

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

AUG 03 2009

Date: AUG 03 2009

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

Subj: Radiation Safety Program Inspection and Notice of Violation - Inspection Report 539-08-I01

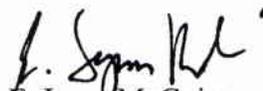
To: Director (539/00), VA Medical Center, Cincinnati, Ohio

1. We performed an announced reactive inspection of the radiation safety program at the VA Medical Center, Cincinnati, Ohio, during October 16-17, 2008, and June 30 - July 1, 2009. We closed the inspection on July 29, 2009. The focus of the inspection was possible medical events discovered on October 7, 2008, and an additional medical event discovered on July 22, 2009. Darrel Wiedeman, Nuclear Regulatory Commission (NRC), accompanied NHPP during the first on-site visit.

2. Attachment A to this memorandum is the inspection report narrative. Attachment B is a prostate brachytherapy checklist completed in October 2008. Attachment C is a Notice of Violation citing two violations that are deviations from NRC requirements of radioactive material use.

3. We concluded that information regarding the reasons for the violations, the corrective actions taken and planned to prevent recurrence, and the date when full compliance was achieved was adequately described by your staff during the inspection and is documented in this inspection report. You are not required to respond to this Notice of Violation unless the description herein does not accurately reflect your corrective actions or your position. In that case, you may submit a response directly to us.

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 10 (10N10)

RADIATION SAFETY PROGRAM INSPECTION
Inspection Report Number 539-08-I01
VA Medical Center, Cincinnati, Ohio
October 16, 2008 – July 29, 2009

1. Introduction

a. Edwin M. Leidholdt, Jr., Ph.D., Joseph Wissing, and Gary E. Williams, M.S., VHA National Health Physics Program (NHPP), performed an announced reactive inspection of the radiation safety program at the VA Medical Center, Cincinnati, Ohio, beginning October 16, 2008. Dr. Leidholdt and Mr. Wissing performed the initial on-site portion of the inspection during October 16-17, 2008. The inspectors presented their preliminary findings at a meeting with medical center executive management and other staff on October 17, 2008. Dr. Leidholdt and Mr. Williams conducted another on-site visit during June 30 - July 1, 2009, as part of the inspection.

(1) The inspection was initiated in response to six possible medical events involving permanent implant prostate seed brachytherapy (hereafter referred to as prostate brachytherapy), all discovered on October 7, 2008. The possible medical events were discovered as part of a review of 10 consecutive cases from each VHA facility performing prostate brachytherapy. The review was performed by the Radiation Oncology Service staff at the VA Puget Sound Healthcare System, Seattle, Washington. The 10 reviewed implants were performed on 4 consecutive Thursdays in June 2008. In each of the six procedures declared as medical events, the post-implant D90 (defined as the largest dose that covers 90% of the prostate), determined from a CT scan performed the day after the prostate brachytherapy procedure, was assessed as being less than 80% of the prescribed dose. NHPP notified the Nuclear Regulatory Commission (NRC) Operations Center of the six medical events on October 7, 2008.

(2) A VHA Clinical Risk Assessment Advisory Board (CRAAB) was convened to assess prostate brachytherapy procedures performed at several VHA facilities. For I-125 implants performed as monotherapy, the CRAAB established the criteria that an implant achieving a D90 equal to or greater than 80% of 145 Gy is clinically acceptable and that further review of previous procedures is advisable if more than 10% of the procedures did not meet this criterion. The CRAAB extended the review of procedures at Cincinnati to 20 additional consecutive prostate brachytherapy procedures performed at the facility. These procedures were reviewed by the staff at Seattle. Thus, the CRAAB reviews assessed a total of 30 procedures performed at Cincinnati. Twenty-seven of the 30 reviewed procedures were found to meet the CRAAB's criterion. The CRAAB concluded that further review of earlier implant procedures would not be required.

