on August 27, 2009, Ms. Henderson and Ms. Simmons informed Ms. Grigiani, Mr. Januseski, and you, that the NRC was considering escalated enforcement for an apparent violation involving Virtua's failure to provide high confidence that each administration is in accordance with the written directive, including verification of the position of the prostate for permanent prostate implants. During that conversation, Ms. Henderson and Ms. Simmons also informed Virtua that, while the NRC had sufficient information regarding the apparent violation and Virtua's corrective actions to make an enforcement decision, Virtua had the opportunity to attend a predecisional enforcement conference (PEC) or provide an additional written response. On August 28, 2009, you informed Ms. Simmons that Virtua did not desire a PEC, and did not intend to provide an additional written response.

Based on the information developed during the inspection and the information that Virtua provided in its correspondences referenced above, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report issued on September 8, 2009. This violation involved the failure to provide high confidence that each administration is in accordance with the written directive, as required by 10 CFR 35.41(a) (2). Specifically, on January 19, 2009, during a prostate implant procedure using 93 Iodine-125 (I-125) brachytherapy sources (seeds), Virtua staff, including the authorized medical physicist

(AMP), questioned the accuracy of prostate visualization prior to implantation of the seeds. However, no action was taken to resolve this question. On March 19, 2009, the AMP performed the post-implant dosimetry calculations based on the post-implant CT scan and determined that no seeds had been placed in the prostate, and that the implant was fully displaced from the intended position. As a result, none of the prostate received the target dose of 145 Gray (14500 Rad, in this case, 14500 Rem). Through an analysis of the root cause of the event, the NRC determined that Virtua's procedures did not adequately address the requirements of 10 CFR 35.41(a)(2) related to target identification, and contributed to the failure of the implant team to accurately visualize and identify the target organ prior to placement of the implant needles. As a result, the radioactive sources were implanted outside of the target volume.

This event was considered a medical event because the patient received a dose to an organ and tissue other than the treatment site that exceeded the expected dose, as defined in the written directive, by 50 rem and 50 percent or more (10 CFR 35.3045(a)(3)). The NRC recognizes that once the error was identified by the AMP on March 19, 2009, the event was reported to the NRC and corrective actions were taken. However, Virtua had an opportunity to identify the medical event earlier, on February 23, 2009, when the authorized user reviewed the post-implant CT scan and identified possible mispositioning of the sources. The NRC understands that Virtua's corrective actions included a review of NRC medical event criteria and reporting requirements by all implant team members. The NRC encourages Virtua to promptly analyze implant data in the future to ensure timely reporting of medical events.

The failure to have adequate procedures to ensure that the target organ is accurately localized resulted in a patient receiving a dose to the prostate that was less than the prescribed dose for the given treatment, and receiving a dose to unintended tissue. While the NRC's medical consultant concluded that for this medical event, other than the patient's prostate cancer, the probability of long-lasting negative health effects is low, this deficiency created the potential for additional medical events. 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 \$3,500 is considered for a SL III violation.

Because Virtua 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 Virtua's actions were considered to have been prompt and comprehensive. These actions included revising Virtua's policy and procedures to require that: (1) all members of the implant team be present before the patient is brought to the operating room and placed under anesthesia; (2) the AMP be included in the pre-implantation ultrasound; (3) the authorized user consult with the urologist before needle insertion; (4) both the radiation oncologist and the urologist agree on the positioning and the visualizing of the target anatomy; (5) any objection or questions by an implant team member is cause for stopping the implant and performing a review; and, (6) the implant be stopped if there are any ultrasound image questions.

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 an escalated enforcement action that may subject Virtua to

increased inspection effort.

The NRC has concluded that information regarding the reason for the violation, 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 this letter, in Inspection Report No. 03002443/2009001, dated September 8, 2009, and in the referenced Virtua correspondences. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect Virtua's corrective actions or 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, Virtua's 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 the response that identifies the information that should be protected and a redacted copy of the response that deletes such information. If you request withholding of such information, you must specifically identify the portions of the 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 Dapas for

Samuel J. Collins
Regional Administrator

Docket No. 030-02443
License No. 29-01862-02

Enclosure: Notice of Violation

cc: State of New Jersey

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Sincerely,
/RA/ Original Signed by Marc Dapas for
 Samuel J. Collins
 Regional Administrator

Docket No. 030-02443
 License No. 29-01862-02

Enclosure: Notice of Violation

cc: State of New Jersey

Distribution: see next page

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NOTICE OF VIOLATION

Virtua Health System - West Jersey Hospital
Vorhees, New Jersey

Docket No. 030-02443
License No. 29-01862-02
EA-09-212

During an NRC inspection conducted between March 20 and August 26, 2009, for which an exit meeting was conducted on August 26, 2009, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.41(a)(2) states 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.

Contrary to the above, as of January 19, 2009, Virtua Health System - West Jersey Hospital (Virtua) did not develop, implement, and maintain procedures for permanent prostate implants, an administration requiring a written directive, which provide high confidence that radioactive seeds would be implanted in the prostate in accordance with the written directive. Specifically, during patient setup on January 19, 2009, Virtua staff raised questions concerning the visualization and positioning of seeds in the prostate, and there were no procedures to ensure resolution of the questions. As a result, all seeds were implanted outside the prostate.

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

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03002443/2009001, dated September 8, 2009, and in the Virtua correspondences dated March 25, April 3, 20, May 15, 18, and August 5, 2009. Therefore, Virtua is not required to respond to this Notice of Violation (Notice). However, Virtua is required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect Virtua's corrective actions or position. In that case, or if Virtua chooses to respond, clearly mark the response as a "Reply to a Notice of Violation, EA-09-212," 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 Virtua 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, Virtua may be required to post this Notice within two working days.

Dated this 21st day of October 2009