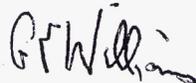


**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

Date: SEP 04 2009
From: Interim Director, VHA National Health Physics Program (115HP/NLR)
Subj: Radiation Safety Program Inspection - Oncology Inspection Report 528A8-09-I01
To: Director (528A8/00), Samuel S. Stratton VA Medical Center, Albany, New York

1. Edwin M. Leidholdt, Jr., Ph.D., and Joseph Wissing, VHA National Health Physics Program (NHPP), performed an announced inspection of the radiation safety program at the Samuel S. Stratton VA Medical Center, Albany, New York, on August 18-19, 2009. 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 no violations cited and a prostate brachytherapy checklist completed during this inspection.
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 Dr. Leidholdt at 707-562-8374, or Joseph Wissing at 734-845-3083, if you have any questions about the inspection.



Gary E. Williams

Attachment

cc: Chair, National Radiation Safety Committee
Network Director, VISN 2 (10N2)
Director, VHA National Radiology Program
Director, VHA National Radiation Oncology Program

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. PERMITTEE/PERMIT NUMBER:</p> <p>Samuel S. Stratton VA Medical Center Albany, New York 31-02755-05</p>	<p>2. LOCATION(S) INSPECTED:</p> <p>113 Holland Avenue Albany, New York 12208</p>
<p>3. INSPECTION DATES: August 18-19, 2009</p>	<p>4. INSPECTION REPORT NUMBER: 528A8-09-I01</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	Edwin M. Leidholdt, Jr., Ph.D.		August 19, 2009

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist
(Samuel S. Stratton VA Medical Center, Albany, New York – August 18-19, 2009)

1. Handling and security of sealed sources

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

Incoming packages are received by the warehouse and promptly transported to Nuclear Medicine Service by warehouse staff. The Radiation Safety Officer (RSO) performs and documents receipt surveys. Radioactive material package receipt surveys and records appear to conform to NRC and VA requirements and permit conditions.

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

Seeds are stored in a locked cabinet in a locked room in Radiation Oncology Service. The inspectors asked the RSO to review the security of keys to the locked cabinet during the August 2008 NHPP inspection. The RSO did review the security of keys with radiation oncology staff. The keys to the storage safe now are under a separate lock and key system. Security procedures appear to conform to NRC and VA requirements and permit conditions.

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

The August 27-28, 2008, NHPP inspection found that electronic record keeping did not fully conform to 10 CFR 35.2406, but the information missing from the electronic records was available in patient charts or files. During that inspection, the inspectors asked the RSO to modify the electronic record format to conform to 10 CFR 35.2406 and ensure that these records are backed up. During this inspection, the inspectors verified the electronic record format was modified to conform to 10 CFR 35.2406 and the files are backed up onto a server using the facility network. The RSO and oncology staff perform a physical inventory all of seeds prior to implantation and after the completion of the treatment. The records of source accountability appear to conform to NRC and VA requirements and permit conditions.

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

The RSO performs a physical inventory of all sealed sources at least quarterly, including brachytherapy seeds in storage for decay. The RSO maintains a list of all brachytherapy seeds used and in possession. The records of sealed source inventories appear to conform to NRC and VA requirements and permit conditions.

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

Unused seeds are returned to the vendor or stored for decay. Biologically contaminated seeds are stored for decay. The seeds returned to the vendor are physically counted by the RSO and a staff member of radiation oncology. The records of sealed source inventories and source disposal appear to conform to NRC and VA requirements and permit conditions.

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2. Preparations for seed implant procedures

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

The permittee revised written procedures and associated checklists and forms. These revised documents were prepared, reviewed, and approved by the RSO, radiation oncology staff, and Radiation Safety Committee (RSC). The permittee incorporated into their procedures the VA standard procedures attached to the NHPP Memorandum dated January 28, 2009. The facility's procedures were dated March 17, 2009. The revised procedures appear to conform to NRC and VA requirements and permit conditions.

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

Patient identity verification, written directives, and treatment plan checking procedures appear to conform to NRC and VA requirements and permit conditions.

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

The pre-implant imaging volume study is typically done about 2 weeks before an implant. A transrectal ultrasound (TRUS) system is used.

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

The pre-plan is prepared by a medical physicist or dosimetrist. An authorized user physician draws the contours of the prostate and other organs.

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

The preparation of the pre-implant parts of the written directives appears to conform to NRC regulations and the VA standard procedures. The authorized user physicians prescribe 144 Gy for I-125 seeds when used as monotherapy.

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

Surveys after source implant for misplaced seeds and associated records appear to conform to NRC and VA requirements and permit conditions.

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

Patient release procedures, surveys, and associated required records appear to conform to NRC and VA requirements and permit conditions.

