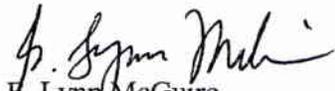


**DEPARTMENT OF  
VETERANS AFFAIRS**

**Memorandum**

Date: **JAN 15 2009**  
From: Director, VHA National Health Physics Program (115HP/NLR)  
Subj: Radiation Safety Program Inspection - Inspection Report 618-08-I02  
To: Director (618/00), VA Medical Center, Minneapolis, Minnesota,

1. Joseph Wissing, VHA National Health Physics Program (NHPP), performed an announced inspection of the radiation safety program at the VA Medical Center, Minneapolis, Minnesota, on December 8, 2008, with continuing review through January 5, 2009. This inspection focused entirely on permanent implant prostate brachytherapy and did not serve as a routine NHPP inspection of the radiation safety program.
2. The inspection report is attached. The report consists of an NHPP Form 591 with no violations cited, a permanent implant prostate brachytherapy checklist completed during this inspection, and a list of recommendations.
3. You are not required to respond to this memorandum or return a signed NHPP Form 591.
4. Thank you for the courtesy and cooperation extended during the inspection. Please contact Mr. Wissing at 734-845-3083, if you have any questions about the inspection.

  
E. Lynn McGuire

Attachment

cc: Chair, National Radiation Safety Committee  
Network Director, VISN 23 (10N23)

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

<p>1. PERMITTEE/PERMIT NUMBER:</p> <p>VA Medical Center Minneapolis, Minnesota Permit No. 22-01859-01</p>	<p>2. LOCATION(S) INSPECTED:</p> <p>One Veterans Drive Minneapolis, Minnesota 55417</p>
<p>3. INSPECTION DATE(S): December 8, 2008 – January 5, 2009</p>	<p>4. INSPECTION REPORT NUMBER: 618-08-102</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:

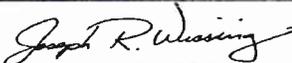
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited, are not being cited because they were self-identified, non-repetitive, corrective action was or is being taken, 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:

**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	Joseph R. Wissing		January 5, 2009

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

VA Medical Center, Minneapolis, Minnesota  
December 8, 2008 – January 5, 2009

### 1. Handling and security of sealed sources

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

The Radiation Safety Officer (RSO) is responsible for package receipt and associated survey records. The RSO is also responsible for the policy and procedures. Written policies and procedures are maintained by the RSO with copies maintained within service manuals. Packages containing seeds are delivered to the warehouse. The RSO is notified of received packages and retrieves and transfers the packages to Radiation Oncology Service, Building 49, Room SV-13, where the package receipt surveys are performed. Results of package monitoring are recorded on a receipt log record sheet. Procedures and records appear to conform to NRC regulations.

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

The RSO and radiation oncology dosimetrist are responsible for these procedures. The seeds are stored in a locked shielded container in Radiation Oncology Service, Building 49, Room SV-13. The room is secured with a standard door lock and is locked at all times. Excess seeds and calibration seeds are temporarily stored in this room until the RSO transfers them to the final radioactive waste storage area. Procedures and records appear to conform to NRC regulations and permit conditions.

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

The dosimetrist is responsible for records accounting for seeds used in implant procedures and extra or excreted seeds to be decayed on site. Extra or excreted seeds are never reused. New forms for record keeping were implemented approximately 2 months ago. Procedures and records appear to conform to NRC regulations.

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

Procedures and records appear to conform to NRC regulations.

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

Seeds are decayed on site. Unused seeds are temporarily stored in Room SV-13 until the RSO picks them up and moves them to the Radiation Safety Waste Disposal Room for decay in storage. Procedures and records appear to conform to NRC regulations.

### 2. Preparations for seed implant procedures

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

The RSO and Radiation Oncology Service maintain written policies and procedures. The written directive is a 3-page form initiated by the authorized user. The form includes the

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

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written directive, patient identification by at least two methods, pre/post-treatment verification, computer treatment planned source requirements, post-treatment source information, final seed accountability, and dose verification. Written policies and procedures appear to conform to NRC regulations.

