

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

Date: **APR 23 2009**

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

Subj: Radiation Safety Program Inspection and Notice of Violation - Inspection Report 691-09-I01

To: Director (691/00), VA Greater Los Angeles Healthcare System, Los Angeles, California

1. Edwin M. Leidholdt, Jr., Ph.D., and Paul Yurko, M.S., of the VHA National Health Physics Program, completed a reactive inspection at your healthcare system beginning January 21, 2009, with continuing review through March 26, 2009. The initial inspection focus was the permanent implant prostate brachytherapy program. The final scope of the inspection included all elements of a routine, core inspection.
2. The inspection report has four attachments. Attachment A is the inspection report narrative. Attachment B is a Notice of Violation citing a Severity Level IV violation related to the prostate brachytherapy program. Attachment C is an audit checklist with the results for a review of that program, and Attachment D is a list of recommendations based on the review.
3. You must respond to the Notice of Violation within 30 days of the date of this memorandum. You must follow the instructions in the Notice of Violation when preparing your response.
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

Attachments

cc: Chair, National Radiation Safety Committee
Network Director, VISN 22 (10N22)

RADIATION SAFETY PROGRAM INSPECTION
Inspection Report Number 691-09-I01
VA Greater Los Angeles Healthcare System, Los Angeles, California
January 21 - March 26, 2009

1. Introduction

a. Edwin M. Leidholdt, Jr., Ph.D., and Paul Yurko, M.S., VHA National Health Physics Program (NHPP), performed an announced reactive inspection of the radiation safety program at the VA Greater Los Angeles Healthcare System (GLAHCS), beginning on January 21, 2009. The initial focus of the inspection was permanent implant prostate brachytherapy (hereinafter referred to as "prostate brachytherapy"). The final scope of this inspection included two medical events discovered during reviews of patient treatments, a medical event discovered for a patient treatment on February 12, 2009, and all elements of a broad-scope permittee core inspection.

(1) The initial inspection focus was the prostate brachytherapy program. Due to the medical events involving prostate brachytherapy at several other VHA facilities, VHA committed to the Nuclear Regulatory Commission (NRC) to perform reactive inspections at all VHA facilities performing prostate brachytherapy. This inspection was initiated as part of that commitment. Also, the VA Deputy Under Secretary for Health directed each of these VHA facilities to send post-plans for 10 treatments to a designated VHA expert for review. The review for GLAHCS found that the post-implant CT images for one treatment were inadequate and raised the possibility this treatment might be a medical event. This treatment was reviewed during the inspection.

(2) Dr. Leidholdt conducted the initial on-site visit of this inspection during January 21-22, 2009. On January 22, 2009, he conducted a preliminary exit meeting with GLAHCS executive management, the Radiation Safety Officer (RSO), and Radiation Oncology Service senior staff. GLAHCS staff was requested to review implants previously performed to determine if any had been medical events due to doses to extraprostatic tissues exceeding by 50% or more the doses expected from the procedures. The inspection was left open.

(3) GLAHCS reviewed the previous prostate brachytherapy procedures and, reported two medical events involving prostate brachytherapy to NHPP on January 27, 2009. NHPP notified the NRC Operations Center on January 28, 2009, of the events. The bases for these events were seeds implanted outside of the patients' prostates.

(4) Another prostate implant procedure was performed at GLAHCS on February 12, 2009. On that date, after that procedure, GLAHCS staff discovered five of the implanted I-125 seeds were significantly outside the prostate toward the patient's perineum. GLAHCS reported this to NHPP on February 13, 2009, as a medical event. NHPP notified NRC of the event the same day.

(5) Dr. Leidholdt and Mr. Yurko performed an on-site visit to GLAHCS to evaluate the medical events during February 23-26, 2009. A core inspection of the radiation safety program was also performed during this visit. The exit meeting for the second visit was on February 26, 2009. The inspection was left open.

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- b. The inspection was closed on March 26, 2009.

2. Scope of inspection

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

- a. Interviews with GLAHCS and contract staff regarding the medical events.
- b. Reviews of records related to the medical events.
- c. A tour of facilities and review of equipment involved in the medical events.
- d. Review of GLAHCS initial actions regarding the medical events, including a review of effectiveness and comprehensiveness of the initial actions to prevent a recurrence.
- e. Review of compliance with other regulatory requirements under 10 CFR 35 for the prostate brachytherapy program.
- f. Evaluation of root (basic) causes for the medical events.
- g. Comparison of identified deficiencies with other therapy modalities to determine if the medical events were isolated occurrences or a programmatic issue.
- h. Evaluation of the radiation safety practices and regulatory compliance as a broad-scope permittee.