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- h. Patient release measurements after source implantation with a survey meter capable of accurately measuring energy emitted or a method to correct measurements for energy response.

Surveys for patient release are being performed mostly with a Fluke/Victoreen 451B ambient air ionization chamber survey meter. During the previous NHPP inspection, it was noted a correction was not being made for the energy response of the survey meter. A review of the response curve in the operator's manual indicated that the indicated exposure rate is about 85% of the actual exposure rate for the x-rays emitted by I-125. The previous NHPP inspection results tasked the RSO to modify the survey record to indicate survey measurements that are energy corrected. During this inspection, the inspectors verified the RSO has implemented and documented energy correction to the survey meter readings with results of surveys incorporating the energy correction factor.

- i. Patient instructions (10 CFR 35.75).

Patient instructions and associated records of instructions provided to patients appear to conform to NRC and VA requirements and permit conditions.

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

The facility purchases I-125 seeds from Bard. Documents from Bard attest that each seed is individually assayed. Furthermore, 10 seeds or 10% of the seeds are calibrated by Bard in accordance with national standards. In addition, the facility purchases two calibration seeds with each order. These seeds are assayed using a well-type ionization chamber and electrometer, which are calibrated by an ADCL every 2 years. This procedure has not changed since the last NHPP inspection. Calibration measurements of sources substantially conform to NRC and VA requirements and permit conditions.

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

The facility uses the CMS Interplant treatment planning system (TPS). The facility was not able to locate records of acceptance testing of the system during the last NHPP inspection. The facility was tasked to either to locate the records or repeat the testing.

During this inspection, the facility was able to locate and provide old acceptance testing records back to 2004, in conjunction with recently performed tests in 2007 and 2008. Records were provided and reviewed with NRC regulations. A set of quality control tests are performed monthly and annually by the oncology staff to ensure accurate performance of the equipment. The facility has not purchased any new equipment or software since the last NHPP inspection. A new CIRS Model 045 TRUS phantom was purchased and it has been incorporated into the ongoing quality control program.

A recommendation was made to modify written procedures to refer to quality control protocols accepted by nationally recognized bodies. Acceptance testing records of the TPS substantially conform to NRC and VA requirements and permit conditions.

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

The previous NHPP inspection noted that testing of the geometric fidelity of the TRUS is being measured, but image quality is not. Testing of the CT and transfer of its images to the TPS was not being performed. The previous NHPP inspection asked the facility to initiate testing of the CT and transfer of its images to the TPS.

A new CIRS Model 045 seed implant phantom was purchased and has been incorporated into the ongoing quality control program that includes testing of image quality of the TRUS equipment. Currently, CT images are not transferred via a computer network. CT images are copied onto a CD or DVD and manually transferred to the TPS. Image quality is verified by the physicist reviewing the parameters of spatial accuracy, resolution, and orientation using the same ultrasound phantom. Quality assurance of imaging substantially conforms to VA requirements and is generally consistent with standards of practice and manufacturers recommendations.

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

The inspectors interviewed radiation oncology staff and the RSO and concluded they had an adequate understanding of requirements for a medical event or other incident circumstances, including after-hours recall or notifications of key staff.

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

The currently approved authorized user physicians are “grandfathered” authorized users previously approved by the local RSC under an NRC license of broad-scope prior to the VA master materials license. RSC approval of physician authorized users (broad-scope) conforms to NRC and VA requirements and permit conditions.

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

Surveys of seed packaging and empty needles that could indicate the possibility of leaking seeds have not identified any leaking seeds. The facility has procedures to evaluate for possible leaking seeds and procedures for leaking seeds. These appear to be adequate.

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

The RSO ensures all participating staff receives initial and periodic (at least annually) refresher radiation safety training consistent with their roles in the brachytherapy program. Interviews with an authorized user physician, medical physicists, dosimetrists, and the RSO indicated they had adequate understanding of NRC requirements, VA procedures, and facility procedures for prostate brachytherapy. Training (i.e., initial and

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periodic) for authorized user physicians, medical physicists, and other staff conform to NRC and VA requirements and permit conditions.

The inspectors recommended improvements to the training of participating urology residents to ensure full compliance with 10 CFR 35.27.

q. Usual type of anesthesia.

Anesthesia is patient specific and dictated by each physician. Robert Belgam, M.D., typically uses general anesthesia and Ralf Kiehl, M.D., typically uses spinal blocking anesthesia.

r. Prescribed dose for each radionuclide used.

For I-125, 144 Gy is the typical full-implant prescription dose and the boost dose prescription is typically 108 Gy. The dose prescriptions are signed by the authorized user physicians.

Pd-103 was used in the past, but has not been used in the last 2 years.

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?