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

See above. Two checks for patient identity verification are on the form. The authorized user and dosimetrist confirm the written directive and pre-plan prior to implant including number and strength of seeds. This procedure appears to conform to NRC regulations.

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

TRUS is performed typically 30 days before an implant. Ultrasound images are used to measure the size of the prostate.

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

The dosimetrist creates the pre-plan. Ultrasound images cannot be directly transferred into the treatment planning software, as the ultrasound machine is not DICOM compliant. A 3-D pre-plan is prepared from printed hardcopy 2D ultrasound images. The actual needle template is placed over the transverse ultrasound image. Transverse plane images provide right and left, and anterior and posterior dimensions of the prostate. Sagittal images yield height, width, and length measurements of the prostate. From these, the pre-plan is generated.

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

Completed by the authorized user physician before any seeds are implanted. Records appear to conform to NRC regulations.

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

Performed by dosimetrist or physicist after the procedure is completed using a Ludlum Model 3 portable survey meter equipped with a GM pancake probe. The surveys include the OR procedure area, suction containers, drainage basin, loading/needle storage boxes, floor, table, trash containers, linens, catheter bag, all needles, and other areas deemed appropriate. Surveys and records appear to conform to NRC regulations.

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

Patients are released in accordance with NRC release criteria (1 mR/hr @ 1 meter). Records of surveys are recorded in the 3-page QM form noted above. Survey is performed by a

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dosimetrist or physicist. Patient release procedures, surveys, and records appear to meet regulatory requirements.

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 above. Survey equipment is calibrated at least annually using I-129 and the RSO maintains equipment calibration certificates. These appear to meet regulatory requirements. An outside vendor calibrates the meter. Records are on file with the RSO.

i. Patient instructions (10 CFR 35.75).

The authorized user provides the patients with verbal and written instructions. Written instructions are given to the patient. These appear to meet regulatory requirements.

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

Due to a change in the operating room sterilization policy, 10% of the seeds are independently calibrated by a third party measuring activity. Prior to the change, seeds were calibrated using Standard Imaging Max 4000 electrometer calibrated by the University of Wisconsin Accredited Dosimetry Calibration Laboratory and well-type ionization chamber calibrated by the University of Wisconsin Accredited Dosimetry Calibration Laboratory. Records indicate all seeds are measured by the manufacturer. Policy, procedures, and records appear to meet regulatory compliance.

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

The physicist performs the acceptance testing of the VariSeed™ computer. Records are maintained by Radiation Oncology Service. The RSO is knowledgeable of the testing results. Records appear to meet regulatory requirements.

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

The ultrasound unit is calibrated for image quality and measurement by biomedical engineering. The ultrasound unit is a BK Falcon and as noted previously, it is not DICOM compliant. A test of CT image transfer was performed and noted in binder labeled VariSeed™ 7.1, Install June 6, 2006, where significant deficiencies were not identified. Biomedical engineering maintains records of ultrasound tests and calibrations. Radiation oncology staff does not review details of biomedical engineering reports, but merely receives a pass/fail report from Biomedical Engineering Service. Quality assurance of imaging does not appear to be in accordance with the ACR Practice Guideline for Transperineal Permanent Brachytherapy of Prostate Cancer. This is a recommendation for improvement.

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

The RSO, dosimetrist, and physicist are prepared for such events and incidents. The new authorized user and new physicist were knowledgeable with NRC's definition of a medical event as Minnesota's regulations are consistent with NRC's. The RSO and new authorized user gave assurances and committed to review all NRC and VA requirements related to medical event regulations including the definition of a medical event and actions that must be taken if one occurs prior to the new authorized user's first implant procedure. Deviations from regulatory requirements were not identified.

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

The permit is a broad-scope. There is one new authorized user. The user was approved by the RSC on the basis of being named on an agreement state license. RSC approval is consistent with NRC regulations and MML permit conditions.