3. Findings and impressions (background information)

- a. The inspectors gathered information about the facility inspection history.
 - (1) The most recent NRC inspection, July 31-August 1, 2006, did not identify any violations.
 - (2) NHPP inspected GLAHCS during March 6-23, 2007, and cited two Severity Level IV violations. The first was for not reviewing all procedures requiring written directives and not reviewing the Quality Management Program. The second was for several issues, including the Radiation Oncology Service staff having made changes to the written procedures for prostate brachytherapy without Radiation Safety Committee (RSC) review and lack of RSO reviews of written directives for prostate brachytherapy procedures.
 - (3) A medical event involving prostate brachytherapy had occurred at GLAHCS before the inspection noted above and involved the first prostate brachytherapy procedure performed. This procedure, on March 31, 2004, resulted in 31 seeds being mistakenly implanted into the patient's bladder. The medical event was reported to NRC. NHPP conducted a reactive inspection that

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resulted in a report, dated May 11, 2004, citing several violations constituting two Severity Level III problems.

b. The inspectors gathered details about the history of the GLAHCS prostate brachytherapy program and workload.

(1) From program inception until March 20, 2009, 40 patients have been treated. In 2007, 13 procedures were performed and, in 2008, only 2 procedures were performed. One implant procedure has been performed to date in 2009.

(2) The first prostate brachytherapy procedure, performed on March 31, 2004, resulted in a medical event as described in Item 3a(3) above.

(3) On June 8, 2005, the second prostate brachytherapy procedure was performed.

(4) On or shortly before October 12, 2005, the written directive form was changed to state explicitly the prescribed dose as being to the D80. The D80 is defined as the maximal dose that covers 80% of the prostate volume.

(5) From June 8, 2005, until November 23, 2005, eight implant procedures were performed. However, post-plans and dose analyses for these procedures were not performed until, or after, January 19, 2006. The minutes from the March 8, 2006, RSC meeting state that, by the date of the meeting, post-plans had been performed for only four of the eight procedures. This extreme delay in performing post-plans was, and is, contrary to standards of care.

(6) In approximately March 2006, Radiation Oncology Service assumed control of a Picker PQ 5000 CT system from Radiology Service. This CT system was used for post-implant CT imaging of patients. Radiology Service trained Radiation Oncology Service therapists to operate the system, but daily quality assurance (QA) tests were not performed after Radiation Oncology Service assumed control.

(7) In October 2006, NHPP met with the GLAHCS Director and Chief of Staff to bring to their attention several implants with reported clinically-low D90s and excessive delays between implants and post-implant dose analyses.

(8) On November 14, 2006, a new transrectal ultrasound (TRUS) system was delivered and soon thereafter put into service. The urologist supervising the implants had raised an issue about image quality produced by the previous system.

(9) In the summer of 2007, the experienced urologist who had been supervising needle placement during all prostate brachytherapy procedures left the facility. This experienced urologist performed his last prostate brachytherapy procedures at GLAHCS on June 20, 2007.

(10) Following an implant procedure on May 16, 2007, post-implant CT images of the patient's pelvic region were acquired on June 25, 2007, using the Picker PQ 5000 scanner, for

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the purpose of dosimetric evaluation of the implant. In the CT images, the prostate was obscured by severe streak artifacts. Despite the artifacts, a post-plan was created using the CT images.

(11) In approximately March 2008, a Philips Brilliance CT simulator was installed in the Radiation Oncology Service, replacing the Picker PQ 5000 system.

(12) Since June 2007, until the end of February 2009, only three prostate brachytherapy procedures have been performed. In all three cases, a University of California, Los Angeles, Medical Center urologist, experienced in prostate brachytherapy procedures, mentored a staff urologist less experienced in prostate brachytherapy.

(13) In late October 2008, the external review of 10 implant procedures, as requested by the VA Deputy Under Secretary for Health, found the CT images for 1 of the GLAHCS treatments were inadequate and raised the possibility that this procedure, performed on May 16, 2007, may have been a medical event. (See Item 3b(10) above.) GLAHCS subsequently sent the implant records to another VHA expert for review. The second expert opined the CT images were not usable. GLAHCS then initiated efforts to have the patient return for a second CT scan.

(14) On February 2, 2009, the patient, whose implant procedure was performed on May 16, 2007, returned to GLAHCS for a second CT scan to allow a second post-plan to be created using better images. Several days later, the post-plan was created, the D90 was calculated as 84% of the prescribed dose, and the D80 was calculated as 94% of the prescribed dose.

(15) On February 12, 2009, a prostate brachytherapy procedure was performed. At the end of the procedure, patient imaging revealed 5 of 108 seeds were outside the patient's prostate. GLAHCS notified NHPP of a medical event the next day. Several days later, a post-plan was created. The D90 was calculated as 88% of the prescribed dose.

c. The inspectors gathered workflow information for prostate brachytherapy at GLAHCS.

(1) GLAHCS has a Radiation Oncology Service. The supervisory medical physicist is a full-time VA employee. Another medical physicist, a part-time contract employee, performs nearly all the medical physics duties regarding prostate brachytherapy, including preparation of pre-plans and post-plans and assisting in the operating room during implant procedures. Only one radiation oncology physician is currently approved as an authorized user for prostate brachytherapy; he is currently a full-time VA employee.

(2) GLAHCS obtains I-125 seeds, loaded in needles and sterilized, from a commercial vendor. The seeds are stranded. Seed strength assays are performed by the vendor and not by GLAHCS.

(3) Within about a month before each patient procedure, a urologist and the authorized user physician obtain TRUS images for the purpose of creating a treatment plan. Prostate contours are drawn on the images by the urologist. The images are transferred to a treatment planning computer system (TPS) and the medical physicist creates a treatment plan to achieve the dose

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distribution prescribed by the authorized user physician. The authorized user physician reviews and approves each pre-plan.