(3) Of the 30 implants reviewed by the CRAAB, 7 implants were reported by the assessment team at Seattle to have D90s less than 80% of the prescribed dose of 160 Gy. Six were from the first set of 10 implants reviewed and had been reported to NRC as medical events on October 7, 2008. However, the other was from the set of 20 implants and had not been reported to NRC as a medical event. This latter procedure had been performed on May 22, 2008.

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(4) NHPP requested an additional review by the Director, VHA National Radiation Oncology Program (DRO), of the 6 implants previously declared as medical events and the 1 implant from the set of 20 reviewed. The DRO is certified by the American Board of Radiology in Radiation Oncology, an expert in prostate brachytherapy, and an authorized user physician for 35,400 uses at a VHA facility. The DRO reviewed the pre-implant transrectal ultrasound (TRUS) images and post-implant CT images, pre- and post-implant treatment plans prepared by the Cincinnati staff, and reviews performed by the Seattle team. The DRO concluded that the D90 of the implant performed on May 22, 2008, was less than 80% of the prescribed dose.

(5) Dr. Leidholdt and Mr. Williams performed a second on-site visit to the medical center during June 30 - July 1, 2009, to perform an inspection to assess the medical center's readiness to resume prostate brachytherapy and evaluate the additional possible medical event. An exit meeting with executive management for the second visit was conducted on July 1, 2009. This inspection was left open pending continuing review. The medical center's readiness to resume prostate brachytherapy is addressed in a separate inspection report.

(6) VHA, as the master materials licensee, determined at a meeting on July 22, 2009, with the Chair, National Radiation Safety Committee; DRO; Chief Patient Care Services Officer; and Director, NHPP to use the dose determination by DRO. Since the DRO had assessed the D90 as less than 80%, the additional medical event was considered to have been "discovered" on July 22, 2009, as part of the meeting. NHPP notified the medical center to complete required notifications.

(7) NHPP notified the NRC Operations Center of the additional medical event on July 23, 2009.

b. The inspection was closed on July 29, 2009.

2. Scope of inspection

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

- a. Interviews with medical center, affiliate university, and contract staff regarding the events,
- b. Reviews of records related to the events,
- c. Tour of facilities and review of equipment involved in the events,
- d. Review of the medical center's initial actions regarding the events, including a review of the effectiveness and comprehensiveness of the initial actions to prevent a recurrence,
- e. Review of compliance with other regulatory requirements under 10 CFR 35 for the prostate brachytherapy program,
- f. Evaluation of root or basic causes for the events, and

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g. Comparison of identified deficiencies with other therapy modalities to determine if the events were an isolated occurrence or a programmatic issue.

3. Findings and impressions (background information)

a. The most recent NRC inspection at the medical center, on February 14-15, 2005, did not result in the citation of any violations. NRC had initiated an inspection at the medical center on October 15, 2008, before the NHPP inspectors arrived to begin this NHPP inspection. The status of that NRC inspection is unknown. NHPP inspected the medical center on June 30, 2009, as a separate core inspection and did not cite any violations.

b. No medical events involving prostate brachytherapy have previously been reported by the medical center.

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

(1) The prostate brachytherapy program began in 1998.

(2) The program was the second busiest in the VHA. Since program inception, about 940 patients have been treated. In 2007, 129 procedures were performed; and in 2008, prior to the October suspension, 66 procedures had been performed.

(3) The prostate brachytherapy program serves patients from other VHA medical centers and the brachytherapy program is designed to accommodate patients who must travel to Cincinnati for the procedures.

d. The inspectors gathered information about the workflow for prostate brachytherapy procedures at the medical center.

(1) The medical center does not have a Radiation Oncology Service or section. There are three physicians listed on the permit as authorized users for 35,400 uses. However, according to the Radiation Safety Officer (RSO), only one serves as an authorized user for prostate brachytherapy procedures. This physician is an employee of the University Hospitals of the University of Cincinnati. The medical physicists and dosimetrists are employees of the University Hospitals and are assigned to the VHA medical center on contract. According to one of the medical physicists, the roles of the medical physicists and dosimetrists were entirely limited to preparing pre-plans and post-plans. The RSO is also the Chief, Nuclear Medicine Technologist. The Nuclear Medicine Service provides support for the patient procedures.

