

**DEPARTMENT OF  
VETERANS AFFAIRS**

**Memorandum**

Date: **JAN 06 2009**

From: Director, VHA National Health Physics Program (115HP/NLR)

Subj: Radiation Safety Program Inspection - Inspection Report 652-08-I01

To: Director (652/00), Hunter Holmes McGuire VA Medical Center, Richmond, Virginia

1. Edwin M. Leidholdt, Jr., Ph.D., and Paul L. Yurko, M.S., VHA National Health Physics Program (NHPP), performed an announced inspection of the radiation safety program at the Hunter Holmes McGuire VA Medical Center, Richmond, Virginia on December 18-19, 2008. This inspection was focused entirely on permanent implant prostate brachytherapy and did not serve as a routine NHPP inspection.
2. The inspection report is attached and consists of an NHPP Form 591 with two violations cited, a prostate brachytherapy checklist completed during this inspection, and a list of recommendations.
3. You should note the NHPP Form 591 outlines reasons for the violations, corrective actions, and a full-compliance date. You must sign and return the NHPP Form 591 within 30 days of the date of this memorandum.
4. Thank you for the courtesy and cooperation extended during the inspection. Please contact Dr. Leidholdt at 707-562-8374, if you have any questions about the inspection.

  
E. Lynn McGuire

Attachment

cc: Chair, National Radiation Safety Committee  
Network Director, VISN 6 (10N6)

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

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|--|--|
| <p>1. PERMITTEE/PERMIT NUMBER:</p> <p>Hunter Holmes McGuire VA Medical Center<br/>Richmond, Virginia<br/>45-09413-06</p> | <p>2. LOCATION(S) INSPECTED:</p> <p>1201 Broad Rock Boulevard<br/>Richmond, Virginia 23249</p> |
| <p>3. INSPECTION DATES: December 18-19, 2008</p>   | <p>4. INSPECTION REPORT NUMBER: 652-08-101</p>   |

**PERMITTEE:**

The inspection was an examination of activities under your permit as they relate to radiation safety and compliance with Nuclear Regulatory Commission rules and regulations and your permit conditions. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and performance-based observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited, are not being cited because they were self-identified, non-repetitive, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(s) and corrective action(s):

- 4. During this inspection certain of your activities, as described below and/or attached, were in violation of Nuclear Regulatory Commission requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting per 10 CFR 19.11. The violations and corrective actions are as follows:

10 CFR 35.404(a) requires that, immediately after implanting sources, the permittee shall make a survey to locate and account for all sources that have not been implanted. 10 CFR 35.2404 requires a record of these surveys to be maintained for at least 3 years. Contrary to this, the facility made surveys to comply with 10 CFR 35.404, but did not retain a record of the surveys as required. Corrective actions include retraining the staff and modifying forms to include a record of the post-implant surveys.

10 CFR 35.75 allows a permittee to release from its control any individual who has been implanted with radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). Contrary to this, the permittee made surveys to comply with 10 CFR 35.75 with a survey meter not calibrated to measure the type and energy of the radiation. Corrective actions include utilizing a properly calibrated meter or correcting the reading for the energy response of the meter.

The full compliance date is December 19, 2008.

**STATEMENT OF CORRECTIVE ACTIONS**

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made per 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand no further written response to the VHA National Health Physics Program will be required, unless specifically requested.

| TITLE          | PRINTED NAME                                    | SIGNATURE                      | DATE              |
|----------------|---|--------------------------------|-------------------|
| PERMITTEE      |   |                                |                   |
| NHPP INSPECTOR | Paul L. Yurko<br>Edwin M. Leidholdt, Jr., Ph.D. | <i>Edwin M. Leidholdt, Jr.</i> | December 22, 2008 |

## Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

**Hunter Holmes McGuire VA Medical Center, Richmond, Virginia  
December 18-19, 2008**

*The audit checklist should be used to determine overall status for the seed implant program and to ensure compliance with specific regulatory requirements and best clinical practices. The issues or categories to evaluate and review are in the six major sections below.*

### 1. Handling and security of sealed sources

- a. Radioactive material package receipt surveys and records (10 CFR 20.1906).

Packages of seeds are delivered to the warehouse and stored in a secure area. The warehouse staff notifies radiation safety and radiation safety picks up the seeds, performs the receipt surveys, and delivers them to Radiation Oncology Room 1Z-113. Receipt records are maintained in the nuclear medicine hot lab. These appear to conform to NRC regulatory requirements.

- b. Security requirements (10 CFR 20.1801 and 20.1802) and two delay methods if stored.

Cage in warehouse is locked, Rooms 1Z-113 and 1H-152 hot lab are locked. Conform to NRC regulations and MML permit conditions.

- c. Source accountability (10 CFR 35.406) and records of accountability (10 CFR 35.2406).

Source accountability records largely conform to the pertinent NRC regulations. However, very minor deficiencies were noted – there were no units for activity and the records had initials and not names.

- d. Physical inventory (10 CFR 35.67(g)).

Inventory of seeds is maintained in nuclear medicine. Substantially conforms to NRC regulations (the records had initials and not names).

