

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

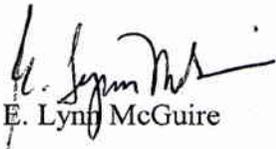
Date: **MAR 10 2009**

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

Subj: Radiation Safety Program Inspection - Inspection Report 558-09-I01

To: Director (558/00), VA Medical Center, Durham, North Carolina

1. Paul L. Yurko, NHPP, performed an announced reactive inspection on January 26-27, 2009, with continuing review until February 19, 2009. This inspection was focused entirely on a medical event and the permanent implant prostate brachytherapy program and did not serve as a routine NHPP inspection.
2. The inspection report is attached. The report consists of a narrative report with no violations cited and a permanent implant prostate brachytherapy audit checklist completed during this inspection.
3. You are not required to respond to this memorandum.
4. Thank you for the courtesy and cooperation extended during the inspection. Please contact Mr. Yurko at 410-642-2411, extension 6288, if you have any questions about the inspection.


E. Lynn McGuire

Attachment

cc: Chair, National Radiation Safety Committee
Network Director, VISN 06 (10N6)

RADIATION SAFETY PROGRAM INSPECTION
Inspection Report Number 558-09-I01
VA Medical Center, Durham, North Carolina
January 26 - February 19, 2009

1. Introduction

a. Paul L. Yurko, M.S., VHA National Health Physics Program (NHPP), performed an announced reactive inspection of the VA Medical Center, Durham, North Carolina, on January 26-27, 2009, with continuing review until February 19, 2009.

(1) The inspection focus was a medical event involving transperineal permanent implant prostate brachytherapy (hereafter referred to as prostate brachytherapy) that was implanted on December 18, 2008, discovered on January 15, 2009, and reported to the Nuclear Regulatory Commission (NRC) Operations Center on January 15, 2009.

(2) The medical event was discovered following a post-implant CT and post-plan dose determination performed January 15, 2009. The event was reported to the NRC on January 15, 2009, and assigned Event Number 44779. A 15-day report was sent to NRC on January 28, 2009.

(3) The inspector presented his preliminary findings at a meeting with key medical center staff on January 27, 2009.

b. The inspection was focused on the medical event.

(1) NRC regulations in 10 CFR 35.3045 define a medical event. The inspector used this definition as a basis to evaluate the medical event.

(2) The inspector conducted an exit meeting on January 27, 2009, and left the inspection open pending a review of the pre-plan and post-plan data by the VA Puget Sound Health Care System, Seattle, Washington. The inspection was closed on February 19, 2009.

c. NHPP reviewed the medical event and agreed with the medical center position that the post-plan data supported the definition of a medical event. No further medical events were discovered during the inspection. The identification of a medical event under 10 CFR 35.3045 is not, by itself, a violation of NRC regulations

2. Scope of inspection

The inspection was risk-informed and performance-based. All items on the inspection plan were completed to include, but were not limited to, the following.

- a. Interviews with medical center and contract staff.
- b. Review of records related to the event and radiation safety program.
- c. Tour of facilities and review of equipment involved.

**Radiation Safety Program Inspection
VA Medical Center, Durham, North Carolina**

d. Review of the medical center's initial actions regarding the event, including a review of the effectiveness and comprehensiveness of the initial actions to prevent a recurrence.

e. Review of compliance with other regulatory requirements under 10 CFR 35 for a prostate brachytherapy program.

f. Evaluation of root or basic causes for the event.

3. Findings and impressions (background information)

a. The most recent NRC inspection at the medical center, on September 15, 2008, cited no violations. NHPP inspected the medical center on November 5-6, 2008, and did not cite any violations.

b. The medical center had previously reported a medical event involving prostate brachytherapy on February 24, 2005. NHPP performed an announced reactive inspection on March 2-3, 2005, and did not cite any violations.

c. The inspector gathered information about the history of the prostate brachytherapy program at the medical center and the workload.

(1) The first prostate brachytherapy procedure was performed on January 26, 1999.

(2) The facility has performed 217 cases since the beginning of the program.

d. The inspector gathered information about the workflow for prostate implant procedures.

(1) The medical center obtains sterilized pre-loaded needles, from a commercial vendor. The seeds in the pre-loaded needles are stranded.

(2) Within a few weeks before each patient procedure, an authorized user physician obtains transrectal ultrasound (TRUS) images. The images are transferred to a treatment planning system (TPS) for a medical physicist to create a treatment plan to achieve the dose prescribed by the authorized user physician. Creation of this treatment plan requires designation of the prostate boundaries on the images by the physician.

(3) The authorized user physician reviews the treatment plan prepared using the TPS, and prepares and signs a written directive. The physician may be assisted by a medical physicist.