(2) The medical center obtains I-125 seeds from a commercial vendor and loads needles on-site. Until about 2 months before the beginning of this inspection, the medical center used Oncoseed Model 6711, both as seeds in strands and as loose seeds, and loaded the seeds into needles on-site. Since that time, the facility has loaded Core Oncology Model 125SL seeds into needles using the Mentor Isoloader.

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(3) Nuclear Medicine Service ordered the seeds, typically the week before the procedure. The same number of seeds was ordered for each patient. Until about 2 months before the initial visit of this inspection, the seeds were ordered from Medi-Physics. Since then, the seeds were ordered from Core Oncology.

(4) The seed vendor shipped a package of sterilized seeds to the medical center for each procedure. Most recently, the seeds were in a pre-loaded cartridge for the Mentor Isoloader system. The package was delivered to the warehouse and the warehouse staff transported the packages to nuclear medicine. Nuclear medicine technologists performed the package receipt surveys. The seeds were then stored in Room C-216 until loaded into needles.

(5) Two days before each patient procedure, typically on a Tuesday, the authorized user physician obtained images with a TRUS system. These TRUS images were transferred to a Varian VariSeed™ treatment planning system (TPS) for a medical physicist or dosimetrist to create a treatment plan to achieve the dose prescribed by the authorized user physician. Creation of this treatment plan requires designation of the prostate boundaries on the images by the authorized user physician.

(6) The authorized user physician reviewed the treatment plan prepared using the TPS and signed the treatment plan.

(7) Prior to the use of the Mentor Isoloader, the treatment plan and needle loading diagrams were given to the nuclear medicine technologists for needle loading. Since then, this information was stored on a CD that was transferred to the nuclear medicine technologists.

(8) For calibration of the strengths of the seeds, the facility primarily relied upon calibration of the seeds by the vendor. However, the Mentor Isoloader performs checks of the seed strengths. No other checks of seed strengths were performed. NRC regulations permit assays of seed strength to be performed by a vendor.

(9) Seeds of at least two and sometimes three different activities were used in all patients. Most seeds of the higher activity were stranded and those of the lower activity were not stranded. The use of three seed activities occurred in about 10% of the cases. Multiple seed activities were used for both historical reasons – in the past, higher strength seeds had been loaded peripherally and half-strength seeds placed in the interior of the prostate, and also for economic reasons. Because many or most patients came from out-of-town and seeds were ordered before the patients' arrivals without knowledge of the prostate sizes, on some weeks many seeds would remain after the week's implants had been performed. The average seed activity was used for post-plan calculations.

(10) Seeds were implanted in patients in a cystoscopy suite at the medical center under TRUS guidance, typically on Thursdays. Fluoroscopy was not used to supplement the TRUS imaging during a procedure. The team for the procedure included an authorized user physician, who was a radiation oncologist; a urologist was usually not present. Often, residents in radiation oncology participated under supervision of the authorized user physician. Other staff present

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included an anesthesiologist and nursing staff. Neither a therapeutic medical physicist, a health physicist, a nuclear medicine technologist, nor the RSO was usually present during a procedure.

(11) After the procedure, the patient recovered from the anesthesia in a post-surgical recovery room and stayed in the Fisher House overnight. On the day after the prostate seed brachytherapy procedure, CT images were obtained of the patient's pelvic region. The CT images were acquired at the Barrett Cancer Center or the medical center. At some time thereafter, the CT images were transferred to the TPS, the authorized user physician contoured the prostate, and a medical physicist created a post-plan to assess the dose distribution. Indices of the dose distribution to the prostate, including V100 and D90, were calculated and provided to the authorized user physician.

