

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

Date: **NOV 06 2008**

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

Subj: Radiation Safety Program Inspection - Inspection Report 662-08-I02

To: Director (662/00), VA Medical Center, San Francisco, California

1. Edwin M. Leidholdt, Jr., Ph.D., NHPP, inspected the radiation safety program at the VA Medical Center, San Francisco, California, on October 28-29, 2008. This inspection was focused entirely on permanent implant prostate brachytherapy and did not serve as a routine NHPP inspection.
2. The inspection report is attached and consists of an NHPP Form 591 with no violations cited, a prostate brachytherapy checklist completed during this inspection, and a list of recommendations.
3. You are not required to respond to this memorandum or return a signed NHPP Form 591.
4. Thank you for the courtesy and cooperation extended during the inspection. Please contact Dr. Leidholdt at (707) 562-8374, if you have any questions about the inspection.


E. Lynn McGuire

Attachment

cc: Chair, National Radiation Safety Committee
Network Director, VISN 21 (10N21)

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. PERMITTEE/PERMIT NUMBER:</p> <p>VA Medical Center San Francisco, California 04-00421-05</p>	<p>2. LOCATION(S) INSPECTED:</p> <p>4150 Clement Street San Francisco, California 94121-1598</p>
<p>3. INSPECTION DATES: October 28-29, 2008</p>	<p>4. INSPECTION REPORT NUMBER: 662-08-102</p>

PERMITTEE:

The inspection was an examination of activities under your permit as they relate to radiation safety and compliance with Nuclear Regulatory Commission rules and regulations and your permit conditions. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and performance-based observations by the inspector. The inspection findings are as follows:

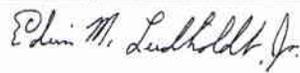
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited, are not being cited because they were self-identified, non-repetitive, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(s) and corrective action(s):

- 4. During this inspection certain of your activities, as described below and/or attached, were in violation of Nuclear Regulatory Commission requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting per 10 CFR 19.11. The violations and corrective actions are as follows:

STATEMENT OF CORRECTIVE ACTIONS

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made per 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand no further written response to the VHA National Health Physics Program will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
PERMITTEE			
NHPP INSPECTOR	Edwin M. Leidholdt, Jr., Ph.D.		November 5, 2008

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

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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).

Appear to conform to NRC regulations. Packages are delivered to the warehouse. Radiation safety staff is notified and transfers the packages to the radiation safety laboratory, Building 2, Room 10A, where the package receipt surveys are performed.

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

Appear to conform to NRC regulations and permit conditions. Packages are stored in Building 203, Room B-51, in the nuclear medicine area, prior to use in procedures. Excess seeds are stored in Building 2, Room 10A, after procedures.

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

Substantially conform to NRC regulations. Minor deviations from 10 CFR 35.2406 were identified. These were corrected during the inspection.

- 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 5.3092).

Shipped back to vendor. Appears to conform to NRC regulations.

2. Preparations for seed implant procedures

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

Appears to conform to NRC regulations.
The written procedures required by 10 CFR 35.40 are the written directive form itself.
There is a separate prostate brachytherapy checklist.

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

Appears to conform to NRC regulations.

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

TRUS, typically within a month before an implant. Performed jointly by urologist and authorized user physician.

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

The TRUS images are printed on a high quality grayscale printer. The urologist draws the contours of the prostate on the images in ink. The images are sent to ProQura in Seattle. The pre-plan is prepared by ProQura.

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

Completed in the procedure room by the authorized user physician before any seeds are implanted.

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

Surveys and records appear to conform to NRC regulations. Performed by radiation safety staff using a Ludlum portable survey meter equipped with a Model 44-3 thin window thin-crystal NaI probe.

- g. Patient release procedures, surveys, and records (10 CFR 35.75 and .2075).

Performed in the PACU by radiation safety staff at 1 meter anterior to the patient with the patient standing. The staff use one of two Bicon MicroRem survey meters. One has a thin window and the other does not. The radiation safety staff was not aware of the difference and used the two meters interchangeably. When tested with a vial of I-125 seeds, the thin window meter provided a reading about two to three times larger than the other meter. The radiation safety staff was not correcting the reading of the non-thin-window meter for the degraded energy response. A review was performed of the records of several patients released on the basis of measurements made with the non-thin-window meter; these recorded measurements, when multiplied by 2.5, did not approach the release limit of 1 mR/hour. Recommendation: If the non-thin window meter is used, correct the readings for the degraded energy response of the meter. Except for this deficiency, the procedures 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.

See Item above.

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- i. Patient instructions (10 CFR 35.75).

The patients are provided with verbal and written instructions. These appear to conform to NRC regulations.

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

Appear to conform to NRC regulations. Sources are calibrated by the seed vendor and again by Anazao Health Corporation.

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

Appears to conform to NRC regulations. The RSO provided an e-mail message from ProQura attesting to the acceptance testing of the TPS.

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

Not performed. This is not in accordance with the ACR Practice Guideline for Transperineal Permanent Brachytherapy of Prostate Cancer.

