

March 25, 2011

EA-11-027
NMED No. 100347

Stephen L. Tancin
Vice President
West Virginia University Hospitals, Inc.
Medical Center
P.O. Box 9006
Morgantown, WV 26506-9006

SUBJECT: NOTICE OF VIOLATION - NRC Inspection Report Nos. 03020233/2010001,
03036074/2010001

Dear Mr. Tancin:

This refers to the on-site inspection conducted on June 8-11, and September 8, 2010, at West Virginia University Hospitals, Inc. (WVUH) in Morgantown, West Virginia. 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 a medical event reported by WVUH on July 7, 2010, to the NRC Operations Center. In addition, a medical consultant was retained by the NRC to review WVUH's prostrate brachytherapy program. The consultant completed the review on December 28, 2010. Subsequent to the onsite inspection, the NRC also performed in-office reviews of: (1) information WVUH provided the NRC on July 16 and 21, and October 12, 2010; and, (2) the medical consultant's report. After concluding the in-office review, the results of the inspection were discussed with you and other members of your organization at the conclusion of the inspection on February 8, 2011, during a telephonic exit. The findings were also described in NRC Inspection Report Nos. 03020233/2010001 and 03036074/2010001, issued on February 8, 2011.

In a telephone conversation on March 2, 2011, Mr. Marc Ferdas of my staff informed you that 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. You responded that WVUH declined the opportunity to submit an additional written response or attend a PEC, and noted that WVUH agreed with the facts as presented in the subject NRC inspection reports.

Therefore, based on the information developed during the inspection, the NRC has determined that four 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 reports. The most significant violation involves the failure to notify the NRC Operations Center of a medical event (which requires a report within the next calendar day of discovery). The other violations involve the failures to: (1) date, or include the prescribed dose, on written directives prepared for prostate brachytherapy implants; (2) properly calibrate a

dose calibrator at the Heart Institute; and, (3) properly designate an individual to be an authorized user for therapeutic use of beta emitters.

The medical event occurred during a microsphere treatment that was conducted on January 20, 2010, during which a patient received less than the intended dosage by greater than 20 percent. After the treatment, the physician documented in the patient's record that less than the prescribed dose was delivered due to leakage within the device used to administer the treatment. As of January 20, 2010, WVUH personnel had information available to determine that a medical event had occurred, and should have therefore reported the event by January 21, 2010. This did not occur; rather, following NRC questioning of the circumstances during the inspection, WVUH evaluated the occurrence as a medical event, and verbally reported it to the NRC on July 7, 2010, and subsequently submitted a follow-up written report to the NRC on July 21, 2010.

The failure to promptly inform the NRC of a medical event impacts the NRC's ability to assess the event circumstances and implement appropriate follow-up actions to ensure that WVUH had proper controls in place to ensure radiation safety during subsequent medical treatments. Therefore, in accordance with the NRC Enforcement Policy, this violation is 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: (1) having the manufacturer of the treatment delivery device provide refresher training on proper administration techniques; (2) revising your dose preparation form to require the signatures and documentation by the authorized user and the physician to state the reason for doses delivered less than 80% of the prescribed dose; (3) having the Radiation Safety Officer meet with the physicians and radiation safety staff to discuss the medical event and the appropriate reporting requirements, as well as the content of the revised dose preparation form; and, (4) providing training to the staff regarding proper communication between the radiation safety staff and the physician.