(4) The pre-implant part of the written directive is signed by the authorized user physician before the seeds are ordered.

(5) The supervisory medical physicist orders the pre-loaded needles from the seed vendor, currently Theragenics.

(6) The seed vendor ships a package to the facility for each procedure. The package is delivered directly to Nuclear Medicine Service. A nuclear medicine technologist performs the package receipt survey and contacts a medical physicist or dosimetrist in Radiation Oncology Service. The medical physicist or dosimetrist then brings the package to Radiation Oncology Service in Building 500 and stores the package in the "Radioisotope Storage Room."

(7) Seeds are implanted into patients in an operating room under TRUS guidance. Fluoroscopy is not used to supplement the TRUS imaging but is performed after each procedure. The treatment team includes the authorized user physician, a medical physicist, a urologist, an anesthesiologist, nurses, and a member of radiation safety staff. For all implants during the period from June 2005 until the end of June 2007, seeds were implanted by urology resident physicians under the direct supervision of a staff urologist and the authorized user physician. Since June 2007, three procedures were performed. In these procedures, the seeds were implanted by a staff urologist being mentored by an experienced urologist from the affiliated university or by the experienced urologist. Residents did not participate in these three procedures. The authorized user physician was present during these procedures.

(8) After a procedure, the patient recovers from the anesthesia in a post-surgical recovery room and, in most cases, is hospitalized overnight. CT images are currently obtained of the patient's pelvic region about 30 days after each procedure. CT images are transferred to the TPS, and a medical physicist contours the prostate and creates a post-plan to assess dose distribution. Indices of the prostate dose distribution, including V100 and D90, are calculated. The post-plan is typically created within about a week of the post-implant CT scan. The post-plan, including prostate contours, is reviewed by the authorized user physician.

4. Findings and impressions (compliance with NRC regulations regarding the prostate brachytherapy program and broad-scope uses of radioactive materials)

a. The inspectors confirmed regulatory compliance for the following.

(1) Methods and records for patient release radiation measurements under 10 CFR 35.75.

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

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

(4) RSC approval of the authorized user physician.

b. The inspectors used the "Transperineal Permanent Implant Prostate Seed Brachytherapy - Audit Checklist" to review the prostate brachytherapy program in detail. The audit checklist is provided as Attachment C. The recommendations from the audit are in Attachment D.

c. The inspectors reviewed actions to prevent a recurrence of the two violations cited in the NHPP Notice of Violation (NOV), dated April 20, 2007. The inspectors confirmed that actions listed in the NOV response, dated May 17, 2007, were implemented.

d. The inspectors evaluated the radiation safety program and regulatory compliance under the broad-scope permit for program elements other than prostate brachytherapy and did not identify any findings or deficiencies.

5. Findings and impressions (circumstances for prostate brachytherapy medical events in 2005)

a. The inspectors gathered information about circumstances for two prostate brachytherapy procedures in 2005 that GLAHCS declared to be medical events on January 27, 2009.

(1) The first of the procedures was performed on June 8, 2005. This was the second prostate brachytherapy procedure performed and the first performed after a period of over a year since the first procedure, which was declared to be a medical event. Although a CT scan was performed about a month later, a post-plan was not performed until at least 6 months later. The D90 calculated from this post-plan was 72% of the prescribed dose. The D90 was re-evaluated in 2009, from the original CT images, as 67%. The D80 calculated from this post-plan was 85% of prescribed dose. The D80 was re-evaluated in 2009, from the original CT images, as 83%.

(2) The second of these procedures was performed on November 23, 2005. It was the ninth prostate brachytherapy procedure performed at the facility and the eighth performed after prostate brachytherapy resumed in June 2005. Although a CT scan was performed about a month after the procedure, a post-plan was not performed until at least 2 months later. The D90 calculated from this post-plan was 77% of the prescribed dose. The D90 was re-evaluated in 2009, from the original CT images, as 76%. The D80 calculated from this post-plan was 92% of the prescribed dose. The D80 was re-evaluated in 2009, from the original CT images, as 88%.

(3) Interviews with the authorized user physician, medical physicist involved in prostate brachytherapy, supervisory medical physicist, and Chief, Radiation Oncology Service, found the facility was using the D80 (maximal dose covering 80% of the prostate volume) as a metric of dose to the prostate. This criterion was made explicit in written directives, beginning with a prostate brachytherapy procedure performed on October 12, 2005. Patient procedures with D80s exceeding 80% of the prescribed dose were not considered medical events.

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(4) As discussed above in Items 1a(2) and (3), these two medical events were discovered as part of a GLAHCS review, requested by an NHPP inspector as part of this inspection. The basis for the events was seeds implanted outside of the patients' prostates.

(5) The RSO noted that, in 2005, the focus for review by the medical physicist was to seeds inside the prostate and seeds in critical organs such as the rectum and bladder.

b. The inspectors attempted to identify the causes of the two medical events. The root cause or causes for the two medical events could not be determined with any degree of certainty.

(1) The two medical events occurred due to inadequate seed distributions achieved by the implanting physicians.

