



1325 Locust Avenue
Fairmont, West Virginia 26554
(304) 367-7100
website: www.FGHI.com

July 10, 2012
U.S. Nuclear Regulatory Commission – Region I
2100 Renaissance Blvd., Suite 100
King of Prussia, Pennsylvania 19406-2713

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REGION I
2012 JUL 23 AM 7:56

Docket No. 03013661

Subject: Inspection Report of Radioactive Materials License No. 47-17929-01

Dear Ms. Lanzisera:

We are responding to Item A of the Notice of Violation found during the 3-21-12 NRC inspection. In addition, I confirm that the corrective and preventative actions previously submitted are true and have been implemented. I trust that our responses and dates of such will show our commitment to return to full compliance with the regulatory and quality standards.

Our previously submitted documentation described prompt actions taken on 3-21 through 3-29-12. On 6-5-12 we also submitted our revised Prostate Brachytherapy policy, and the Written Directive for Interstitial Brachytherapy and the Post-Implant Imaging policies from Fairmont Regional Cancer Center.

ITEM A, Regarding 10 CFR 35.24(f):

Through an oversight, an Authorized User for Nuclear Medicine was no longer a regular member of the Radiation Protection Committee ever since our Consulting Physicist replaced a Radiologist as the Radiation Safety Officer. When brachytherapy information was sent 6-5-12, we did not include our intention to appoint one of our Authorized User Radiologists to the scheduled 6-7-12 Radiation Protection Committee meeting. Compliance was formally achieved on 6-7-12 when we had our most recent RP Committee meeting. *Please see attached meeting minutes* addressing the AU issue, particularly in light of physicians' work rotations.

Regarding 35.40 In reference to Interstitial Brachytherapy

Please see attached second revisions to better connect the Post-Implant assessment to the Written Directive:

1. Brachytherapy of Prostate, rev. 6-12-12
2. Written Directive, rev. 3-26-12
3. Written Directive: Interstitial Brachytherapy Post-Implant verification
4. Post-Brachytherapy Implant Imaging, 6-28-12

There were opportunities for improvement in communications between individuals and departments, and we responded with immediate action. We look forward to your assessment of our facility.

Please review all attached documents. Specific questions may be placed to Sandie Wells at 304-367-7237, or by e-mail at swells@fghi.com.

Sincerely,

Robert C. Marquardt, MACHE
President and CEO
Fairmont General Hospital, Inc.

NMSS/RGNI MATERIALS-004

The quarterly meeting of the **RADIATION PROTECTION COMMITTEE** of F. Mont General Hospital was held on Thursday, June 7, 2012 at 9:40 AM in the Radiology Lounge. Mark Perna, Chairman, presided.

Members Present

M. Perna, Physicist – Chairman
 L. Stanley, RT - Radiology
 S. Wells, CNMT – Nuclear Medicine
 J. Kosik – Environmental Services
 A. Wyant, RN
 Heather Swiger, RT (T) -- for Michael Stewart, MD
 Jon LaPlante, MD -- for Radiological Physicians Associates