- e. Source disposal (i.e., ship to vendor or decay on site) (10 CFR 35.92 and 35.3092).

Store on site for decay. None has been discarded since program inception. All seeds from previous implants are stored in either Room 1H-152 (nuclear medicine hot lab) or in long-term storage area Room BC-129.

### 2. Preparations for seed implant procedures

- a. Written procedures and checklists (10 CFR 35.40 and 35.41).

Substantially conform to NRC regulations.

- b. Patient identity verification, written directive, and treatment plan checking procedures (10 CFR 35.40 and 35.41).

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Substantially conforms to NRC regulations.

- c. Pre-implant imaging (volume study), modality (TRUS, CT), how long before implant?

Dr. Addesa's patients – CT; if patient is on protocol, TRUS.

Dr. Hagan's patients – TRUS.

For both physicians, the pre-implant imaging is typically performed about two weeks before each implant procedure.

- d. Pre-plan preparation. Who draws the contours of the prostate and other organs?

The organs contoured by the authorized user physicians, or by a resident, with approval by an authorized user physician.

- e. Written directive, pre-implant part preparation, including prescribed dose.

Pre-implant portion printed soon after the pre-plan is approved, but is signed in the OR.

- f. Surveys after source implant for misplaced seeds and records (10 CFR 35.404 and 35.2404).

Performed by radiation oncology physics staff after patient is removed from OR using a survey meter with a thin window thin crystal NaI scintillation probe. However, records were not maintained per 10 CFR 35.404 and 35.2404. This is a violation of NRC regulations.

- g. Patient release procedures, surveys, and records (10 CFR 35.75 and 35.2075).

Patient release surveys were performed at 1 meter using survey meters equipped with thin window thin crystal NaI scintillation probes and calibrated using a pulser. Both meters have both cpm and mR/h scales. However, the cpm scale was calibrated, but not the mR/h scale. Records were kept in accordance 10 CFR 35.2075. The meter readings were recorded in units of mR/h. Not performing release measurements using a survey meter calibrated for the radiation measured is a violation of NRC regulations.

During the inspection, the RSO and Chief Therapeutic Medical Physicist demonstrated, using I-125 and Pd-103 seeds to compare the responses of these survey meters with the response of a calibrated Keithley ion chamber survey meter, that the measurements of the patients permitted release under 10 CFR 35.75 were within the limits of NUREG-1556, Volume 9.

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h. Patient release measurements after source implantation with a survey meter capable of accurately measuring exposure rate, air kerma rate, or dose rate for photons of the energy emitted or a method to correct the measurements for the energy response of the meter.

See item immediately above.

i. Patient instructions (10 CFR 35.75).

Patients receive instructions from nursing staff on the short stay surgery unit or ward before release. The nurses give the patients written instructions addressing the possibility of a seed or seeds in the urine and on precautions for minimizing doses to others. These appear to conform to NRC regulatory regulations.

j. Calibration measurements of sources (10 CFR 35.432).

All seeds are calibrated by the vendor. Documentation appears to meet the requirements of 10 CFR 35.2432. The facility has the ability to assay seeds, but does not routinely do so.

k. Acceptance testing of treatment planning system (10 CFR 35.457).

Appears to conform to NRC regulations.

l. Quality assurance of imaging (i.e., TRUS, CT, and accuracy of image transfer to TPS).

Appears to conform to or exceed standards of practice.

m. Requirements for a medical event or other incident circumstances including after-hours recall or notifications (10 CFR 35.3045).

Radiation oncology staff appears to be aware of the requirements for medical events. Radiation oncology staff has information to contact the RSO and designees both during and outside normal working hours. The NHPP inspectors recommended that written procedures be prepared for medical events and lost seeds.

n. Radiation Safety Committee approval of physician authorized users (broad-scope) or named on the permit (limited-scope).

Limited-scope permit, authorized user physicians are named on the permit.

o. Procedures to evaluate for possible leaking seeds and follow-up actions.

Facility does not have procedures, but plans to prepare written procedures to address the possibility of leaking seeds.

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- p. Training (i.e., initial and periodic) for authorized user physicians, medical physicists, and other staff.

Records of training of radiation oncology staff, for 2007 and 2008, listed physicists and physics residents, but not authorized user physicians. Furthermore, the training syllabus for radiation oncology did not address many relevant issues, such as written directives and medical events. According to Dr. Saleh, additional issues not on the syllabus, including written directives and medical events, were discussed. The NHPP inspectors recommend revision of the syllabus to make it relevant to radiation oncology and annual training of the physicians.

- q. Usual type of anesthesia?

General or spinal.

- r. Prescribed dose for each radionuclide used?

145 Gy I-125 monotherapy, 110 Gy boost  
124 Gy Pd-103 monotherapy, 85 Gy boost

May differ for protocol patients.

- s. How are images (TRUS, radiographs, and CT) used for prostate brachytherapy stored (e.g., film, PACS, server in radiation oncology), are backup copies maintained, how long are the images retained?

Stored on server in radiation oncology, not on VA system, backed up on VCU system.