(2) Clinical reasons for not achieving adequate seed distributions are not within the scope of health physics expertise.

(3) The inspectors interviewed healthcare system staff participating in or familiar with the prostate brachytherapy program about the causes of the events.

(4) A causal factor for the June 8, 2005, implant procedure may have been a lack of recent experience performing implant procedures given that more than a year had elapsed since a procedure was performed at the facility and that only one procedure had been performed. If this was a significant causal factor of the inadequate seed distributions, a root cause would be "Training - Practice/Repetition Needs Improvement."

(5) Another causal factor may have been the image quality produced by the TRUS system used at the time. A new ultrasound system was delivered on November 14, 2006. The urologist who supervised seed implantation from June 2005 until June 20, 2007, had raised an issue about ultrasound image quality of the previous system. If this was a significant causal factor of the inadequate seed distributions, a root cause would be "Equipment Difficulty," in that the TRUS system used until November 2006 was reported to have been producing suboptimal images.

(6) Another causal factor may have been resident physician participation. According to the medical physicist and authorized user physician, most or sometimes all, seeds were implanted by resident physicians under the direction of the staff urologist. If this was a significant causal factor of the inadequate seed distributions, a root cause would be "Work Direction - Preparation and/or Supervision During Work," in that resident physicians implanted most or all seeds during the procedures. A graduated approach to resident physician participation, with the attending physician implanting most seeds until a resident physician gained experience, was apparently not employed.

(7) Another causal factor for the procedure performed on November 23, 2005, may have been that, for the procedures performed from June 8 through November 20, 2005, post-plans and dosimetric analyses were not performed until mid-January 2006 or later. Thus, the authorized

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user physician, urologist, and medical physicist lacked information on the quality of these implants. If this was a significant causal factor of the inadequate seed distributions, a root cause would be "Management System - Standards, Policies, or Administrative Controls Need Improvement," in that written procedures did not specify how soon a post-implant dosimetric analysis should be performed after each implant.

(8) These causal factors and root causes discussed above are not an established certainty. Other possible causal factors could include team or individual preparation, patient bowel preparation, overly conservative pre-plans, improper alignment of equipment and patient anatomy before each procedure during the pre-plan volume study, inadequate use of sagittal mode of the TRUS system, and lack of use of fluoroscopy during procedures.

c. The authorized user physician, supervisory medical physicist, and medical physicist who were primarily involved in the prostate brachytherapy program were asked why these procedures were not declared as medical events when the post-plans were performed. They stated the D80 was used as the dose metric at that time. The D80s for the two procedures, calculated in 2006, were 84.7% and 91.5% of the prescribed doses. The use of the D80 as the prescription dose metric was made explicit in written directives beginning October 12, 2005, but was not stated in writing before that. For implantation of seeds outside the intended treatment site, they stated that seeds outside the prostate in non-critical tissues were not considered to be potential medical events.

d. The inspectors identified one violation of NRC regulations for the two medical events.

(1) 10 CFR 35.41(a) requires each permittee to develop, implement, and maintain written procedures for prostate brachytherapy to provide high confidence each administration requiring a written directive is per the written directive. Contrary to this requirement, the permittee's written procedures did not require prompt post-implant dose evaluations and, in fact, for 3 procedures in 2005, dose evaluations were performed approximately 6, 5, and 3 months after post-implant CT images were acquired. Furthermore, these written procedures did not require a review of seeds outside of the prostate to determine if a medical event had occurred.

(2) A possible violation under 10 CFR 35.3045 for failure to report a medical event is held in abeyance given a lack of clear and explicit regulatory guidelines to determine a medical event for seeds outside the prostate.

e. The inspectors evaluated the root causes for the violation. The root causes for the violation were as follows.

(1) "Management System - Standard Policies, Procedures, or Administrative Controls Need Improvement," in that the written procedures did not specify a timeframe for the performance of post-implant dosimetric analyses after a prostate brachytherapy procedure was performed.

(2) "Procedures - Inadequate," in that written procedures did not specify considering seeds outside the treatment site as possible medical events.

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f. The inspectors concluded that failure to complete post-implant dosimetric analyses for prostate brachytherapy procedures performed June through November 2005 until, or after, late January 2006, despite the fact the prostate brachytherapy program was new and objective evidence of the team's ability to perform high-quality implants was not available, to be contrary to the concept of a "safety culture."

g. GLAHCS's review of these two treatments indicated adverse deterministic effects to the patients are not expected due to the locations of seeds outside the prostates. The lower than expected dose distributions to patients' prostates may increase the chance of disease recurrence.

6. Findings and impressions (external review of 10 implant procedures and, in particular, the patient implant procedure performed May 16, 2007)

a. The VA Deputy Under Secretary for Health directed each VHA facility performing prostate brachytherapy to send post-plans for 10 prostate brachytherapy treatments to a designated VHA expert for review.

b. The expert review for GLAHCS treatments confirmed that, in 9 of the 10 cases, the D90s were above 80% of the prescribed doses. However, in one case, performed on May 16, 2007, the prostate was obscured by severe streak artifacts in the post-implant CT images. The VHA expert reviewer stated that the D90 was likely less than 80% of the prescribed dose.

c. GLAHCS subsequently sent records of this one case to a second VHA expert reviewer. This reviewer was unable to assess the D90 due to the poor quality of the CT images.

d. The inspectors reviewed the causes of the inadequate CT images.

