# U.S. NUCLEAR REGULATORY COMMISSION
# REGION I

## INSPECTION REPORT

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| Inspection No. | 03013661/2012001 |
| Docket No. | 03013661 |
| License No. | 47-17929-01 |
| Licensee: | Fairmont General Hospital |
| Location: | 1325 Locust Avenue<br>Fairmont, West Virginia |
| Inspection Dates: | March 21, 22 and 26, June 5, 2012 |
| Date Followup Information Received: | April 27 and June 5, 2012 |

Inspector: ***/RA/*** ***06/18/12***

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## EXECUTIVE SUMMARY

Fairmont General Hospital
NRC Inspection Report No. 03013661/2012001

A routine, unannounced inspection was conducted on March 21, 22 and 26, 2012, at Fairmont General Hospital in Fairmont, West Virginia. Additional information provided by Fairmont General Hospital in a letter dated June 5, 2012, was also reviewed. The inspection consisted of a review of licensed activities associated with the use of radioactive material in the Nuclear Medicine and Radiation Oncology Departments. The inspector also reviewed the complete records for several permanent prostate brachytherapy implants that occurred since the last inspection and requested a medical consultant review an implant performed in the Spring of 2011. The inspector conducted interviews with Fairmont General Hospital personnel, observed day-to-day operations, toured Fairmont General Hospital facilities, and reviewed documents and procedures. In addition, an in-office review to evaluate the prostate brachytherapy program and the medical consultant's report continued through April 27, 2012. The medical consultant concluded 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, described in detail on Page 4.

Based on the results of this inspection, the inspector identified the following apparent violations:

- Fairmont General Hospital did not include an Authorized User (AU) on the Radiation Safety Committee (RSC) as required by 10 CFR 35.24. Specifically, an AU from Nuclear Medicine was not named to the RSC and the AU from Radiation Oncology was named to the RSC, but had not attended for several years.

- Fairmont General Hospital did not leak test a transmission flood source as required by 10 CFR 35.67. Also, a flood source in storage on the 6$^{th}$ floor was not visually inventoried, as required by 10 CFR 35.67.

- Fairmont General Hospital did not secure from unauthorized removal radioactive waste and a sealed source stored in the waste storage room in accordance with 10 CFR 20.1801/1802.

- Fairmont General Hospital did not include the dose on written directives prepared for permanent prostate brachytherapy implants as required by 10 CFR 35.40(b)(6)(i).

In addition, a concern involving patient release surveys of prostate brachytherapy patients, and whether the limits in 10 CFR 35.75 were being met, required additional information for review. On June 5, 2012, the licensee submitted the additional information that indicated that the limits in 10 CFR 35.75 were met for all patients released. The licensee also committed to review their survey techniques and instrumentation to ensure that appropriate surveys were being conducted. No further information on this item is required.

## REPORT DETAILS

a. Inspection Scope

A routine, unannounced inspection was conducted on March 21, 22 and 26, 2012 at Fairmont General Hospital in Fairmont, West Virginia. Additional information provided by Fairmont General Hospital in a letter dated June 5, 2012, was also reviewed. The inspection was performed in accordance with NRC Inspection Procedures 87131 and 87132 and consisted of a review of licensed activities associated with the use of radioactive material in the Nuclear Medicine (NM) and Radiation Oncology Departments. The following focus areas were reviewed during the inspection: security and control of licensed material; shielding of licensed material; comprehensive safety measures; radiation dosimetry program; radiation instrumentation and surveys; radiation safety training and practices; and management oversight. The inspector also reviewed the complete records for several permanent prostate brachytherapy implants that occurred since the last inspection and requested a medical consultant review an implant performed in the Spring of 2011. The inspector conducted interviews with Fairmont General Hospital personnel, observed day-to-day operations, toured Fairmont General Hospital facilities, and reviewed documents and procedures. In addition, an in-office review to evaluate the prostate brachytherapy program and the medical consultant's report continued through April 27, 2012.

b. Observations and Findings

Fairmont General Hospital is a medical institution authorized for the possession and use of radionuclides permitted by 10 CFR 35.100, 35.200, 35.300 and 35.400. The Radiation Safety Officer is a consultant who goes on-site quarterly to perform audits. The inspector reviewed: audits, survey records, RSC meeting minutes, equipment calibration records, dosimetry records, inventory/leak test records, and training records. The audit was noted to focus on the NM Department only and discussions with the consultant RSO indicated that he would include the brachytherapy program in future audits. During review of the radiation safety program, the following concerns were noted:

(i) The RSC does not include authorized users on the committee as required by 10 CFR 35.24. A NM AU was invited to attend the meeting on March 16, 2011, to discuss fluoroscopy doses; however this doctor is not a regular member of the committee. In addition, the radiation oncologist AU is a member of the committee, but had not attended for several years.