Members Absent

C. Moore, RN

PERCENTAGE OF ATTENDANCE: 90%

ITEM	CONCLUSIONS/RECOMMENDATIONS	ACTION/FOLLOW-UP
Old Business		
Review of Minutes	The meeting was called to order and the minutes of the meeting held March 20, 2012 were distributed for review.	Approved as written.
New Business		
Film Badge Report	The 1 st Quarter, 2012 film badge report revealed no ALARA overages.	For information. / Film badge reports will be reported annually.
Reappointment of Authorized Users to Committee	<p>The NRC requires a Radiologist and Radiation Oncologist (or representatives) be members of the Radiation Protection Committee. Due to limited availability of a specific Radiologist and Radiation Oncologist during work rotations, alternates will represent them. Another option can be a statement from Oncologist Dr. Stewart.</p> <p><u>Today's alternate attendees for reinstated members are:</u></p> <ul style="list-style-type: none"> - Heather Swiger, RT(T), for authorized user, Michael Stewart, MD, Radiation Oncologist. - Jon LaPlante, MD, Radiologist, authorized user from Radiological Physicians Associate 	For information. / Continue to monitor annually.
NRC Inspection of Nuclear Medicine & Brachytherapy (performed 3-21-2012)	<p>Sandie reported on the surprise NRC Inspection done on March 21, 2012. The following items had to be corrected/reviewed:</p> <ul style="list-style-type: none"> ➤ The decay room on the 6th floor was waste free and posing no risk, however, it was found to be unsecured. <i>Corrected immediately.</i> ➤ Some minor documentation omissions were found. <i>Has been corrected.</i> ➤ The Inspector reviewed 2 prostate brachytherapy cases performed by Dr. Stewart and questioned that, after review of the CT's, > 20% of the therapy dose did not reach the intended area, which is a reportable event that could warrant escalated enforcement. 	For information. / Continue to monitor and comply with NRC standards.

**RADIATION PROTECTION
COMMITTEE**

June 7, 2012

Page Two

NRC Inspection (continued)

Note: Dr. Stewart was not in agreement with the Inspector's review/finding of the 2 prostate brachytherapy cases. The Inspector sent these 2 cases to be reviewed by the **NRC Medical Consultants** and they determined that the **Inspector was mistaken.**

The official result of the inspection has not been received yet. In previous years, a typed letter is mailed out with the issues needing resolved and FGH sends back a former letter stating that all codes and standards have been met. This is not the case this year and the reason is unclear. Sandie has sent the NRC all of the supporting documentation requested but without a formal letter signed by the CEO. Mr. Marquardt will sign a formal letter once he receives a hardcopy response that is not in the form of an e-mail.

Instead of sending a letter yet, the NRC inspector chose to set up a second "exit" interview conference call on 6-5-12 with Mr. Marquardt and Mrs. Wells. The inspector had not seen documents faxed the week before to know our corrective actions. She shall review before issuing further decision on any violations.

Update Committee when a final report on the NRC Inspection is received.

WV Board of Radiological
Health inspection

It has been reported that the state inspector is citing hospitals if Radiological or Nuclear Medicine Technologists' Annual Certification is expired or not displayed.

Mr. Perna to send out an e-mail to remind X-ray & Nuc. Med. Techs of the licensure standards.

With no further business to discuss, meeting was adjourned at 9:55 am.

Other Business

Adjournment

**PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.**

Submitted by:

Julie Nichols
Administrative Assistant
Quality Management

Verified by:
MARK PERNA

Mark Perna, Physicist
Chairman

Digitally signed by MARK PERNA
DN: cn=MARK PERNA, o=Perna Health
Physics, Inc., ou,

Date: 2012.06.22 08:29:12 -04'00'

FAIRMONT GENERAL HOSPITAL
POLICY AND PROCEDURE MANUAL

SUBJECT: Brachytherapy of Prostate
INDEX CATEGORY: Nuclear Medicine

POLICY NO: RA.NM.QMP.003
DATE: 8-20-04

POLICY: It is the policy of the Nuclear Medicine Department to establish safe radiation handling practices in the provision of radioactive therapy implantation devices.

Scheduling...

1. Radiation Oncologist preplans the treatment by prostate ultrasound. This Oncologist must be approved as an Authorized User on the FGH Nuclear Regulatory Commission license.
2. Prostate Brachytherapy will be scheduled with Surgical Services, Nuclear Medicine and Ultrasound by a Radiation Therapist from Fairmont Regional Cancer Center, usually for a Wednesday at 7:15 a.m.
3. The Radiation Oncologist will write the prescription and fill out the Written Directive for the seeds, indicating the name of nuclide, millicurie dosage per seed, quantity of seeds and the total activity of dose.
4. Nuclear Medicine Department shall have 2 Technologists to staff the department during the time 1 Tech must be in Surgery and PACU (approx. 1 hr). If only 1 Tech can staff the department during the procedure then the schedule of the non-cardiac camera must be cleared for that length of time.
5. The Tech who went to Surgery should be the one to do the pre-discharge survey in Ambulatory Surgery. This may be 2 ½ - 3 hours later and will take approximately 15 minutes.
6. New staff Technologists must be trained when the opportunity arises.