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 three aforementioned violations have been classified at SL IV, 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 Nos. 03020233/2010001 and 03036074/2010001. 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/ Original Signed by David C. Lew for

William M. Dean
Regional Administrator

Docket Nos. 03020233; 03036074
License Nos. 47-23066-02; 47-23066-03

Enclosure: Notice of Violation

cc with Enclosure:
Nasser Razmianfar, Ed.D., Radiation Safety Officer
State of West Virginia

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Docket Nos. 03020233; 03036074
License Nos. 47-23066-02; 47-23066-03
Enclosure: Notice of Violation

cc with Enclosure:
Nasser Razmianfar, Ed.D., Radiation Safety Officer
State of West Virginia
SUNSI Review Complete: AEP

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Enforcement Coordinators

RII, RIII, RIV (C Evans; S Orth; R Kellar)

C Scott, OGC

E Hayden, OPA

H Bell, OIG

C McCrary, OI

M Williams, OCFO

S Titherington-Buda, OCFO

D Collins, DNMS, RI

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NOTICE OF VIOLATION

West Virginia University Hospitals, Inc. (WVUH)
Morgantown, West Virginia

Docket Nos. 03020233; 03036074
License Nos. 47-23066-02; 47-23066-03
EA-11-027

During an NRC on-site inspection conducted on June 8-11 and September 8, 2010, as well as an in-office review of information provided by WVUH on July 16 and 21, and October 12, 2010, and an NRC medical consultant report received on December 28, 2010, for which a telephonic exit was conducted on February 8, 2011, four 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 in which the administration of byproduct material results in a dose that would have resulted from the prescribed dosage by more than 0.50 Sv (50 rem) to an organ or tissue and the total dosage delivered differs from the prescribed dosage by 20 percent or more.

10 CFR 35.3045(c) requires that the NRC Operations Center be notified no later than the next calendar day after discovery of the medical event.

Contrary to the above, WVUH did not notify the NRC Operations Center by the next calendar day after discovering that a dose administered on January 20, 2010 differed from the prescribed dose by 50 rem to an organ or tissue, and the total dosage differed by more than 20 percent from the prescribed dosage. Specifically, the licensee did not notify the NRC Operations Center of the medical event until July 7, 2010.

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

- B. 10 CFR 35.40 requires, in part, that a written directive must be dated and signed by an authorized user before the administration of any therapeutic dose of radiation from byproduct material; and that for brachytherapy, the written directive must contain the treatment site, the radionuclide, and dose.

Contrary to the above: (1) prior to June 8, 2010, written directives prepared for prostate brachytherapy treatments were not dated by an authorized user; and, (2) on August 3, 2009, a written directive for a prostate brachytherapy treatment did not include the prescribed dose.

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

- C. 10 CFR 35.60(b) requires, in part, that the licensee calibrate the instruments used to measure the activity of unsealed byproduct material in accordance with nationally recognized standards or the manufacturer's instructions.

Contrary to the above, as of June 8, 2010, WVUH did not calibrate instrumentation used to measure the activity of unsealed byproduct material, in accordance with nationally recognized standards or the manufacturer's instruction. Specifically, geometric testing

with a five cubic centimeter syringe had not been performed on a dose calibrator at the WVUH Heart Institute, as described in the manufacturer's instructions.

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

- D. Condition 12.B. of License No. 47-23066-02 requires, in part, that individuals designated in writing by the licensee's Radiation Safety Committee to work as authorized users, as defined in 10 CFR 35.2, shall meet the training and experience requirements in 10 CFR Part 35.

10 CFR 35.300(b)(2) requires, in part, that a physician who is an authorized user meet the requirements specified in 10 CFR 35.390.

10 CFR 35.390(b)(1)(ii)(G) requires, in part, that work experience include administering dosages of radioactive drugs to patients involving a minimum of three cases in each category for which the individual is requesting authorized user status.

Contrary to the above, on October 29, 2009, an individual was authorized for all uses in 10 CFR 35.390 without having obtained the necessary work experience involving a minimum of three cases in each category in 10 CFR 35.390(b)(1)(ii)(G). Specifically, the Radiation Safety Committee designated an individual to be an authorized user for therapeutic use of beta emitters, even though that individual had not obtained the necessary work experience.

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 Nos. 03020233/2010001 and 03036074/2010001. 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-2011-027], 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.

Notice of Violation

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In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this the 25th day of March 2011