(ii) A transmission flood source was not leak tested, as required by 10 CFR 35.67. Also, a flood source in storage on the 6$^{th}$ floor was not visually inventoried, as required by 10 CFR 35.67.

(iii) The door lock on the 6$^{th}$ floor storage area had been removed leaving radioactive material unsecured, in violation of 10 CFR 20.1801/20.1802. Items stored in the area included radioactive waste collected following I-131 inpatient implants dated September 16, 2011 (measurements on day of storage of 0.18 mR/hour on contact to food containers and 0.15 mR/hour on contact to other disposables)

and October 12, 2011 (measurements of 0.55 mR/hr on contact to linens and 0.5 mR/hr on contact to food waste and paper products); and a 10 mCi Co-57 flood source dated 6-28-04 (current activity of 0.7 microcuries). The estimated activity contained in the waste is less than 1 microcurie based on a gamma constant of 2.2 R/hour-millicurie at 1 meter. The combined values of 0.7 microcuries of Co-57 and 1 microcurie of I-131 are less than 10 times the Appendix C value of 10 CFR Part 20.

(iv) Various errors were noted in the licensee's records. For instance, the stated efficiency of the well counter for Co-57 was 128.33%. Discussions with the consultant RSO indicated that this was an error and that the efficiency should be close to 80%. In addition, the leak test records included an incorrect identification number for the camera flood source being wiped and the sealed source inventory records did not note the correct location of storage for the two old Co-57 dose calibrator sources held in the hot lab. The consultant RSO indicated that all the records would be corrected.

The inspector also observed package opening, dosage measurement, dose calibrator testing, and surveys; with no concerns noted. The inspector performed surveys in all areas of use and storage and noted readings in compliance with the regulatory limits.

Nuclear Medicine

The Fairmont General Hospital NM program performs the full range of diagnostic studies and is staffed from 6:30 a.m. to 4:30 p.m. Monday through Friday, with evening and weekend hours covered by on-call staffing. There are three full-time Nuclear Medicine Technologist (NMTs) who conduct 10-12 diagnostic studies daily. According to the Chief NMT, there have been no changes to the facilities. Unit dosages are received from Pharmalogic-Bridgeport and are used for 90% of the studies. Dosages are assayed in a dose calibrator prior to administration. The licensee also receives one bulk shipment of Technetium-99m daily for unplanned procedures. Cardiac studies account for approximately 50% of their total studies. The rest are hepatobiliary (HIDA), bone, lung, renal, gastric emptying, sentinel node biopsies, and thyroid uptake scans. The licensee primarily uses Technetium-99m, with the occasional use of Gallium-67 and Thallium-201. One non-reportable event involving mislabeling of a lung dosage occurred on December 6, 2011. The licensee notified the radiopharmacy who notified all other facilities supplied about the error. The licensee also uses a mobile PET service, Insight, every other Saturday. Insight parks on a pad outside the NM Department, but does not use Hospital facilities.

Radiopharmaceutical therapy treatments conducted under 10 CFR 35.300 are limited to two carcinoma and four hyperthyroid Iodine-131 therapy treatments per year using capsules with a maximum activity of 100 millicuries. Therapy treatments have been performed primarily on an outpatient basis since August 2010, with inpatient treatments performed if the release criteria cannot be met (e.g., if the patient does not have sole use of a bathroom). Written directives are appropriately documented. The consultant RSO

performed a standard calculation for a patient administered 150 millicuries using an occupancy factor of 0.25 and the NMTs compare the patient's responses to living conditions to justify the use of the 0.25 occupancy factor to support immediate release. The administered dosage and patient responses are provided to the consultant on the day of the administration and the consultant calculates the specific public dose for each patient 1-2 days later. The inspector concluded that since the NMTs confirm that the dosage is less than 150 millicuries and that the patient can meet the 0.25 occupancy factor, prior to release of the patients, that patient release calculations were appropriately documented. In addition, patients are given appropriate release instructions and advised to go straight home. Release to hotels is not allowed.

The NM Department currently possesses 14 sealed sources including two button survey meter sources, three rod well counter sources, six dose calibrator sources, two camera flood sources and one transmission flood source. In addition, two camera flood sources and two dose calibrator sources were returned to the manufacturer on August 19, 2011 and the manufacturer confirmed receipt on August 31, 2011.