(1) Initial post-implant CT imaging was performed with an old Picker PQ 5000 fourth-generation, single-slice helical CT scanner, transferred from Radiology Service to Radiation Oncology Service.

(2) Streak artifacts in the patient's images were most likely due to unbalanced or inoperative detectors in the CT.

(3) The inspectors noted Radiation Oncology Service had not implemented an adequate QA program for the CT scanner when they assumed control of the unit. Standard daily QA may have identified the malfunction and avoided an unnecessary and inadequate CT scan of the patient.

(4) The old Picker CT system was replaced by a modern Philips multi-row detector CT system and an appropriate QA program was implemented for the system.

e. GLAHCS requested the patient to return for a second CT scan to assess the implant. The CT scan was acquired February 2, 2009, and a post-plan was performed on February 12, 2009.

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The D90 was calculated as 84% of the prescribed dose and the D80 was calculated as 94% of the prescribed dose. The pre-implant part of the written directive prescribed the dose to the D80.

f. The inspectors concluded that the implant procedure on May 16, 2007, did not constitute a medical event as defined by 10 CFR 35.3045.

7. Findings and impressions (circumstances for the February 12, 2009, prostate brachytherapy procedure)

a. The inspectors gathered information about the February 12, 2009, implant procedure. The staff urologist, medical physicist, and authorized user physician were all interviewed separately. The experienced urologist from the affiliated university, who was mentoring the staff urologist during the procedure, was not available for interview.

(1) According to the staff urologist, medical physicist, and authorized user physician, the implant procedure appeared to proceed normally, with three exceptions. At one point, the patient began moving during the procedure. Implantation of the seeds was briefly stopped while the anesthesiologist increased the amount of anesthesia. At another point in the procedure, the staff urologist withdrew a needle before the university urologist holding the stylet verbally indicated that the needle should be withdrawn. The staff urologist stated this could possibly be the cause of seeds outside the prostate. At another point, as a needle was handed by the medical physicist to a urologist, the wax plug and strand of seeds were noticed to be hanging from the needle. The seeds and wax plug were pushed back into position, the needle was inserted into the patient, and the seeds were placed. Whether these actions resulted in the misplaced seeds is unclear.

(2) At the end of the procedure, fluoroscopic imaging was performed. Approximately 5 of the 108 implanted seeds were seen to be placed outside the prostate toward the patient's perineum. Although not known with certainty, these were likely in a single strand of seeds from a single needle.

(3) A post-implant CT study was performed and a post-plan was performed on February 17, 2009. The D90 was calculated as 88% of the prescribed dose.

(4) The authorized user physician opined the five seeds outside the prostate are not likely to cause any harm to the patient. Furthermore, the authorized user physician stated that this was a clinically-acceptable implant.

(5) GLAHCS's notifications to NHPP, the patient, and referring physician and their required written report appear to conform to 10 CFR 35.3045.

b. The inspectors did not identify any regulatory violations related to the February 12, 2009, prostate brachytherapy procedure.

c. The inspectors performed a causal analysis for the medical event.

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(1) The inspectors identified a root cause as “Human Engineering, Non-fault Tolerant System, Errors Not Recoverable,” in that, if an error is made in seed or seed strand placement and the error is promptly identified, the seeds cannot be recovered.

(2) Other causes were not determined with certainty. However, the staff urologist stated in the case of one needle, she began needle retraction before the experienced urologist, who was holding the stylet, verbally indicated readiness for retraction of the needle and release of the seed strand to begin. The experienced urologist may not have fully advanced the stylet to release the wax plug and this may have caused the seed strand to follow the needle as it was withdrawn. If so, a second root cause is “Communication - Standard Terminology Not Implemented.”

8. Findings and impressions (actions for compliance, patient assessment, and to prevent recurrence)

a. After the February 12, 2009, medical event, GLAHCS Chief of Staff directed a cessation of further prostate brachytherapy procedures until a program review was performed and all necessary actions taken to reduce the chance of additional medical events.

b. The RSO stated, in a report sent by e-mail on March 19, 2009, that GLAHCS would implement specified actions to reduce the likelihood of medical events and ensure that, if a medical event occurs, the event is promptly discovered. These actions include:

(1) Before resident physicians participate in future implant procedures, a graduated approach to resident physician training will be implemented. This approach will include training that must be completed before participating in seed implantation in the operating room.

(2) QA measures will be established and implemented for TRUS that follow appropriate professional society standards and guidelines in “VHA Standard Procedure - Clinical Requirements.” TRUS will not be used if the imaging system does not conform to the standards. To assist with QA measures, an appropriate phantom will be procured as soon as possible.

(3) Audits and evaluations of individual prostate brachytherapy case, including post-implant dosimetric analysis, will be performed at a set timeframe consistent with current guidelines and include reviewing the 3D image of the seed placement for seeds outside the prostate. In addition, an index of rectal dose will be evaluated for each case. Also, the urology physicians will review results of individual cases in a timely manner to help identify areas for improvement.