All images and raw data are stored electronically on local department computers. All post-plan records (data and images) are backed up via DVD. Currently, all images and associated data are retained indefinitely. Hard copies of all records and images are maintained in patient charts.

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

Deficiencies with digital information transfer hindering the preparation of pre- and post-plans for prostate brachytherapy were not identified during the inspection or reported by radiation oncology staff.

3. Performance-based interviews and observations

All staff listed below demonstrated adequate knowledge of NRC and VA regulatory requirements and brachytherapy procedures for successful brachytherapy treatments. See Section 7(e) and 10.

a. Authorized user physicians.

Robert Belgam, M.D., interviewed.

Ralf Kiehl, M.D., not available and not interviewed

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b. Medical physicists and dosimetrists.

John P. Balog, Ph.D., interviewed
Viola Heleba, CMD, interviewed
Yanni Stathakos, interviewed
Wade Smith, Ph.D., interviewed

c. Other physicians including urologists and/or residents.

Resident urologists participate in procedures. None interviewed.
Urologists do not typically participate in procedures. None interviewed.

d. Radiation Safety Officer.

Kris Cipperley is present and involved in all procedures and she was interviewed.

e. Support staff.

None identified and none interviewed.

f. Person completing internal audit.

Kris Cipperley, interviewed.

4. Performance-based tours and observations

a. Radiation oncology areas.

A room in Radiation Oncology Service is used for seed storage and assays of calibration seeds. There were no changes in areas of use since the last NHPP inspection. Authorized areas of use are consistent with permit conditions.

b. Package receipt areas.

Incoming packages are received in the warehouse, promptly taken to Nuclear Medicine Service, and transferred to the RSO, who performs the package receipt surveys. There were no changes in areas of use since the last NHPP inspection. Authorized areas of use are consistent with permit conditions.

c. Seed implant preparation areas.

A room in Radiation Oncology Service is used for seed implant preparation. There were no changes in areas of use since the last NHPP inspection. Authorized areas of use are consistent with permit conditions.

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d. Seed storage areas.

A room in Radiation Oncology Service is used for seed storage. There were no changes in areas of use since the last NHPP inspection. Authorized areas of use are consistent with permit conditions.

5. Evaluation of patient treatment results

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

TRUS and fluoroscopy are used during each procedure to determine proper seed placement. A fluorograph taken at end of each procedure is also used to assess seed placement and accountability. CT images are obtained after procedure and post-plans are prepared within about a week after the CT imaging.

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

Yes. Fluoroscopy is used to supplement TRUS during the brachytherapy procedures.

c. Confirm radiograph acquired after implant to verify seed placement.

Yes. A radiograph is acquired after each implant to verify seed placement.

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

The post-implant part of the written directive is completed in the operating room, after the implant is performed.

e. Post-implant CT scans: when completed?

Dr. Belgam has CT scans typically performed on the day after each implant. Dr. Kiehl has CT scans typically performed about 3 weeks after each implant. Authorized user physicians take into account patient needs as well as clinical outcomes and regulatory compliance when scheduling the post-implant CTs.

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 typically completed within 1 week of post-implant CT imaging. The authorized user physician contours the prostate and other organs. Seed locations found by software are manually corrected and documented. The final assessment of delivered dose using D90 values is compared to the prescribed treatment dose and determined by the authorized user physician. An index of rectal dose, the R100, is calculated and documented.

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- g. Review of treatment results to dose criteria D90.

Dose indices, including the D90, are calculated for each patient. The inspectors reviewed D90 values for all treatments since the last NHPP inspection, approximated 15 brachytherapy treatments. All brachytherapy treatment post-plan D90s exceeded 80% of the prescribed dose of 144 Gy.

- h. Review of treatment results to V100 criteria.

Dose indices, including the V100, are calculated and documented for each patient.

- i. Clinical quality assurance, including peer review.

The previous NHPP inspection reported that Dr. Belgam stated there was only limited peer review, but that a more complete peer review process was being instituted.

During this inspection, the inspectors determined the permittee has implemented a peer review process. The post-plans of all treatments are reviewed by the non-treating authorized user physician. One hundred percent of all pre-plans are reviewed by non-planning physicist or dosimetrist.

6. Workload data

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

Preloaded needles are used as the method of implantation.

- b. Date of program inception.

The program inception date is March 5, 2004.

- c. Number of patients implanted per year.

On average, the permittee performs 16 to 20 implants per year.

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

For the past 3 years, permanent prostate brachytherapy implant procedures utilized I-125. Currently the manufacturer is Bard and the seed model is STM1251.

7. Implementation of standard procedures for training (including for medical events)

- a. Periodicity of training and how completed.