Prostate Brachytherapy Program

The radiation oncology program at Fairmont General Hospital is limited to permanent prostate brachytherapy implantation for the treatment of prostate cancer in accordance with 10 CFR 35.400. The Radiation Oncology Department for prostate brachytherapy consists of one AU and one radiation therapist, with assistance by the NMT. There is no medical physics support. Fairmont General Hospital performs approximately 5 prostate brachytherapy procedures per year using Palladium-103 (Pd-103) or Iodine 125 (I-125) seeds. Prostate brachytherapy implant patients are released in accordance with 10 CFR 35.75 and return approximately two to four weeks after surgery for post-plan computerized tomography (CT) imaging. No post-plan dosimetric evaluation of the implant is performed; however, films are collected immediately following the implant to confirm the number of sources implanted and the CT images are reviewed by the AU to confirm placement of the sources. Written directives are prepared and include activity/seed, isotope, treatment site, and number of seeds. The tracking sheet used by the Radiation Oncologist after the implant also includes the total source strength; however neither the written directive nor the tracking sheet include the dose to be administered, as required by 10 CFR 35.40(b)(6)(i). During the on-site inspection, the licensee revised the written directive form to include this information and submitted the revised form in the letter dated June 5, 2012. In general, Fairmont General Hospital utilizes the following process to perform prostate brachytherapy treatments:

> The AU performs pre-planning ultrasound imaging and uses the L.L. Anderson nomogram from 1984 for determining the number of seeds to order per patient and the strength of the seeds. The NM Department receives the seeds and assists the AU in the implant, including conduct of the source inventory and patient/operating room release surveys. The AU uses the Patterson Parker implant method using the Mick Applicator with one centimeter needle spacing. A radiation therapist creates a dose plan in the Pinnacle software and the AU

reviews the isodose lines. The radiation therapist also counts the number of sources seen on x-ray films taken after the implant and compares the number identified in the CT images to ensure that most seeds are accounted for. The AU does not digitize the prostate, rectum, or bladder in the CT images; however, he stated that he has never had a case with seeds found in the rectum. In addition, the AU reviews any side effects with the patients during 1 month, 3 month, 6 month, and annual visits; and indicated that he has seen no unusual effects thus far. The implant itself is conducted at Fairmont General Hospital and all other activities take place at the AU's office in the Fairmont Cancer Center attached to the Hospital. Patient release instructions are provided.

During review of prostate implant data, one implant suggested additional review and was forwarded to a medical consultant on March 30, 2012. The following details were collected: In the Spring of 2011, a permanent brachytherapy implant was performed for treatment of prostate cancer with 72 seeds implanted. Approximately two weeks later, the patient returned for a CT scan for "dosimetric evaluation of the implant" where brachytherapy seeds were digitized and isodose lines calculated without definition of the prostate or surrounding organs. The patient returned one seed to the Hospital. The patient returned for routine follow-up three months and six months later and was scheduled for the next follow-up in a year, with quarterly PSA monitoring. In the Spring of 2012, the patient returned complaining of chronic rectal discomfort. The AU noted that the patient "seems to have a good chemical response" but that "his discomfort is unusual." The patient was scheduled for a repeat appointment in six months. During a telephone conversation with the AU on March 26, 2012, the physician stated that his re-review of the CT images concluded that only one to two seeds are located peripheral to the prostate, with no seeds identified in the rectum. In addition, the physician clarified that the proctitis observed in this patient was not unusual. With regards to requests to outline the prostate, rectum, and bladder on the CT images, the physician indicated that the swelling renders any dose volume histograms generated inaccurate. The case was reviewed in the region and it was concluded that further guidance to evaluate the case was necessary and a medical consultant was contracted to review the case. The licensee was notified and provided the name of the medical consultant.

The NRC medical consultant completed their review on April 27, 2012, and concluded that "the post-implant CT scan shows that most of the seeds are well within a typical planning target volume for a prostate implant and more than 80% of the sources are well within the prostate gland. Hence this does not meet the criteria for a medical event." The medical consultant noted in their report that "a radiograph will show the location of the seeds in the left-right and cranio-caudad directions, but not in the anterior-posterior directions" and suggested that "the AU identify and note the location of the seeds in relation to the prostate or clinical target volume in the post-implant CT scan within a few days after the implant" and "that while the shape and size of the organ changes, the relative position of the seeds in relation to the prostate (or CTV) does not change." The medical consultant further stated that he "agrees that proctitis and urethritis can occur after a permanent prostate implant" and concluded that "no significant adverse effect"

occurred and “the patient treatment was not compromised.”