(4) A more formal communication system among the implant team will be developed that includes positive verbal confirmation of critical steps.

(5) Written procedures will be revised to include a protocol for the identification of medical events, including those from seeds implanted outside the treatment site and subsequent reporting to NHPP.

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c. The NHPP inspectors deemed these actions to prevent a recurrence to be responsive to the possible causes and violations.

d. GLAHCS's actions after discovery of the medical events, to notify NHPP of the events no later than the day after discovery, notify the referring physicians, notify the patients, and submit written reports appeared to conform to the requirements of 10 CFR 35.3045.

9. Notice of Violation: The inspection identified one violation of NRC regulations for failure to develop and implement written procedures to provide high confidence each administration is per the written directive and is cited for the two medical events that occurred in 2005. This violation is assessed as being a Severity Level IV violation. No violations were identified regarding the single medical event that occurred in 2009. The violation is cited in Attachment B.

**Notice of Violation (NOV)
Inspection Report Number 691-09-I01**

**VA Greater Los Angeles Healthcare System,
Los Angeles, California**

VHA Permit Number 04-00181-04

1. Violation(s)

Written procedures for written directives: 10 CFR 35.41(a) requires for any administrations requiring a written directive, that written procedures be developed, implemented, and maintained to provide high confidence that each administration is per the written directive.

Violation: Contrary to the above, for prostate brachytherapy procedures performed during 2005, the permittee did not develop and implement written procedures to provide high confidence that each administration was per the written directive. Specifically, the permittee's written procedures did not require prompt post-implant dose evaluations and, in fact, for 3 procedures, such dose evaluations were performed approximately 6, 5, and 3 months after the post-implant CT images were acquired.

This is a Severity Level IV violation.

2. Required action

a. The healthcare system must take prompt action to correct the violation listed in this NOV and ensure the violation does not recur.

b. The healthcare system must submit a written statement to the National Health Physics Program within 30 days of the date of the memorandum transmitting this NOV. For each violation, the healthcare system response must describe the following.

(1) Basic cause or causes for the violation or agreement with the basic causes identified in the inspection report narrative, or, if contested, the basis for disputing the violation or severity level.

(2) Corrective steps already taken.

(3) Corrective steps which will be taken.

(4) Date full compliance will be achieved.

c. Where good cause is shown, the National Health Physics Program will consider extending the response time.

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist**VA Greater Los Angeles Healthcare System, January 21-22, 2009****1. Handling and security of sealed sources**

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

Federal Express delivers the packages of seeds directly to Nuclear Medicine Service. Packages are usually labeled as Radioactive Yellow II. A nuclear medicine technologist performs the package receipt survey. The nuclear medicine technologist contacts a physicist or dosimetrist in Radiation Oncology Service. The physicist or dosimetrist then brings the package to Radiation Oncology Service in Building 500, where it is stored in the "Radioisotope Storage Room," an unnumbered room inside Room 0425D. These appear to conform to Nuclear Regulatory Commission (NRC) regulations.

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

Seeds are stored in the Radioisotope Storage Room, an unnumbered room inside Room 0425D in the Radiation Oncology Service in Building 500. The doors to both Room 0425D and the inner room comprise two delay methods. These measures appear to conform to NRC regulations and VHA permit requirements.

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

Appear to conform to NRC regulations.

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

Appears 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 returned to the vendor only if an entire case is cancelled. Otherwise, the seeds are stored for decay and disposed of as non-radioactive waste. The pre-disposal survey is performed by radiation safety staff. These appear to conform to regulatory requirements.

2. Preparations for seed implant procedures

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

Written procedures and written directive form were reviewed. They appear to conform to NRC regulations. It was noted that written procedures do not explicitly require verifying patient identity, although this is required by the written directive form. It was also noted that written procedures do not specify how soon after each implant the post-implant CT and post-implant dose analysis must be performed. Recommendation – modify written procedures to describe requirements for confirming patient identity and that the seeds and pre-plan are for

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that patient. Modify written procedures to specify how soon after each implant the post-implant CT and post-implant dose analysis must be performed. Ensure compliance with VHA standard procedures.

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

Appear to conform to NRC regulations.

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

Done by transrectal ultrasound (TRUS), usually within 1 month prior to an implant.

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

A urologist draws the contours of the prostate and a medical physicist creates the pre-plan. The authorized user physician reviews and approves each pre-plan.

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

The written directive is signed by the authorized user physician before the seeds are ordered. The pre-implant part of the written directive appears to conform to NRC regulations.

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

Substantially conform to NRC regulations.

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

Substantially conform to NRC regulations.

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.

The form used to record release measurements states release dose rate limits that take into account the energy responses of the survey meters used.

i. Patient instructions (10 CFR 35.75).

Appear to comply with NRC regulations.

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

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The vendor assayed 100% of the seeds. No seeds are assayed by the facility. Appears to comply with NRC regulations.

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

Appears to comply with NRC regulations.

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

There is currently no QA program for TRUS and transfer of its images to the VariSeed TPS. The Chief Therapeutic Medical Physicist has recently implemented a QA program for the new Philips 16 slice MDCT. It is recommended that a QA program be established that substantially conforms to AAPM Task Group 128 Report. The program should ensure compliance with VHA standard procedures.