(a) Title 10 CFR 35.40 specifies that the part of the written directive completed before an implant procedure must state the treatment site, radionuclide, and dose.

(b) The medical center written directive procedures require preparation of a written directive form before each implant. This information includes the radionuclide, treatment site, planned

**Radiation Safety Program Inspection
VA Medical Center, Durham, North Carolina**

number of seeds, strength per seed, and dose in cGy. The information is transcribed from the treatment plan and needle loading diagrams onto the written directive form.

(4) A medical physicist orders pre-loaded needles from the seed vendor.

(5) The seed vendor ships a package to the medical center. The package is delivered to the Radiation Safety Office. A member of the radiation safety staff performs a package receipt survey and takes the package of seeds to Room EB-003 in Radiation Therapy. The vendor is required to provide a certificate of assay of 10% of the seeds in an order.

(6) Seeds are implanted in patients in an operating room under TRUS guidance. Digital radiography is used to supplement the TRUS imaging.

(7) After the procedure, the patient recovers from the anesthesia in a post-surgical recovery room and hospitalized overnight. Currently, CT images are obtained on the day after the procedure and, if indicated, again at about 30 days after the procedure. The CT images are transferred to the TPS, an authorized user physician contours the prostate, and a medical physicist creates a post-plan to assess the dose distribution. Indices of the dose distribution to the prostate, including V100 and D90, are calculated and given to the physician. The post-plan is typically created within a day of the post-implant CT scan.

d. The inspector confirmed regulatory compliance for the following:

(1) Radiation safety practices and record keeping under 10 CFR 35.404, 35.406, 35.432, and 35.457.

(2) Security of stored sealed sources before and after prostate brachytherapy procedures under 10 CFR 20.1801 and permit conditions.

4. Findings and impressions (regulatory compliance)

a. The inspector reviewed and evaluated information about the medical event that had been reported and overall implementation of the prostate brachytherapy program.

b. The inspector concluded that, even though there had been a medical event, no violations could be identified.

5. Findings and impressions (medical event)

a. The inspector collected information regarding the medical event.

(1) The implant procedure that was declared a medical event was performed December 18, 2008. The post-implant radiograph did not indicate that seeds were positioned outside the target volume.

**Radiation Safety Program Inspection
VA Medical Center, Durham, North Carolina**

(2) A post-implant CT study of that patient was performed December 19, 2008, and showed that eight seeds had migrated inferior to the prostate. A second CT performed December 23, 2008, showed an additional 4 seeds had migrated inferior to the prostate for a total of 12 seeds that had migrated inferior to the prostate. In accordance with medical center brachytherapy procedures, a CT was performed on January 15, 2009, to determine post-plan dose to the prostate. The CT showed the same 12 seeds as the CT performed on December 23, 2008, inferior to the prostate. The D90 was discovered to be 56% of the prescribed dose. The reason for the low D90 was the seed migration inferior to the prostate.

(3) The authorized user physician recommended to the patient a supplemental procedure to implant additional seeds.

6. Causes of Medical Event

a. The inspector performed a causal analysis. In a 2004 article in "*Brachytherapy*," *Journal of the American Brachytherapy Society*, the authors state, "Although the brachytherapy technique has been refined, there remain imperfections in the process. Among these imperfections is seed migration, in which one or more implanted seeds migrate a distance from the intended target volume location." The authors further state that the most common causes for seed migration are "the process of vascular embolization" and "migration down needle tract." Neither of these common causes appears to be the cause for the migration in this event. The pre-plan and post-plan data was sent to the VA Puget Sound Health Care System, Seattle, Washington, for their review. Their report is dated February 19, 2009, and was received on the same date. The inspection was closed as of the date of receipt of the Seattle report. Their conclusion was that the most probable cause for the seeds inferior to the prostate was seed migration. Because seed migration is a random and isolated event and is beyond the control of the authorized user physician no corrective actions could prevent its occurrence.

b. The error due to seed migration was an isolated and infrequent event.

7. Notice of Violation

The inspector did not identify any violations.

8. Persons contacted

Ralph T. Gigliotti, FACHE, Medical Center Director
James Oleson, M.D., Authorized User Physician
Haijun Song, Ph.D., Therapy Physicist
Walter L. Furr, III, Radiation Safety Officer

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

VA Medical Center, Durham, North Carolina Inspection January 26-27, 2009

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 are received and surveyed by the Radiation Safety Office. Procedure and records are in compliance with regulatory requirements.

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

Radioactive material is secured at all times. Facility now has two-delay method in place for storage of seeds.

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

Source log contains all required information. Records were reviewed by inspector and found to be in compliance.

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

Sources are inventoried every 3 months. Records are in compliance.