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

Facility does not have formal written procedures in place to attempt to detect leaking seeds before an implant and protect a patient if leaking seeds are discovered to have been implanted in a patient. The RSO committed to contact other programs to obtain written procedures to be implemented. This is a recommendation for improvement.

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

Training is provided by the RSO and dosimetrist on an ongoing basis. Interviews demonstrated staff has an acceptable level of knowledge regarding regulatory requirements, internal policies and procedures, and safety procedures and precautions regarding this use. Staff responses to questions demonstrate training is appropriate in content and is effective.

q. Usual type of anesthesia?

The anesthesiologist decides on the best course of anesthesia. General anesthesia is typically used.

r. Prescribed dose for each radionuclide used?

144 Gy for I-125 using 0.31 mCi per seed  
125 Gy for Pd-103 using 1.4 mCi per seed

Pd-103 has not been used in years and the new authorized user does not intend to use Pd-103 seeds. Boost dose treatments are rarely used.

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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?

TRUS images are stored on floppy disks. As noted previously, the ultrasound machine is not DICOM compliant. X-ray radiographs taken during the procedure are stored on BRIT PACS and stored forever. One post-implant radiograph taken in the operating room is printed and maintained in the patient record and stored in BRIT PACS. Local VariSeed™ computers are backed up on the radiation therapy share drive and kept permanently. VA medical center IT Service backs up shared drives. CT images are stored and backed up on BRIT PACS.

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

Yes. Failure to have an ultrasound machine that generates DICOM images prevents uploading of ultrasound images into treatment planning software.

3. Performance-based interviews and observations

a. Authorized user physicians.

Xing Wang, M.D., the new authorized user physician - Based on performance-based interviews, he appeared to be adequately familiar with the NRC definition of a medical event. Additional training will be provided by the RSO prior to his first implant treatment.

b. Medical physicists and dosimetrists.

Joseph Lynch, Dosimetrist - Based on performance-based interviews, he appeared to be adequately familiar with the NRC definition of a medical event and overall radiation safety program procedures.

Lihong Qin, Ph.D., Physicist - Based on performance-based interviews, she appeared to be adequately familiar with the NRC definition of a medical event and overall radiation safety program procedures.

Jane Johnson, Ph.D., Physicist (University of Minnesota) - Based on performance-based interviews, she appeared to be adequately familiar with the NRC definition of a medical event. Additional training will be provided by the RSO prior to her first implant treatment.

c. Other physicians including urologists and/or residents. None.

d. Radiation Safety Officer.

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

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

e. Support staff. None interviewed.

4. Performance-based tours and observations

a. Radiation oncology areas.

Toured radiation oncology seed preparation and temporary storage area. No violations noted.

b. Package receipt areas.

Toured package receipt area. No violations noted.

c. Seed implant preparation areas.

Toured radiation oncology seed preparation area. No violations noted.

d. Seed storage areas.

Toured radiation oncology seed temporary storage area. No violations noted.

5. Evaluation of patient treatment results

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

A "Hybrid Interactive" technique that utilizes biplane ultrasound and fluoroscopy for both needle placement within the prostate gland and subsequent seed placement and spacing is used. This is performed in the operating room during the procedure.

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

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

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

Completed by authorized user physician the same day of the implant. No violations noted.

e. Post-implant CT scans: when completed?

Performed the same day. CT is transferred to VariSeed™ software to calculate same day D90.

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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-plans are completed within 2 weeks after implants. The dosimetrist draws the contours on VariSeed™ and the authorized user draws any changes on the printed plan. If significant contour changes in volume are made, post-plans are redone with new contours. Seed locations are found by software and manually corrected as necessary. Indices of rectal dose are not typically calculated. Software generates a D30 rectal dose assessment by default.

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

The authorized user physician and dosimetrist review all post plans to verify V100 and D90 meet requirements set by AAPM Task Group 64.

h. Clinical quality assurance, including peer review.