Ordering & Receiving...

1. Confirm date & time of surgery with Oncologist's office before ordering seeds.
2. If the Oncologist does not have a WRITTEN DIRECTIVE to fill out and deliver to the department, one must be provided to him. This must be completed before ordering the seeds.
3. **One week prior** to the procedure, a registered/ certified Nuclear Medicine Technologist will call, plus FAX the Written Directive and the Pharmalogic order form for seeds to Pharmalogic of Bridgeport, WV. Seeds should be received in the department 1 day prior to therapy.
 - a. Technologist must be listed on PERSONNEL PERMITTED TO HANDLE RADIOACTIVE SEEDS.
 - b. Order must match the Written Directive, and have the patient's NAME.
4. At time of submitting the order, also submit info to the Perna Health Physicis so the Physicist can prepare the patient release form with calculation of the maximum likely dose that will be emitted from patient. This will include the patient's name, date of planned procedure, the isotope, the number of seeds, activity per seed, total activity.
5. Verify the shipment is correct on Pharmalogic's I-125 & Pd-103 SEED LOADING sheet script sticker. Also verify these match the WD for patient name, nuclide, quantity & activity per seed. Place the sticker on the "Seed Loading" sheet.
6. Survey & the receipt into the Hot Lab NMIS. Fill in the BRACHYTHERAPY SEED TRACKING SHEET.
7. Seeds are preloaded in cartridges: 15 seeds/ cartridge. Cartridges are to be numbered 1 through (Example: 64 seeds are loaded as 15 in 4 cartridges & 4 remaining seeds in a 5th cartridge.)

Documentation of patient's dose...

1. The dose is entered into the Hot Lab NMIS.
2. Print both the Draw Dose sticker & the Exposure Report card.

Sterilization...

Take loaded seed carrier to SURGERY for "flash" sterilization at approx. 6:30 a.m. on day of surgery.
Surgical personnel handle the carrier from this point.

Surgical Procedure...

1. Prior to 7:15 a.m. surgery, Tech goes to Surgery changes into scrubs, shoe covers & hat. Take into OR:
 - o **scintillation detector** (*cleaned with disinfectant first*)
 - o clipboard with pencil w/ good eraser & all associated paperwork for this patient
 - o paperwork includes: WD. .. signed order ... FAX order form .. Seed Loading Sheet... Pharmalogic script sticker... vendor's packing list ... Brachytherapy Seeds Tracking sheet ... Needle Position Template (2 copies in case extra needed)... Needle & Seed Insertion Inventory ... Post-Op Radiation Survey Sheet (for Ambulatory Surgery)... and ... Post-Op and Pre-Discharge Radiation Survey... Draw Dose sticker... Exposure Report card.
2. Before procedure begins, have either a Technologist or Surgical RN identify seeds are correct for patient name & type seeds. Have this person sign the "**TIME OUT**" line on the SEED TRACKING SHEET. Oncologist verbally verifies with Technologist the type, number and strength of seeds. He directs the circulating nurse how many needles to have ready. Surgical staff performs the the "**TIME OUT**" before Oncologist starts.
3. Tech stands with the clipboard & paperwork behind the Oncologist and the Ultrasound Technologist. when Oncologist places needles, he will say the position on the NEEDLE POSITION TEMPLATE. Darken the corresponding circle on template. (Example: "Fox 4" is F 4, "Echo 5" is E5)
Approx. 14-22 needles may be placed.
4. Periodically the doctor asks to see the sheet. If he moves a needle, erase the darkened circle.
5. When all needles are in place, seeds are then implanted via needles. Use the NEEDLE/ SEED INSERTION INVENTORY sheet to log implantation. Doctor calls out the first inserted needle; write this needle position in #1 slot. As he inserts each seed, he counts. There may be 2-5 inserted per needle site; check or number the blocks on that needle line to keep track of seeds. As Dr. advances to fill each needle, and each seed is implanted, keep a running total at the end of each line to know when all 15 are used from a cartridge. Note the block for the 15th seed to be prepared to "Cartridge is empty" immediately. He will switch cartridges.
8. When complete, he will say "Done". Fill in the sheet for initial seed count, seeds used and seeds returned. If seeds are dropped or retrieved, fill this in on the SEEDS TRACKING SHEET.
9. In room, Oncologist signs: *Brachytherapy Seed Tracking, Needle Template & Seed Insertion Inventory*