(12) The authorized user physician stated that, at the end of each procedure, he reviewed the PA fluoroscopic image and used the TRUS to image the prostate in the transverse and sagittal planes to assess the implant. He also reviewed the CT images later. He stated that he did not pay much attention to the dose indices such as the V100 and D90, which are based upon CT images acquired the day after the implant procedure. He stated that he relied upon PSA control at 5 years to assess the implants.

4. Findings and impressions (compliance with NRC regulations involving prostate brachytherapy)

a. The inspectors confirmed regulatory compliance for the following.

- (1) Radioactive material package receipt surveys and records under 10 CFR 20.1906.
- (2) Written directives and written directive procedures under 10 CFR 35.40 and 35.41.
- (3) Methods and records for patient release radiation measurements under 10 CFR 35.75.
- (4) Radiation safety practices and record keeping under 10 CFR 35.404, 35.406, 35.432, and 35.457.
- (5) Security of stored sealed sources before and after prostate brachytherapy procedures under 10 CFR 20.1801 and permit conditions.
- (6) Approval of authorized user physicians.

b. The inspectors identified one violation of 10 CFR 35.67(g).

(1) I-125 sources being stored for decay prior to disposal were not subject to semiannual inventories. This violation is listed in Paragraph 8 below and is cited in the attached Notice of Violation (Attachment C).

(2) The inspectors interviewed the RSO regarding the reason for the violation. The RSO stated that he considered these seeds in storage for decay to be the equivalent of radioactive

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waste and not sealed sources required to be inventoried pursuant to 10 CFR 35.67(g). The inspectors noted the sources being stored for decay were secured in accordance with 10 CFR 20.1801.

(3) During the visit on June 30 - July 1, 2009, the inspectors verified these sources were being included in required inventories.

5. Findings and impressions (circumstances for medical events involving prostate brachytherapy procedures)

a. The inspectors gathered information about circumstances for the prostate brachytherapy procedures that resulted in medical events.

b. NRC regulations define a medical event, in part, as a delivered dose that differs from the prescribed dose by more than 50 rem and by 20% or more (10 CFR 35.3045 (a)(1)(i)). The dose prescribed to the prostate in the pre-implant written directives was 160 Gy.

(1) The dose distributions, as reflected by the D90 as a percent of the prescribed dose, were relatively low. However, the dose prescribed for each patient, 160 Gy, exceeded by more than 10% the dose most commonly prescribed for prostate brachytherapy at other VHA medical centers, 145 Gy. Therefore, the post-implant D90s exceeded 80% of 145 Gy for about 90% of the 30 cases receiving external review and would be deemed clinically adequate. An additional factor is that the post-implant CT scan was typically performed on the next day after each implant, at which time post-implant swelling of the prostates would be near maximal. It is likely that the post-implant D90s, which were based upon these CT scans, underestimated the actual D90s in many cases.

(2) A primary cause of the low D90s, when expressed as a percent of the prescribed dose, appears to be the pre-plans. For the 10 consecutive treatments reviewed by the radiation oncology staff at Seattle, the median pre-plan D90 was 104% (range 101% to 114 %) of the prescribed dose and the median pre-plan V100 was 94% (range 90% to 98%).

c. The inspectors reviewed the post-plan CT images for the seven medical events using the Varian VariSeed TPS at the Barrett Cancer Center, with the assistance of a medical physicist. The primary reason for this review was to assess whether significant numbers of seeds were implanted outside the intended treatment volumes. It appeared that all seeds were implanted in or within about a centimeter of the intended treatment volume. Thus, were the VHA basing its definition of a medical event on the fraction of the prescribed source strength implanted in the intended treatment volume, none of these seven procedures would be medical events.

d. The inspectors interviewed a medical physicist to determine the roles of the medical physicists in prostate brachytherapy procedures.

(1) The role of the medical physicists was limited to attending volume studies to obtain the TRUS images in digital form for transfer to the VariSeed treatment planning computer system, creating pre-plans, creating post-plans using CT images, and providing the information in post-

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implant dose analyses to the authorized user physician. Commissioning had been performed of the VariSeed TPS, which is the property of the university medical center.