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

Sources are disposed of by decay in storage. Some sources returned to vendor. Records of disposal are kept per current requirements.

2. Preparations for seed implant procedures

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

Current procedures include written directive procedures, radiopharmaceutical therapy procedures, radiopharmaceutical written directive, and checklist and brachytherapy procedures. All procedures approved by RSC. Standard VHA procedures have not been incorporated at this time.

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

Written procedures require two identification methods. Procedures require written directive.

January 14, 2009, version

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

**VA Medical Center, Durham, North Carolina
Inspection January 26-27, 2009**

- c. Pre-implant imaging (volume study), modality (TRUS, CT), how long before implant?
The volume ultrasound study is performed 2 weeks to 1 month before implant.
- d. Pre-plan preparation. Who draws the contours of the prostate and other organs?
Pre-plan is prepared 2 weeks before implant. Physician draws contours.
- e. Written directive, pre-implant part preparation, including prescribed dose.
Pre-plan is signed and dated by authorized user. Pre-plan is Part 1 of written directive.
- f. Surveys after source implant for misplaced seeds and records (10 CFR 35.404 and 35.2404).
Records of required surveys are maintained. Survey instrument is adequate for survey.
- g. Patient release procedures, surveys, and records (10 CFR 35.75 and 35.2075).
Patients released per 10 CFR 35.75 survey are adequate.
- 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.
Yes
- i. Patient instructions (10 CFR 35.75).
Yes, both verbal and written instructions are provided.
- j. Calibration measurements of sources (10 CFR 35.432).
Vendor performs calibrations and documentation of calibration is maintained.
- k. Acceptance testing of treatment planning system (10 CFR 35.457).
Acceptance testing was performed by the medical physicist, documentation on file.
- l. Quality assurance of imaging (i.e., TRUS, CT, and accuracy of image transfer to TPS).
Quality assurance testing for TRUS and CT is on file.

January 14, 2009, version

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

**VA Medical Center, Durham, North Carolina
Inspection January 26-27, 2009**

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

Facility has adequate procedures for recall and notifications.

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

Authorized user approved by RSC, copy on file.

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

Radiation safety monitors needles with low-energy NaI probe for contamination.

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

Initial and periodic training in procedures is documented in facility files.

- q. Usual type of anesthesia?

General.

- r. Prescribed dose for each radionuclide used?

145 gray.

- 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?

CT on CD and transferred to treatment computer; pre-plan and post-plans achieved on tape.

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

None.

3. Performance-based interviews and observations (includes knowledge of NRC regulations and assessment of whether there is a safety culture)

- a. Authorized user physicians.

Dr. Oleson demonstrated an understanding of current regulations and written procedures.

January 14, 2009, version

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

**VA Medical Center, Durham, North Carolina
Inspection January 26-27, 2009**

b. Medical physicists and dosimetrists.

Dr. Song demonstrated an understanding of current regulations and written procedures.

c. Other physicians including urologists and/or residents.

Urologists are not active participants in the procedure.

d. Radiation Safety Officer.

Mr. Furr demonstrated a thorough understanding of current regulations and written procedures for implants.

e. Support staff.

Mr. Dass, technician, demonstrated an understanding of current regulations and written procedures.

4. Performance-based tours and observations

a. Radiation oncology areas.

Area adequate.

b. Package receipt areas.

Area adequate.

c. Seed implant preparation areas.

Area adequate.

d. Seed storage areas.

Area adequate.

5. Evaluation of patient treatment results

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

Digital radiography.

January 14, 2009, version

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

**VA Medical Center, Durham, North Carolina
Inspection January 26-27, 2009**

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

Digital radiography.

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

Yes.

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

Part 2 completed by AU after implantation, but before completion of procedure.

- e. Post implant CT scans: when completed?

CT scan acquired the day after implantation, but if D-90 dose less than 80% a second post-implant CT is performed 4 to 6 weeks to assess dose.

- 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?

Post-plan completed within 1 week of implantation. AU draws contours of prostate and other organs. Seed location corrected by physicist. Yes, rectal dose is assessed (see spread sheet of patient results).

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

Yes.

- h. Clinical quality assurance, including peer review.

Each case is reviewed by a second authorized user physician.

6. Workload data

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

Preloaded needles.

- b. Date of program inception.

January 26, 1999.

January 14, 2009, version

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

**VA Medical Center, Durham, North Carolina
Inspection January 26-27, 2009**

c. Number of patients implanted per year.

40 cases per year; 217 cases performed since 1999.

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

IsoAid Advantage I-125 Model No. AIA-125A; seeds are preloaded into needles in a configuration called Vari-Strand by Advanced Care Medical.