Post-op procedure:

1. Tech uses the **scintillation detector** to survey the areas listed on the top portion of RADIATION SURVEY.
2. Tech writes dose into Progress Notes of hospital chart; notifies that the room is cleared for cleaning.
3. Tech takes the POST-OP RADIATION SAFETY instructions to Ambulatory Surgery, stressing to RNs the patient cannot be discharged until NM comes down to survey the patient and room.
4. Tech reminds RN in Recovery /Amb Surg that all urine must be strained to catch any expelled seeds. If seed is found, it must be kept in a strainer, set aside & saved for Nuclear Medicine to pick up.
5. Tech returns to NM Dept. with the detector, seed carrier, any remaining seeds & the paperwork.
6. Seed carrier & remaining seeds are packed up for return to Pharmalogic.

7. Tech makes copies of the following for the patient's Cancer Center chart:
 - Written Directive
 - Vendor's technical data sheet
 - Brachytherapy Seed Tracking Sheet w/ note of seeds expelled/ returned
 - Needle Position Template
 - Needle/ Seed Insertion Inventory w/ notation of seeds at bottom
 - Physicist's patient release form

Pre-Discharge Survey:

1. Ambulatory Surgery is to call Nuclear Medicine several hours later when patient is ready for discharge.
PATIENT IS NOT TO BE DISCHARGED UNTIL NM TECH GOES DOWN TO SURVEY.
2. Using a **Geiger-Muller counter**, Tech surveys & logs patient, linens, floor & checks with RN for any seeds strained from urine. Bottom portion of POST-OP & PRE-DISCHARGE RADIATION SURVEY is filled out.
3. Tech confirms that the patient understands the radiation protection precautions given to him by the Cancer Center, that he shall strain his urine for 1 week, and will take any expelled seeds (wrapped in aluminum foil) and take to the center.
4. Technologist gives the patient the EXPOSURE REPORT card, asking him to keep in his wallet. It should be presented in the event of going through airport security screening, or if questions arise about implants.

Quality Management Review: (To be performed by RSO quarterly.)

Minimum of 8 forms from each patient brachytherapy will be kept together in the QMP: BRACHYTHERAPY notebook in time-sequential order:

1. Written Directive
2. Dr's order
3. FAX'd order to Pharmalogic
4. Pharmalogic prescription sticker
5. I-125 or Pd-103 Seed Loading sheet & attached dose label (Pharmalogic)
6. Vendor Technical Data Sheet
7. Brachytherapy Seeds Tracking Sheet, signed in OR by Radiation Oncologist
8. Needle Position Template, “ “ “ “
9. Needle/ Seed Insertion Inventory, “ “ “ “
10. Post-Op Radiation Safety Instructions (AmSurg)
11. Post-op/ Pre-Discharge Radiation Surveys
12. Physicist's calculation of emitted exposure

written: 8-20-04

revised: 9-04

Policy Committee: 9-04

P&P: 12.05

Reviewed: 8-06-08

Revised: 4-13-11

Reviewed: 2-24-12

Revised: 3-27-12, 6-03-12, 6-12-12



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Fairmont, West Virginia 26554
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WRITTEN DIRECTIVE: INTERSTITIAL BRACHYTHERAPY

Date - _____

I request and direct the Nuclear Medicine Department of Fairmont General Hospital to purchase and prepare the following encapsulated radioactive therapy seeds for permanent implantation.