(2) Medical physicists did not evaluate the dose distributions.

(3) The lack of evaluations of post-implant seed and dose distributions by the medical physicists is an area for corrective action and improvement.

(4) Lack of involvement of the medical physicists in the oversight of all aspects of the prostate brachytherapy program is another area for improvement. In particular, there was not a quality assurance program for the TRUS system and for the transfer of images from the TRUS system and CT to the TPS. However, the lack of this quality assurance did not appear to have caused the medical events.

e. The inspectors sought to discover why a medical event was not identified and reported when a post-implant D90 was assessed at 20% or more less than the prescribed dose of 160 Gy.

(1) The authorized user physician was asked by the inspectors why medical events were not identified and reported when a post-implant D90 was assessed to be less than 20% of the prescribed dose of 160 Gy. The authorized user physician stated that his understanding had been that, if the implanted activity was within 20% of that prescribed, the procedure complied with the written directive.

(2) The inspectors noted that, although this interpretation of the definition of a medical event is contrary to that being currently used in the VHA, it is consistent with the definition of "prescribed dose" in 10 CFR 35.2 and thus does not constitute a violation of NRC regulations.

f. The inspectors evaluated the root (basic) cause for the medical events as follows.

(1) "Procedures – Need Improvement," in that the practice was to prescribe a dose of 160 Gy, but to create pre-plans with pre-implant V100s significantly less than 100% and D90s only a little above 100%, which were likely to produce post-implant D90s less than 20% of the prescribed dose.

(2) "Quality Control – Need Improvement," in that the process of post-implant CT imaging, post-plan creation, and dose evaluation was not designed in a way that would permit optimal evaluation of individual implants to determine if a medical event had occurred.

6. Findings and impressions (other brachytherapy procedures)

a. The medical center participates in a multi-institution research project involving permanent implant brachytherapy, in conjunction with surgery, of human subjects with lung cancer.

b. Two patients have received permanent implants of I-125 seeds at the medical center as part of this project.

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c. The inspectors verified compliance with the requirements of 10 CFR 35.6.

d. For an implant procedure performed on June 3, 2009, the inspectors determined that the post-implant part of the written directive was not completed before completion of the procedure, but was instead completed about a month later. This is a violation of 10 CFR 35.40 and is listed in Item 8 below and in Attachment C, the Notice of Violation.

e. The RSO stated the cause for this violation was that the authorized user physician was unaware that NRC interpreted “completion of the procedure” as being before leaving the operating room. The RSO retrained the authorized user physician about the regulatory interpretation of this regulation and agreed to monitor future written directives for compliance.

f. The inspectors considered the root (basic) cause for the violations to be “Training – Understanding Needs Improvement.” The inspectors concluded the corrective actions by the RSO were adequate and sufficient to close the violation.

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

a. In October 2008, medical center executive management suspended prostate brachytherapy procedures. Because patients had been scheduled for treatment on October 9, 2008, these procedures were allowed to be performed. No prostate implant procedures were performed after this date.

b. The inspectors concluded the action taken to suspend prostate brachytherapy procedures was sufficient to prevent a recurrence while the NHPP inspection was being completed.

c. The medical center actions after the discovery of the events, notification of the patients and referring physicians, and submission of a report for NRC appeared to substantially conform to 10 CFR 35.3045.

d. The medical center actions to prevent recurrence of medical events involving prostate brachytherapy included, but were not limited to:

(1) Reducing the prescribed dose for I-125 implants, when performed as monotherapy, from the previously-prescribed 160 Gy to 145 Gy (the most commonly prescribed dose for I-125 prostate brachytherapy at VA facilities), while performing implants with similar activities as before.

(2) In most cases, performing post-implant CTs immediately after each procedure to minimize overestimation of prostate volumes.

e. The medical center also adopted the VHA Standard Procedures for Prostate Brachytherapy.

