UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 18, 2012

Docket No. 03013661 License No. 47-17929-01

Robert C. Marquardt
President & Chief Executive Officer
Fairmont General Hospital
1325 Locust Avenue
Fairmont, WV 26554-1435

SUBJECT: NRC INSPECTION REPORT NO. 03013661/2012001, FAIRMONT GENERAL HOSPITAL, FAIRMONT, WEST VIRGINIA SITE AND NOTICE OF VIOLATION

Dear Mr. Marquardt:

On March 21, 22, and 26, Penny Lanzisera of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The inspection also included a review of the prostate brachytherapy program with a medical consultant reviewing the details of an implant conducted in the Spring of 2011. The medical consultant concluded on April 27, 2012, that the "post-implant CT scan shows that most of the seeds are well within a typical planning volume for a prostate implant and more than 80% of the sources are well within the prostate gland." The medical consultant also provided suggestions for improving the prostate brachytherapy program, as documented in the enclosed Inspection Report. Additional information provided in the licensee's letter dated June 5, 2012, was also examined as part of the inspection. The findings of the inspection were discussed with Dr. Kimberly Cheuvront, Vice President, and Mr. Mark Perna, your Radiation Safety Officer, at the conclusion of the on-site inspection and with you and other members of your staff on June 5, 2012. The enclosed report presents the results of this inspection.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that three Severity Level IV violations of NRC requirements occurred. The violations involved: 1) the failure to include an Authorized User on the Radiation Safety Committee pursuant to 10 CFR 35.24; 2) the failure to leak test a transmission flood source and inventory a separate flood source pursuant to 10 CFR 35.67; and, 3) the failure to include the dose on the written directives prepared for permanent prostate brachytherapy implants as required by 10 CFR 35.40(b)(6)(i).

The violations are cited in the enclosed Notice of Violation (Notice), because the violations were identified by the NRC.

In the letter dated June 5, 2012, and during our inspection exit meeting on June 5, 2012, your staff indicated that you have completed corrective actions for the concerns identified during the inspection. You stated that you have taken corrective and preventative actions to address each violation and that Fairmont General Hospital is committed to radiation safety and to compliance

with NRC regulations and licensed conditions. Further, your staff stated verbally and documented in the June 5, 2012, correspondence, that you have taken the following corrective and preventative actions:

1) Confirmed the membership of the authorized user from Radiation Oncology on the Radiation Safety Committee and will coordinate with the authorized user for presence periodically; however the membership of an authorized user from nuclear medicine was not addressed,

2) Secured the flood source, that was previously located in the 6th floor storage room, in the hot lab and added it to the inventory list,

3) Leak tested the transmission flood source and added the source to the list of sources requiring leak testing, and

4) Updated the written directive form to include the target dose and total activity scheduled for implant for all prostate brachytherapy treatments.

Since this document is marked by you as an "Unofficial Copy," please confirm that the corrective and preventative actions noted therein have been implemented. Pending your confirmation, the NRC has concluded that information regarding the reason for the violations in Items B and C in the enclosed Notice, 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. 03013661/2012001. Therefore, for Items B and C, you are not required to respond to this letter unless the description herein 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.

You are required to respond to this letter in response to Item A of the enclosed Notice and should follow the instructions specified in the enclosed Notice when preparing your response. In particular, you should address the membership requirements for your Radiation Safety Committee to ensure that an authorized user for each type of use permitted by the license is included in the membership. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements."

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. 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.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Regulations, Guidance and Communications.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents;** then **Enforcement Policy (Under 'Related Information').** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free

at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Penny Lanzisera at 610-337-5169 if you have any questions regarding this matter.

Please note that the office of the Region I USNRC Division of Nuclear Materials Safety has moved effective May 9, 2012. Our new address is:

U. S. Nuclear Regulatory Commission
Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

Sincerely,

/RA/

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosures:
1. Inspection Report No. 03013661/2012001
2. Notice of Violation

cc:
Mark Perna, Radiation Safety Officer
State of West Virginia

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James P. Dwyer, Chief
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cc:
Mark Perna, Radiation Safety Officer
State of West Virginia

Distribution:
D. J. Holody, RI

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NOTICE OF VIOLATION

Fairmont General Hospital
Fairmont, WV

Docket No. 03013661
License No. 47-17929-01

During an NRC inspection conducted on March 21, 22, and 26, 2012, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.24(f) requires, in part, that the membership of the Radiation Safety Committee include an authorized user of each type of use permitted by the license, a Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor the Radiation Safety Officer.

Contrary to the above, as of March 21, 2012, the membership of the licensee's Radiation Safety Committee did not include an authorized user of each type of use permitted by the license. Specifically, an authorized user from the Nuclear Medicine Department was not named to the Radiation Safety Committee and the authorized user from the Radiation Oncology Department was named to the Radiation Safety Committee, but had not attended for several years.

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

B. 10 CFR 35.67(b)(2) requires, in part, that a licensee in possession of a sealed source test the source for leakage at intervals not to exceed 6 months.

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

Contrary to the above, as of March 21, 2012, a transmission flood source stored in the hot lab was not tested for leakage at intervals not to exceed 6 months and a flood source in storage on the 6th Floor was not inventoried semi-annually.

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

C. 10 CFR 35.40(b)(6)(i) requires, in part, that written directives prepared for brachytherapy include the dose.

Contrary to the above, as of March 21, 2012, written directives prepared for permanent prostate brachytherapy treatments did not include the dose.

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

The NRC has concluded that information regarding the reason for the violations in Items B and C, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. 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. With regards to the violation in Item A and pursuant to the provisions of 10 CFR 2.201, Fairmont General Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated This 18 day of June 2012