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

RSO is prepared for such events and incidents. On the other hand, the urologist who is currently performing implants and one of the authorized user physicians did not appear to be fully familiar with the NRC's definition of a medical event. Recommend the RSO improve the training of key staff in the definition of a medical event and the actions that must be taken if one occurs.

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

There are two authorized user physicians, both radiation oncologists. Dr. Patrick Swift was approved in July 2000 on the basis of board certification. Dr. James Rembert was approved in December 2006 on the basis of being named on an agreement state license.

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

Facility has procedures in place to attempt to detect leaking seeds before an implant and to protect a patient if leaking seeds are discovered to have been implanted in a patient.

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

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Initial and periodic training is being held, but may not be fully effective. The RSO is sending training material by e-mail to the two radiation oncologists and urologist. However, interviews with one radiation oncologist and urologist indicated they were not fully familiar with the NRC's definition of a medical event with respect to prostate brachytherapy.

q. Usual type of anesthesia?

General or spinal.

r. Prescribed dose for each radionuclide used?

145 gray

3. Performance-based interviews and observations

a. Authorized user physicians.

Interviewed Dr. James Rembert, one of two authorized user physicians. Based on performance-based interviews, he did not appear to be fully familiar with the NRC's definition of a medical event.

b. Medical physicists and dosimetrists.

None interviewed. None participate at the San Francisco VA Medical Center. The dosimetrists who prepare pre- and post-plans are at ProQura in Seattle.

c. Other physicians including urologists and/or residents.

Interviewed Dr. Matthew Cooperberg, the urologist who recently began participating in implant procedures. Dr. Cooperberg is replacing Katsuto Shinohara, M.D., on the implant team. Based on performance-based interviews, he did not appear to be fully familiar with the NRC's definition of a medical event.

d. Radiation Safety Officer.

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

e. Support staff.

None interviewed.

4. Performance-based tours and observations

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- a. Radiation oncology areas.

Not applicable. No radiation oncology areas at San Francisco VA Medical Center.

- b. Package receipt areas.

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

- c. Seed implant preparation areas.

Not applicable. Seeds are obtained in preloaded needles. The packages are opened in the procedure room.

- d. Seed storage areas.

Based on 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 were implanted properly.

At the end of each implant, a radiograph is acquired and a final review using the TRUS is performed. The post-plan is reviewed when it is received from ProQura.

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

On occasion, but not routinely.

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

Yes.

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

Completed by authorized user physician in procedure room after all seeds are implanted.

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

Approximately one month after each procedure.

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f. Post-plans: when completed, who draws the contours of the prostate and other organs, are the seed locations found by software manually corrected, how to verify complies with written directive. Are any indices of rectal dose calculated?

Formerly, printed CT images were sent to ProQura. Currently, a CT with the CT images is sent to ProQura. ProQura contours the prostate and other organs. Indices of rectal dose are computed.

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

The urologist and one authorized user physician.

h. Clinical quality assurance, including peer review.

Not formalized. Each post-plan is reviewed by a physician at ProQura who is experienced in prostate brachytherapy and who adds a written evaluation of the implant to the post-plan. The urologist and one authorized user both review the post-plan and post-implant dosimetry received from ProQura for each implant.

6. Workload data

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

In early years of program, the facility loaded needles on site and sterilized them. Currently use sterile preloaded needles from Anazao Health in Tampa.

b. Date of program inception.

November 1997

c. Number of patients implanted per year.

24 in 2007

24 in 2008 to date

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

I-125 only. Used Best Model 2301 until leaking seeds were implanted into two patients on March 14, 2008. Used Best Model 2301 to complete the implant of one of these patients. Since then, the Oncura Model 6711 Oncoseed has been used. It is obtained in preloaded needles from Anazao Health.

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7. Persons contacted

Ezra R. Safdie, P.E., Acting Medical Center Director ²
Leslie Buchman, Acting Associate Director ^{1,2}
Jean Marie Brown, Administrative Officer for the Associate Director¹
C. Diana Nicoll, M.D., Ph.D., M.P.A., Chief of Staff ²
Gary Cecchini, Ph.D., Chair, Radiation Safety Committee ²
Judy Yee, M.D., Chief, Radiology Service ²
Arnulfo Germes, M.A., Radiation Safety Officer ^{1,2,3}
Roy Herren, Physical Science Technician ³
James L. Rembert, M.D., Radiation Oncologist, and Authorized User Physician ³
Mathew Cooperberg, M.D., Urologist ³

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

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Recommendations

1. An authorized user physician and the urologist who serve on the implant team, when interviewed, did not appear to be fully familiar with the NRC's definition of a medical event in 10 CFR 35.3045 and requirements should one occur. The Radiation Safety Officer (RSO) provided evidence that training was being provided to these physicians by e-mail.

Recommendation: It is recommended the RSO modify the training methods so they are more effective and implement assessments of training effectiveness.

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

Recommendation: It is recommended the services of a therapeutic medical physicist be obtained to develop and oversee a technical quality assurance program for the TRUS, for accurate transfer of the TRUS images to the treatment planning system, and for the accurate transfer of CT images to the treatment planning system.