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f. The inspectors concluded these medical center actions would reduce the likelihood of medical events involving prostate brachytherapy, specifically the likelihood of calculated post-implant D90s being less than 80% of the prescribed doses.

8. Notice of Violation: The inspection identified two violations of NRC regulations. The first violation is for failure to perform periodic inventories of seed sources stored for decay. The second is because an authorized user physician did not complete the post-implant part of a written directive for a pulmonary brachytherapy procedure until about a month after completion of the procedure. The violations are cited in the Notice of Violation (Attachment C) and are assessed as Severity Level IV violations.

9. Persons Contacted

Linda D. Smith, Medical Center Director ^{1,2,3,4}
Sidney R. Steinberg, M.D., FACS, Chief of Staff ^{1,2,3,4,5}
Sheila Gelman, M.D., Chief Medical Officer, VISN 10 ²
Jack Hetrick, Director, VISN 10 ²
Hiroshi Nishiyama, M.D., Chair, Radiation Safety Committee ²
Chris Rauf, RT(N), CNMT, RSO, and Chief Nuclear Medicine Technologist ^{1,2,3,4,5}
Kevin Redmond, M.D., Radiation Oncologist, Barrett Cancer Center, University of Cincinnati, and Authorized User Physician ^{3,4,5}
Michael Lamba, Ph.D., Therapeutic Radiological Physicist, University of Cincinnati Medical Center ^{3,5}
Michael A. Davis, M.S., Therapeutic Radiological Physicist, Barrett Cancer Center, University of Cincinnati ⁵
Howard R. Elson, Ph.D., Therapeutic Radiological Physicist, University of Cincinnati ^{1,2,3,4,5}
Darrel Wiedeman, Senior Health Physicist, Nuclear Regulatory Commission ^{1,5}
Molly Lyons, VISN 10 Patient Safety Officer ²
Daniel S. Zomchek, Health Systems Specialist ²
Diane Richards, Administrative Officer to the Chief of Staff ¹

Contacted during inspection:

1. Individual(s) present at entrance meeting on October 16, 2008
2. Individual(s) present at exit meeting on October 17, 2008
3. Individual(s) present at entrance meeting on June 30, 2009
4. Individual(s) present at exit meeting on July 1, 2009
5. Individual(s) present or participating in inspection discussions

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

**VA Medical Center Cincinnati, Ohio
(October 16-17, 2008)**

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

1. Handling and security of sealed sources

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

Packages of seeds are received at the warehouse. The current vendor ships them as excepted package, limited quantity. The warehouse staff promptly delivers them to nuclear medicine, where package receipt surveys are performed. These appear to comply with NRC regulations.

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

Appear to comply with NRC regulations and conditions of the facility's VHA permit.

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

These appear to substantially conform to NRC regulations. Recommend that the RSO compare the records with 10 CFR 35.3045 and modify for full conformance.

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

The only seeds kept at the medical center sufficiently long to require physical inventories pursuant to NRC regulations and the medical center's VHA permit are seeds stored for decay. These are not being included in inventories of sealed sources. This is an apparent violation of NRC regulations.

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

Most unused seeds are shipped back to the vendor. Currently, these unused seeds are contained in cartridges for the Mentor Isoloader. However, a few seeds, such as those excreted by a patient or stuck in needles, are stored for decay. These appear to conform to NRC regulations.

2. Preparations for seed implant procedures

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

Appear to conform to NRC regulations. However, methods for checking treatment plans are not explicitly described in the procedures. Recommend these be explicitly described.

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

Conform to NRC regulations. Treatment plans are checked by a person other than the person who prepared the plan. However, this is not described in the written procedures.

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

Pre-implant imaging is performed by TRUS 2 days before each implant.

- d. Pre-plan preparation.

Prepared by a dosimetrist or physicist using the Varian VariSeed treatment planning system at the Barrett Cancer Center of the University of Cincinnati Hospitals.

- e. Written directive, Part 1 preparation, including prescribed dose.