With regards to release of prostate brachytherapy patients, a concern was noted with patient release dose rates and possible exposures to members of the public in excess of the regulatory limits. The patient release dose rates are measured by the licensee with a sodium-iodide probe, with results of approximately 20 milliRoentgen/hour/meter (mR/hr/m) for Pd-103 implants and 12 mR/hr/m for I-125 implants. NUREG-1556, Vol. 9, Table U.1 provides a suggested maximum dose rate at one meter at which patients may be released; 1 mrem/hr/m for I-125 and 3 mrem/hr/m for Pd-103. The values measured by the licensee appear to be far in excess of those noted in the NUREG; which appears to require patient specific calculations to support release in accordance with 10 CFR 35.75. Patient specific calculations were not being performed by the licensee; however, the inspector also noted that the sodium-iodide probe used would overestimate the possible exposure to members of the public. The inspector requested additional information from the licensee to support the release of prostate brachytherapy patients. On June 5, 2012, additional information was provided; which indicated that all prior implant patients were released in accordance with the public dose limits in 10 CFR 35.75. The licensee is in the process of evaluating the type of meter used for surveys to ensure that measurements performed do not overestimate potential exposures to members of the public. No further information on this item is required.

c. Conclusions

The inspector concluded that the radiation safety program implemented by Fairmont General Hospital was, in general, adequate to protect health and safety; that the evaluation of prostate brachytherapy implants was adequate to ensure that the activity intended to be implanted was reviewed, but could be better documented; that an implant conducted in the Spring of 2011 was performed as intended by the Radiation Oncologist with no significant adverse effect noted; and that dose rates to members of the public from prostate brachytherapy patients met the limits in 10 CFR 35.75. However, based on the results of this inspection, four apparent violations of NRC requirements were identified:

(i) Fairmont General Hospital did not include an AU on the RSC as required by 10 CFR 35.24. Specifically, an AU from NM was not named to the RSC and the AU from Radiation Oncology was named to the RSC, but had not attended for several years.

(ii) Fairmont General Hospital did not leak test a transmission flood source as required by 10 CFR 35.67. Also, a flood source in storage on the 6$^{th}$ floor was not visually inventoried, as required by 10 CFR 35.67.

(iii) Fairmont General Hospital did not secure from unauthorized removal radioactive waste and a sealed source stored in the waste storage room in accordance with 10 CFR 20.1801/1802. Since the combined values of 0.7 microcuries of Co-57 and 1 microcurie of I-131 are less than 10 times the Appendix C value of 10 CFR

Part 20, this issue is considered a minor violation.

(iv) Fairmont General Hospital did not include the dose on written directives prepared for permanent prostate brachytherapy implants as required by 10 CFR 35.40(b)(6)(i).

In their letter dated June 5, 2012, the licensee provided their corrective and preventative actions taken that included:

(i) Adding the AU from Radiation Oncology on the RSC for future meetings and coordinating with the AU for presence periodically.

(ii) Securing the flood source, that was previously located in the 6th floor storage room, in the hot lab and adding it to the inventory list.

(iii) Leak testing the transmission flood source and adding the source to the list of sources requiring leak testing.

(iv) Disposing of all decayed waste from the 6th floor storage room and installing a lock on the door if used for future storage of licensed material.

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

The inspector reviewed the corrective and preventative actions and found them sufficient to address the concerns noted with the exception of the actions taken in response to the membership on the RSC. 10 CFR 35.24 requires an AU for each type of use permitted by the license. Therefore, an AU for Nuclear Medicine must also be nominated to the RSC.

## Exit Meeting

A preliminary exit meeting was conducted on March 21, 2012 to discuss the scope of the inspection and the inspector's initial observations. On June 5, 2012, an exit meeting was held by telephone with Mr. Robert Marquardt, President and Chief Executive Officer, and other members of Fairmont General Hospital's staff, to discuss the results of this inspection and the medical consultant's report.

**PARTIAL LIST OF PERSONS CONTACTED**

Licensee

+Robert Marquardt, President and CEO
*Kimberly Cheuvront, Ph.D., Vice President Business and Operations Development
*Mark Perna, Radiation Safety Officer
*+Sandie Wells, Chief NMT
+Larry Stanley, Director of Radiology
Michael Stewart, M.D., Authorized User
Other staff in the Nuclear Medicine and Radiation Oncology Departments

+Present at final exit conducted on June 5, 2012
*Present at preliminary exit conducted on March 21, 2012