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

The Radiation Safety Officer (RSO), medical physicists, and authorized user physicians are currently familiar with NRC's medical event definition and reporting requirements.

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

John Horns, M.D., has served as the authorized user physician for all prostate implant procedures since the first procedure in 2004. (It is not clear who served as the authorized user physician for the first implant – two authorized users were in the room, but there was no written directive.) Dr. Horns was approved by the RSC on February 10, 2005, on the basis of his certification in Radiology by the American Board of Radiology. The approval appears to conform to the NRC regulations in effect at the time.

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

The RSO has prepared written procedures for leaking seeds and follow-up actions.

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

The RSO and Chief Therapeutic Medical Physicist jointly perform training initially and annually thereafter.

- q. Usual type of anesthesia?

General.

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r. Prescribed dose for each radionuclide used?

145 Gy

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 images retained?

Treatment plans are stored on the VariSeed laptop hard drive, but are not backed up. CT images are stored on the PACS and almost certainly backed up. It is recommended that an information technology policy be written for Radiation Oncology Service that addresses information security, including creating and maintaining backup copies. This policy should comply with VHA standard procedures.

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

The VariSeed treatment planning computer cannot access CT images over the network. Instead, CT images are printed on CDs by Radiology Service and manually transferred to VariSeed. It is recommended that healthcare system executive management take action to obtain more prompt and efficient transfer of images from the CT or PACS to VariSeed.

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

a. Authorized user physicians.

There is only one authorized user physician, John Horns, M.D. Based upon performance-based interviews, he has adequate and sufficient knowledge of regulatory requirements and understands the concept of a safety culture.

b. Medical physicists and dosimetrists.

The Chief Therapeutic Medical Physicist is Bradford Krutoff, M.S. The department has a full-time dosimetrist, Peggy Unterhalter. However, pre-plans and post-plans are created by a contract physicist, Min Leu, Ph.D. Dr. Leu is typically in the operating room (OR) during implant procedures. Based upon performance-based interviews, the two physicists appear to currently have adequate and sufficient knowledge of regulatory requirements and understand the concept of a safety culture.

c. Other physicians including urologists and/or residents.

Currently, a staff urologist, Isla Garraway, M.D., is learning to perform implants. She is being mentored by a urologist from UCLA, Robert Reiter, M.D., who has many years experience in performing PSIB. She is supervised by Carol Bennett, M.D., Chief of Urology

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Section. Based upon performance-based interviews, Drs. Garraway and Bennett appear to currently have adequate and sufficient knowledge of regulatory requirements and understand the concept of a safety culture.

d. Radiation Safety Officer.

The current RSO, Mark Sitek, M.S., has been employed by the GLAHCS since mid-September 2007 and has been named on the VHA permit as the RSO since October 14, 2008. Based upon performance-based interviews, he has adequate and sufficient knowledge of regulatory requirements.

e. Support staff.

Not applicable.

4. Performance-based tours and observations

a. Radiation oncology areas.

A performance-based tour indicated compliance with NRC regulations and good health physics practices.

b. Package receipt areas.

Packages are received in Nuclear Medicine Service. These areas were not reviewed during this inspection. They are routinely reviewed during routine NHPP inspections.

c. Seed implant preparation areas.

Not reviewed. The seed preparation area is the OR.

d. Seed storage areas.

A performance-based tour indicated compliance with NRC regulations and good health physics practices.

5. Evaluation of patient treatment results

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

TRUS is used during implant procedures, fluoroscopy is used promptly afterwards.

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

No.

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

Not routinely. Fluoroscopy is used after each implant.

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

Completed and signed by authorized user in OR.

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

30 days after each implant.

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?

Completed within a few working days after the CT. Contouring of prostate and rectum performed by authorized user physician. R100 was calculated for the most recent case and will be calculated for future cases.

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

Yes.

- h. Clinical QA, including peer review.

Not formally established yet. It is recommended that a peer-review program be established for the physicians and physicists.

6. Workload data

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

Preloaded needles

- b. Date of program inception.

March 31, 2004

- c. Number of patients implanted per year.

39 patients total, none yet in 2009, 2 in 2008, 10 in 2007

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

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I-125 only, Theragenics Model 125.S06, all stranded seeds suture, all preloaded in needles

7. Persons contacted

Donna M. Beiter, RN, MSN, Director ²
Dean Norman, M.D., Chief of Staff ^{1,2,4}
Michael E. Mahler, M.D., Chief, Organizational and Performance Improvement Section ³
Ahmad Sadeghi, M.D., Chief, Radiation Oncology Service ^{2,4,5}
John Horns, M.D., Authorized User Physician, Radiation Oncology Service ^{2,4,5}
Carol Bennett, MD, Chief, Urology Section ^{4,5}
Isla Garraway, M.D., Urologist ⁵
Mark Sitek, M.S., Radiation Safety Officer ^{1,2,3,4,5}
Ronald Nusbaum, JD, Associate Radiation Safety Officer ^{3,4,5}
Bradford Krutoff, M.S., Supervisory Medical Physicist, Radiation Oncology Service ^{2,4,5}
Joan Lopes, Chief, Quality Management Department ^{1,2,3}
Stuart Mirell, Ph.D., Director, Cyclotron Section ^{4,5}
Morris Berger, Research Compliance Officer ⁴
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Josephine Ribe, CNMT, Chief Technologist, Nuclear Medicine Service ⁵
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Orlando Turner, Chief Therapist, Radiation Oncology Service ⁵
Derrick M. Alcaide, B.S., Electrical Engineer, Cyclotron Section ⁵