Signed by the authorized user physician in the procedure room prior to implantation of any seeds. Appears to conform to NRC regulations.

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

Performed by a nuclear medicine technologist who is called to the procedure room at the end of each procedure. Surveys and records appear to conform to NRC regulations.

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

Patient release procedures are to perform a measurement of the exposure rate from the patient, typically with the patient standing, at a distance of 1 meter. In the past, a Victoreen Model 498 survey meter, equipped with a Model 493-50 GM probe, was used. A Ludlum survey meter with a thin-window pancake GM probe has been purchased for such surveys. The methods and records appear to 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 measurements performed in the past were not corrected for the energy response of the meter and probe. The meter is calibrated with a ^{137}Cs source. However, a review of the energy response curve for the Model 493-50 probe indicates that, with respect to ^{137}Cs gamma rays, the probe over-responds for 28 keV x-rays and so overestimates the true exposure rate. The RSO stated that he has modified procedures to take into account the energy response of the survey instrument used.

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i. Patient instructions (10 CFR 35.75).

Written instructions reviewed. Appear to conform to NRC regulations and good health physics practices.

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

For calibration of the strengths of the seeds, the facility primarily relies upon calibration of the seeds by the vendor. However, the Mentor Isolader performs checks of the seed strengths. No other checks of seed strengths are performed. This appears to conform to NRC regulations.

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

Appears to conform to NRC regulations.

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

The facility recently purchased a CIRS Model 045 phantom and the authorized user physician is using it to test the TRUS system weekly. However, according to a medical physicist, no testing has been performed of the accuracy of CT images acquired at the VA medical center to the treatment planning system. Recommendation: assign medical physicists the responsibility for all technical quality control associated with prostate brachytherapy.

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

The RSO and authorized user physician are aware of regulatory requirements.

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

Authorized user physicians are named on the permit for 35.400 uses.

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

The RSO has implemented procedures for this contingency.

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

The RSO provided documentation of the authorized user physician and nuclear medicine staff participating in prostate implant brachytherapy, but not medical physicists and dosimetrists. Recommend that the RSO provide initial and periodic training to the physicists and dosimetrists.

- q. Usual type of anesthesia?

General or spinal

- r. Prescribed dose for each radionuclide used?

160 gray

3. Performance-based interviews and observations

- a. Authorized user physicians.

There are three authorized user physicians named on the VHA permit. However, all prostate implants are performed by Kevin Redmond, M.D., a radiation oncologist who is employed by the University Hospitals of the University of Cincinnati.

Based on performance-based interviews, the authorized user physician currently has adequate and sufficient knowledge of NRC requirements regarding written directives. Dr. Redmond stated that his understanding was that, if the implanted activity was within 20% of that prescribed, the procedure complied with the written directive.

- b. Medical physicists and dosimetrists.

There are three medical physicists and two dosimetrists participating in permanent implant prostate brachytherapy. All are employees of the University of Cincinnati Hospitals. Based on performance-based interviews, the one medical physicist has adequate and sufficient knowledge of regulatory requirements.

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

Radiation oncology residents commonly participate in the procedures. Urologists do not, except when requested to perform a cystoscopy in response to seeds in the bladder. Neither was interviewed.

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d. Radiation Safety Officer.

Chris Rauf

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

e. Support staff.

Nuclear medicine technologists perform package receipt surveys, load seeds into needles for implantation, perform surveys for misplaced seeds after each procedure, and perform patient release surveys. Based on performance-based interviews of one technologist, they have adequate and sufficient knowledge of regulatory requirements.

4. Performance-based tours and observations

a. Radiation oncology areas.

At the Barrett Cancer Center at the University of Cincinnati Hospitals. The only actions performed there are the preparation of pre-plans and post-plans using the treatment planning system.

b. Package receipt areas.

Warehouse and nuclear medicine. Based on a performance-based tour, these areas did not have any deficiencies or deviations from regulatory requirements.

c. Seed implant preparation areas.