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The RSO performs training on an as needed basis but no less than annually. The RSO completes training through handouts, electronic PowerPoint presentations, and face-to-face communications as needed.

b. Review of training records.

RSO maintains all training records. Training records appear to meet regulatory requirements.

c. Methods used to evaluate effectiveness of training.

RSO supervises the radiation safety aspects of all procedures and periodically reviews the program's records. She assesses training effectiveness by observation of the performance of the staff members.

d. Groups receiving training and evaluation of training topics used for each group.

All involved staff receives training appropriate for their jobs consistent with NRC and VA requirements.

Warehouse staff receives training on receipt of radioactive materials.

Physicians receive training on all aspects of the applicable procedures.

Physicists and dosimetrists receive training on all aspects of the applicable procedures.

Urology residents work under the supervision of the authorized users and RSO.

e. Focus to the key topics of safety culture, reporting concerns or issues through chain of command, use of dose as metric for medical events, roles and responsibilities for seed implant team members, avoiding undue reliance on contractors, consultants, or affiliated universities, and identifying and reporting medical events.

Focus to safety culture statement. The RSO and radiation oncology staff, through consistent and comprehensive communications, frequent training, and audits have developed a radiation safety program consistent with NRC's and NHPP's focus for an effective safety culture. Management and employees appeared dedicated to putting safety first, having a questioning attitude, and a willingness to stop work, if needed, to achieve regulatory compliance. RSO stop-work authority is documented. The RSO is well respected among medical center staff as well as executive management. Interviews with employees indicated they felt free and comfortable to raise safety concerns, both to their management and to the RSO, without fear of retaliation. The inspector believes this attitude and safety culture fostered by the radiation safety program staff is consistent with NHPP FAQ 09-01. Recommendations for improvement were not identified.

8. Implementation of standard procedure for written directives

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- a. Review of written procedures and forms for written directives.

The permittee has implemented the VHA standard procedures for written directives. The forms for written directives document all information as required by NRC regulations.

- b. Review of completed written directives including results of quarterly audits.

The permittee has reviewed completed written directives for all treatments since the last NHPP inspection. The RSO performs audits of written directives at least quarterly. Results of audits are presented to RSC during quarterly meetings.

9. Implementation of standard procedure for clinical requirements

- a. Review of written procedures and forms to incorporate clinical requirements.

The permittee has implemented the VHA standard procedure for clinical requirements.

The TRUS system does not have an inherent grid and it cannot be matched to the TPS. The only grid is the TPS grid, which is used during implants attached to the TRUS system for needle guidance.

- b. Review of completed records that incorporate clinical requirements.

The permittee has reviewed completed records for all treatments since the last NHPP inspection. The RSO performs audits at least quarterly. Results of audits are presented to the RSC during quarterly meetings.

10. Overall evaluation of program implementation and oversight

- a. Compliance with regulatory requirements. Yes

- b. Implementation of VHA standard procedures. Yes

- c. Avoiding undue reliance on consultants, contractors, and affiliated universities.

Yes. The permittee does not have an undue reliance on consultants, contractors, and affiliated universities.

- d. Focus to a safety culture and willingness to report safety concerns or issues.

Yes. The permittee has a strong focus to a safety culture and willingness to report safety concerns or issues.

- e. Oversight by executive management, Radiation Safety Committee, and Radiation Safety Officer.

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Yes. Medical center executive management has implemented adequate oversight mechanisms of the radiation safety and permanent implant brachytherapy program. The RSO and RSC provide consistent and appropriate status reports to the RSC. A member of executive management is a member of the RSC. Quarterly RSC minutes are reviewed by the medical center's Environment of Care Committee.

- f. Understanding of roles and responsibilities by different seed implant team members.

Yes. All staff involved in the brachytherapy implant program has an adequate understanding of their roles and responsibilities for ensuring successful implant treatments and regulatory compliance.

- g. Adequate and sufficient training and allotted time to achieve regulatory compliance.

Yes. The permittee performs adequate and sufficient training and allotted time to achieve regulatory compliance for ensuring successful implant treatments and regulatory compliance.

11. Personnel Contacted

Mary-Ellen Piche, Director ²

Douglas Erickson, Associate Director ²

Robert Belgam, M.D., Chief, Radiation Oncology Service and Authorized User Physician ^{1,2}

John P. Balog, Ph.D., Medical Physicist, Radiation Oncology Service ¹

Viola Heleba, CMD, Dosimetrist, Radiation Oncology Service ^{1,2}

Yanni Stathakos, Dosimetrist, Radiation Oncology Service ¹

Wade Smith, Ph.D., Physicist, Radiation Oncology Service ^{1,2}

Kris Cipperley, Radiation Safety Officer ^{1,2}

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

Note: Executive management were off-site and not available for an entrance briefing.