Not formalized. The authorized user physician and dosimetrist who are experienced in prostate brachytherapy review each post-plan. Specific items reviewed include but are not limited to contours of anatomical structures, doses to structures, radionuclide, number, and activity of seeds implanted.

### 6. Workload data

a. Method of implantation: Mick applicator

b. Date of program inception: January 2002

c. Number of patients implanted per year.

2002 - 64

2003 - 59

2004 - 45

2005 - 58

2006 - 49

2007 - 57

2008 – 28 (last implant performed on September 18, 2008)

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

I-125      Iso Aid Model IAI-125A  
            I-Plant Model 3500  
            Core Oncology Model 125SL

Pd-103    IBt Model 1032P

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Best Model 2335

**7. Persons contacted**

S. Kleinglass, Medical Center Director <sup>1</sup>  
J. Drucker, M.D., Chief of Staff <sup>1,2,3</sup>  
R. Barke, M.D., Chief, Surgery Service <sup>1</sup>  
M. Mylan, Ph.D., Associate Director <sup>1</sup>  
J. Silva, M.D., Chief, Radiation Oncology Service <sup>1,2,3</sup>  
B. Larson, M.D., Chair, Radiation Safety Committee <sup>3</sup>  
X. Wang, M.D., Authorized User Physician <sup>3</sup>  
J. Johnson, Physicist, University of Minnesota <sup>3</sup>  
L. Qin, Physicist, Radiation Oncology Service <sup>3</sup>  
J. Lynch, Dosimetrist, Radiation Oncology Service <sup>2,3</sup>  
T. Hensch, Radiation Safety Officer <sup>2,3</sup>  
J. Schmitz, Dosimetrist, Radiation Oncology Service <sup>3</sup>  
L. Duffy, Acting AA to Chief of Staff <sup>1</sup>  
S. Sheridan, Staff Assistant to Director <sup>1</sup>

1. Individual(s) present at entrance meeting
2. Individual(s) present at exit meeting
3. Individual(s) present or participating in inspection discussions

**Radiation Safety Program Inspection**  
**VA Medical Center, Minneapolis, Minnesota**  
**December 8, 2008 – January 5, 2009**

**Recommendations**

1. The American College of Radiology *Practice Guideline for Transperineal Permanent Brachytherapy for Prostate Cancer* recommends a quality assurance program for the transrectal ultrasound system (TRUS) used for volume studies before procedures and for real-time guidance during procedures. However, such quality assurance is not being performed. Furthermore, there is no formal quality assurance for the transfer of CT images to the treatment planning computer system.

Recommendation: It is recommended that Radiation Oncology Service staff and the Radiation Safety Officer develop and oversee a technical quality assurance program for the TRUS, for accurate transfer of the TRUS images to the treatment planning system, and for the accurate transfer of CT images to the treatment planning system.

2. Digital TRUS images cannot be transferred to the VariSeed™ treatment planning computer because the current ultrasound machine is not DICOM compliant.

Recommendation: The medical center needs to find a solution consistent with current standards of practice and procedures used by the new authorized user physician enabling the transfer of digital TRUS images to the VariSeed™ treatment planning computer.

3. Radiation Oncology Service uses the Varian VariSeed™ software product for treatment planning. The VariSeed™ software is in need of an upgrade. The use of current software is critical to ensure medical care meets current standards of practice.

Recommendation: Obtain and install the most current VariSeed™ software as recommended by radiation oncology staff.

4. Current policies and procedures did not include procedures or actions to be taken for leaking seeds.

Recommendation: It is recommended that Radiation Oncology Service staff and the Radiation Safety Officer develop and implement policies and procedures for leaking seeds.

5. There is no formalized physician and medical physicist peer review of permanent implant prostate brachytherapy procedures and treatments.

Recommendation: Improve physician and physicist peer review by establishing a formal system for physician and physicist peer review regarding permanent implant prostate brachytherapy procedures and treatments.