In nuclear medicine. Based on a performance-based tour, these areas did not have any deficiencies or deviations from regulatory requirements.

d. Seed storage areas.

In nuclear medicine. Based on a performance-based tour, these areas did not have any deficiencies or deviations from regulatory requirements.

5. Evaluation of patient treatment results

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

Dr. Redmond stated that, at the end of each procedure, he reviews the PA fluoroscopic image and uses the TRUS to image the prostate in the transverse and sagittal planes. He also reviews the CT images later.

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

**VA Medical Center Cincinnati, Ohio
(October 16-17, 2008)**

- b. Fluoroscopy used to supplement TRUS during procedure.

No.

- c. Radiograph acquired after implant.

Yes, PA image acquired using C-arm fluoroscope.

- d. Written directive, Part 2: when completed and how.

Completed in OR after each procedure. The post-implant part of the written directive does not state the treatment site.

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

Day after implant.

- f. Post-plans: when completed, how to verify complies with written directive.

Post-plans are completed within a week to a month from each implant procedure using the Varian VariSeed treatment planning system at the Barrett Cancer Center of the University Hospitals of the University of Cincinnati.

Dr. Redmond stated that his understanding was that, if the implanted activity is within 20% of that prescribed, the procedure complied with the written directive.

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

Dr. Redmond stated that he does not pay much attention to these dose indices, which are based upon CT images acquired the day after the implant procedure. He stated that he relies upon PSA control at 5 years.

- h. Clinical quality assurance, including peer review.

William Barrett, M.D., performs peer review.

6. Workload data

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

Needles are loaded in nuclear medicine using the Mentor Isoloader. Until about 2 months ago, they were manually loaded in nuclear medicine with stranded seeds and loose seeds.

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

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b. Date of program inception.

September 1998.

c. Number of patients implanted per year.

2007 - 129

2008 – 66 to date.

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

I-125 only, Oncoseed Model 6711 and 6715 (6711 in strand)

Now, only Core Oncology 125SL

Note: This version of the audit checklist was extant in October 2008 and is used to document results for the inspection initiated during that period. NHPP also inspected the medical center for restart during June 30 to July 1, 2009, and completed an updated version of the audit checklist to evaluate the current status for the prostate seed brachytherapy program.

The restart inspection verified adequate and sufficient program changes in the written procedures and methods had been completed to ensure regulatory compliance and implementation of VHA standard procedures.

**Notice of Violation (NOV)
Inspection Report Number 539-08-I01**

VA Medical Center, Cincinnati, Ohio

VHA Permit Number 34-00799-03

1. Violation(s)

Inventories of sealed sources: 10 CFR 35.67(g) requires inventories of sealed sources to be conducted semi-annually.

Violation: Contrary to the above, the permittee was not performing semi-annual inventories of I-125 seeds being stored for decay.

This is a Severity Level IV violation.

Written directive: 10 CFR 35.40(b)(6)(ii) requires each written directive for brachytherapy, other than high-dose-rate brachytherapy, to state "after implantation, but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose)."

Violation: Contrary to the above, a permanent implant brachytherapy procedure of the lung was performed on June 3, 2009, but the post-implant information was not recorded on the written directive before completion of the procedure, but was instead recorded more than a month after the procedure.

This is a Severity Level IV violation.

2. Required action

a. The medical center was required to take prompt action to correct the violations listed in this NOV and ensure the violations do not reoccur.

b. Based on information collected during the inspection, the identified corrective actions in the inspection report narrative are accepted as adequate and sufficient. NHPP concluded the information provided during the inspection regarding the reasons for the medical events and violations, the corrective actions taken and planned to prevent recurrence, and the date when full compliance was achieved has been adequately addressed. Therefore, the medical center is not required to respond to this NOV. However, the medical center should submit a written statement or explanation if the descriptions in the inspection report narrative do not accurately reflect the medical center corrective actions or positions related to the inspection results.

c. NHPP will review corrective actions during the next scheduled NHPP inspection.