I have performed treatment plan calculations, and now prescribe **INTERSTITIAL BRACHYTHERAPY** to be permanently implanted into the prostate under ultrasonic guidance for the following guidelines:

Patient Name - _____ Date of Birth - _____

Date of Surgery - _____ Diagnosis - _____

Type of Seeds - ☐ Iodine – 125 ☐ Palladium – 103

Number of Seeds - _____ Dose of Each Seed - _____ mCi Total Activity - _____ mCi

Target Dose - ☐ 144 Gy ☐ 120 Gy ☐ 90 Gy

A registered Nuclear Medicine Technologist shall: record the position of seed insertion by template localization, perform post-op and post-discharge radiation surveys, and maintain all records of radioactive implant material receipt, storage, delivery and decay.

The patient will be instructed in pre-operative preparation and post-operative precautions to successfully and safely treat him. These instructions will include observation for expelled radioactive seeds, how to handle them if this occurs, and who to contact for returning them to the Nuclear Medicine Department of Fairmont General Hospital.

Radiation Oncologist & NRC Authorized User
Nuclear Regulatory Commission License 47-17929-01
Fairmont General Hospital

WRITTEN DIRECTIVE: INTERSTITIAL BRACHYTHERAPY POST IMPLANT

Patient Name - _____ Date of Birth - _____

Date of Seed Implantation - _____

The following items checked have taken place on _____.

- ☐ Follow-up with the radiation oncologist at Fairmont Regional Cancer Center
- ☐ CT scan without contrast of the pelvis performed at Fairmont General Hospital
- ☐ AP and Lateral Pelvis x-rays performed at Fairmont General Hospital

The pelvis x-rays have been reviewed and CT scans entered into the treatment planning computer to evaluate the dose within the prostate volume. There are more than 80% of the seeds within the prostate volume.

A copy of the prostate seed implant isodose coverage is attached.

Radiation Oncologist
Fairmont Regional Cancer Center
1325 Locust Ave.
Fairmont, WV 26554

FAIRMONT GENERAL HOSPITAL
ADJUNCT POLICY

SUBJECT: Post-Brachytherapy Implant Imaging

POLICY OF: Fairmont Regional Cancer Center

SUBMITTED TO: Nuclear Medicine Dept. of Fairmont General Hospital
6-13-12

POLICY: Fairmont Regional Cancer Center describes the following procedure performed for every post-plan patient follow-up to verify the location of implanted radioactive seeds.

(This is an independent cancer treatment facility from which Radiation Oncologists refer patients for operative prostate brachytherapy via interstitial radioactive seed implantation. The oncologist performs the procedure as an Authorized User on the NRC License 47-17929-01 of Fairmont General Hospital.)

PROCEDURE:

1. Patient is scheduled between 2-4 weeks after the day of implant to return for a follow-up visit with the Radiation Oncologist.
2. Immediately after the follow-up visit, the Patient goes to Fairmont General Hospital CT Department, where orders have been sent for a CT Scan of Pelvis w/o contrast. The patient also has Pelvis X-Rays in both AP and Lateral positions.
3. Upon completion of the CT and X-Rays the patient is released to go home.
4. The CT scan is downloaded onto disc and the X-Rays are printed onto film; these are given to the Radiation Therapist who will work on the dosimetric plan.
5. The seeds are counted on the X-Rays. Both AP and Lateral images are reviewed for number of seeds and seed positioning. The information is loaded into the treatment planning computer, then the post-plan is performed, reviewed and signed by the Radiation Oncologist.
The following criteria for dose within the prostate volume is:
 - Seed total within a typical planning target volume of a prostate implant must be 80% or more. If more than 20% of the total visualized retained seeds are outside the prostate, this is considered a "medical event."
6. A copy of the plan is inserted into the Patient's chart. A signed copy of the isodose distributions and seed information is also given to the Nuclear Medicine Department.

revised: 6-28-12 sw