Contacted during inspection:

1. Individual(s) present at entrance meeting January 21, 2009
2. Individual(s) present at exit meeting January 26, 2009
3. Individual(s) present at entrance meeting February 23, 2009
4. Individual(s) present at exit meeting February 26, 2009
5. Individual(s) present or participating in inspection discussions

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References

American College of Radiology *Practice Guideline for Transperineal Permanent Brachytherapy of Prostate Cancer*

AAPM Report No. 68 (TG-64), *Permanent Prostate Seed Implant Brachytherapy*, October 1999

AAPM Report No. 51 (TG-43), *Dosimetry of Interstitial Brachytherapy Sources*, March 1995

AAPM Report No. 84, *Update of AAPM Task Group No. 43 Report: A revised AAPM protocol for brachytherapy dose calculations*, February 2004

AAPM Report No. 84s, *Supplement to the 2004 update of the AAPM Task Group No. 43 Report*, June 2007

AAPM Report No. 89, *Recommendations of the American Association of Physicists in Medicine regarding the Impact of Implementing the 2004 Task Group 43 Report on Dose Specification for 103Pd and 125I Interstitial Brachytherapy*, April 2005

AAPM Report No. 98, *Third-party Brachytherapy Source Calibrations and Physicist Responsibilities*

AAPM TG 128, *Quality Assurance Tests for Prostate Brachytherapy Ultrasound Systems*

NRC Regulations - 10 CFR 35, *Medical Use of Byproduct Material*

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Recommendations

1. GLAHCS *Standard Operating Procedure, Prostate Cancer Brachytherapy Procedure*, dated December 2008, specifies, on Page 7, that a post-implant CT scan will be performed and a post-plan completed. The GLAHCS document, *Quality Management Program, Radiation Therapy Permanent Seed Prostate Brachytherapy*, does not require post-implant CT imaging, creation of post-plans, and post-implant dose evaluation. Neither document specifies the timeframe after an implant to perform CT imaging, create and evaluate post-plans after CT imaging, or dose indices (e.g., V100, D90, and R100) that are to be calculated.

Recommendation: Modify procedures to specify when the CT imaging must be performed after each implant procedure, how soon the post-plan must be completed and evaluated after the CT imaging, and the dose indices (e.g., V100, D90, and R100) to calculate. Ensure compliance with VHA standard procedures.

2. Written procedures do not explicitly require verifying patient identity, although this is required by the written directive form.

Recommendation: Modify written procedures to describe the procedure for confirming patient identity and that the seeds and pre-plan are for that specific patient. Ensure compliance with VHA standard procedures.

3. American College of Radiology *Practice Guideline for Transperineal Permanent Brachytherapy for Prostate Cancer* and American Association of Physicists in Medicine report *AAPM Task Group 128: Quality assurance tests for prostate brachytherapy ultrasound systems*, recommend a quality assurance (QA) program for the transrectal ultrasound (TRUS) system used for volume studies before procedures and for real-time guidance during procedures. However, such QA is not being performed.

Recommendation: Develop and implement a QA program for the TRUS system. This QA program should substantially conform to the AAPM TG 128 report and comply with VHA standard procedures.

4. CT images must currently be "burned" onto an optical disk for transfer to the VariSeed treatment planning computer system. This adds to the delay between CT image acquisition and post-plan creation and procedure evaluation.

Recommendation: Take action so CT images can be transferred to VariSeed by computer network.

5. Currently, urologists performing seed implantation do not routinely review post-plans on VariSeed. This may deny them and future patients some of the benefit of past experience.

Recommendations

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Recommendation: Modify procedures to state that the implanting urologist will review, with the assistance of the medical physicist and authorized user physician, each post-plan using VariSeed.

6. Treatment plans are stored on the VariSeed laptop hard drive, but are not backed up. CT images are stored on the PACS and almost certainly backed up.

Recommendation: Develop in writing an information technology policy for Radiation Oncology Service. The policy should address information security, including creating and maintaining backup copies. Ensure compliance with VHA standard procedures.

7. There is not a formal peer-review program for permanent implant prostate brachytherapy.

Recommendation: Establish a peer-review program for physicians and physicists. Ensure compliance with VHA standard procedures.

8. GLAHCS *Standard Operating Procedure, Prostate Cancer Brachytherapy Procedure*, dated December 2008, and GLAHCS document, *Quality Management Program, Radiation Therapy Permanent Seed Prostate Brachytherapy, "Ver12,"* do not appear to fully describe the authorized user physician's authority, as described in 10 CFR 35.26.

Recommendation: Revise procedures to better conform to 10 CFR 35.26. Ensure compliance with VHA standard procedures.