- t. Do any issues with digital information transfer hinder the preparation of pre- and post-plans?

No.

3. Performance-based interviews and observations

- a. Authorized user physicians.

Based upon performance-based interviews, the one authorized physician interviewed has adequate and sufficient knowledge of regulatory requirements.

- b. Medical physicists and dosimetrists.

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Two medical physicists were interviewed. Based upon performance-based interviews, one had adequate and sufficient knowledge of regulatory requirements, but another medical physicist was not completely familiar with the regulations regarding the definition of a medical event. The NHPP inspectors recommended improving the training of medical physicists.

- c. Other physicians including urologists and/or residents.

Urologists do not participate in implant procedures and were not interviewed. Radiation oncology residents do participate, but they were not interviewed.

- d. Radiation Safety Officer.

Based upon performance-based interviews, the RSO has adequate and sufficient knowledge of regulatory requirements.

- e. Support staff.

A radiation oncology nurse, who provides the patients with guidance on minimizing the doses to others per 10 CFR 35.75, was interviewed. Based upon performance-based interviews, she had adequate and sufficient knowledge of regulatory requirements.

4. Performance-based tours and observations

- a. Radiation oncology areas.

Based on performance-based tour, these areas did not have any deficiencies.

- b. Package receipt areas.

Based on performance-based tour, these areas did not have any deficiencies.

- c. Seed implant preparation areas.

Based on performance-based tour, these areas did not have any deficiencies.

- d. Seed storage areas.

Based on performance-based tour, these areas did not have any deficiencies.

5. Evaluation of patient treatment results

- a. Methods and procedures to determine if all seeds were implanted properly.

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TRUS is used throughout the procedure. One of the two authorized user physicians who perform prostate brachytherapy supplements TRUS with fluoroscopy.

- b. Fluoroscopy used to supplement TRUS during procedure (yes or no).

Dr. Hagan uses fluoroscopy to supplement TRUS, Dr. Addesa does not.

- c. Radiograph acquired after implant (yes or no).

Yes.

- d. Written directive, post-implant part: when completed and how.

Completed in the operating room after all seeds are implanted.

- e. Post-implant CT scans: when completed?

Dr. Addesa's patients – CT on day of implant procedure; if patient is on protocol, patient receives a second CT at 4 weeks after the implant.

Dr. Hagan's patients – CT is performed 4 to 6 weeks after each implant procedure.

- f. Post-plans: when completed, who draws the contours of the prostate and other organs, are the seed locations found by software manually corrected, how to verify complies with written directive. Are any indices of rectal dose calculated?

- g. Review of treatment results to dose criteria such as V100 and D90.

Yes.

- h. Clinical quality assurance, including peer review.

Every prostate implant case received peer review at MCV.

6. Workload data

- a. Method of implantation (preloaded needles, Mick applicator, needles loaded at facility).

Preloaded needles almost always used. Loose seeds were ordered for one case a year ago and loaded into needles on site. Only one case (TURP patient) in three years used stranded seeds.

- b. Date of program inception.

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August 1998.

- c. Number of patients implanted per year.

Currently about 70 to 80 patient procedures a year.

- d. Radionuclides (I-125, Pd-103, Cs-131) and seed models currently in use.

I-125, Pd-103 – approximately 60% I-125 cases, 40% Pd-103  
Dr. Hagan uses Pd-103, Dr. Addesa uses I-125

I-125 – Theragenics Model I25.S06  
Pd-103 – Theragenics Model 200

**7. Persons contacted**

DeAnne Seekins, MBA, Acting Medical Center Director  
Judy Brannen, M.D., MBA, Chief of Staff  
Panos Fatouros, Ph.D., Radiation Safety Officer  
Habeb Saleh, Ph.D., Chief Therapeutic Medical Physicist  
Wendy Kemp, Administrative Officer, Radiation Oncology Service  
Michael Hagan, M.D., Radiation Oncology Authorized User  
James Gordon, Ph.D., Therapeutic Medical Physicist  
Belinda Swecker, RN, Radiation Oncology Nurse  
Timothy Burke, M.D., Chairperson, Radiation Safety Committee

**Radiation Safety Program Inspection**  
**Hunter Holmes McGuire VA Medical Center, Richmond, Virginia**  
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**Recommendations**

1. Records of training of radiation oncology staff for 2007 and 2008 listed physicists and other staff, but not authorized user physicians. Furthermore, the training syllabus for radiation oncology did not address many relevant issues, such as written directives and medical events.

Recommendation: It is recommended that the RSO, with the guidance of the chief medical physicist, modify the training syllabus to make it relevant to radiation oncology and to include training of the authorized user physicians.

2. Written procedures regarding leaking seeds were not available. Precautions to detect a leaking seed before implantations and guidance to authorized user physicians for blocking the patient's thyroid if an implanted leaking seed is discovered were not available.

Recommendation: It is recommended that the written procedures be revised to add additional information for leaking seeds as discussed above.

3. Written procedures regarding lost seeds were not available.

Recommendation: It is recommended that the written procedures be prepared for lost seeds.