**DEPARTMENT OF VETERANS AFFAIRS**

# Memorandum

Date: OCT 06 2008

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

Subj: Radiation Safety Program Site Visit

To: Director (663/00), VA Puget Sound Health Care System, Seattle, Washington

1. Edwin M. Leidholdt, Jr., Ph.D., and Gary E. Williams, M.S., of the VHA National Health Physics Program (NHPP), performed a site visit to the VA Puget Sound Health Care System, Seattle, Washington on September 25-26, 2008. The purpose of the visit was to evaluate regulatory compliance and technical quality control regarding permanent implant prostate brachytherapy.

2. Attached is the site visit report describing the program areas evaluated and listing recommendations. You are not required to respond to this memorandum.

3. Thank you for the courtesy and cooperation extended during the site visit. Please contact Dr. Leidholdt at (707) 562-8374 if you have any questions about the site visit.

E. Lynn McGuire

Attachment

cc: Chair, National Radiation Safety Committee
Network Director, VISN 20 (10N20)
Director, VHA National Radiology Program
Director, VHA National Radiation Therapy Program

**Attachment**

**Radiation Safety Program Site Visit**
**VA Puget Sound Health Care System, Seattle, Washington**
**September 25-26, 2008**

## 1. Introduction:

Edwin M. Leidholdt, Jr., Ph.D., and Gary E. Williams, M.S., VHA National Health Physics Program (NHPP), performed a site visit to the VA Puget Sound Health Care System, Seattle, Washington, on September 25-26, 2008. They discussed the site visit results during a meeting with key health care system staff on September 26, 2008.

## 2. Scope of site visit:

The purpose of the visit was to assess regulatory compliance and technical quality assurance regarding permanent implant brachytherapy for prostate cancer. The site visit followed a pre-approved plan. The site visit included observations of rooms, equipment, and radiation safety practices; meetings and discussions with staff; and reviews of procedures and records, with an emphasis on risk and performance.

## 3. Findings and impressions:

It was noted the service was neat and clean and staff was highly professional. Radiation safety and technical quality assurance appeared to substantially conform to regulatory requirements and national standards. However, a few opportunities for improvement were identified. In particular, the following are recommended:

(a) The records of source accountability substantially conform to the Nuclear Regulatory Commission (NRC) regulations in 10 CFR 35.406 and 35.2406. However, minor differences between the records and 10 CFR 35.2406 indicate that the records have likely not been revised in light of the revision to 10 CFR 35 that became effective in 2002. It is recommended that the RSO and therapy physicists modify the records to fully conform to 10 CFR 35.2406.

(b) For the fluoroscopy unit used to supplement ultrasound imaging in guiding seed placement, the digital images cannot be transferred to the health care system's network for printing and archiving. It is recommended that connectivity be established between this fluoroscopy system and the health care system's network.

(c) There does not appear to be a formal process of ongoing clinical peer review for permanent implant prostate brachytherapy. Ten cases have been sent to the Richmond VA Medical Center for review. However, it is recommended that a formal process for ongoing clinical peer review be established for permanent implant prostate brachytherapy.

**4. Persons contacted:**

Sherri Bauch, Assistant Director [1]
Fred Fiscella, Interim Director, Environmental Management Service [1]
Kent Wallner, M.D., Radiation Oncology Physician, and Authorized User
Steven Sutlief, Ph.D., Chief Therapeutic Medical Physicist
Carl E. Bergsagel, M.S., Therapeutic Medical Physicist
David Dunn, Radiation Safety Officer [1]

1. Individual(s) present at exit meeting

# Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

**VA Puget Sound Healthcare System, Seattle, Washington**

*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 are received during normal working hours in the warehouse and held until radiation safety staff picks them up. According to the RSO, surveys are performed in the radiation safety laboratory within 3 hours of receipt.

b. Security requirements (10 CFR 20.1801 and .1802) and two delay methods if stored.

Conform to NRC requirements and permit conditions.

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

Substantially conform to NRC regulations. However, minor differences between the records and 10 CFR 35.2406 indicate that the records have likely not been revised to conform with the revision to 10 CFR 35 that became effective in 2002. Recommend that the RSO and therapy physicists modify the records to fully conform to 10 CFR 35.2406.

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

Appears to conform to NRC requirements.

e. Source disposal (i.e., ship to vendor or decay on site) (10 CFR 35.92 and .3092).

Shipped for storage and decay offsite. After decay offsite, seeds are disposed of without return to the VAMC. Waste broker is Thomas Gray.

2. Preparations for seed implant procedures

a. Written procedures and checklists (10 CFR 35.40 and .41).

Conform to NRC regulations. Procedures, written directive form, and two completed written directives were reviewed.

b. Patient identity verification, written directive, and treatment plan checking procedures (10 CFR 35.40 and .41).

Conform to NRC regulations.

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

Pre-implant imaging is by CT. Only about one of ten patients is local and most of the CT images are acquired at other VA facilities. If the patient is not on hormones, the service will accept CTs acquired as long as 2 years in advance.

d. Preplan preparation.

Dr. Wallner selects a plan from a library, based upon prostate height, width, and length on the CT image set and seeds are ordered according to that plan.

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

Completed and signed prior to insertion of seeds.

f. Surveys after source implant for misplaced seeds and records (10 CFR 35.404 and .2404).

Performed by medical physicist using a thin-window, thin-crystal NaI probe attached to a Ludlum Model 3 survey meter. Appears to meet regulatory requirements.

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

The radiation from the patient is measured at a distance of 1 meter in the anterior direction. A Victoreen Model 450B ion chamber survey meter is used with an open window.

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 are not being corrected for the energy response of the survey meter. However, a medical physicist stated that he reviewed the energy response curve of the Victoreen Model 450B and it is within 20% of the actual exposure rate for the energies measured. He stated that the measured exposure rates are never within 20% of the release criteria.

i. Patient instructions (10 CFR 35.75).

Patient written instructions were reviewed and were found to conform to good health physics practices and regulatory requirements.

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

Appear to conform to NRC regulations. The seed manufacturer assays each seed. Ten percent are then assayed by the seed vendor, which ships the seeds to the VAMC, loaded and sterilized in Mick cartridges. The facility does not assay any seeds.

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

The facility provided a report of TPS testing. The testing appears to conform to NRC requirements.

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

The facility performs QA testing of the TRUS and CT. Images are not transferred from the TRUS to the TPS because CT images are used for preplanning and for postplans. The accuracy of image transfer from the CT to the TPS was tested. Substantially conforms to accepted standards of practice.

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

The RSO, medical physicists, and one authorized user physician interviewed appeared to be familiar with NRC requirements.

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

Appears to meet regulatory requirements. Approval of the authorized user physician was documented in the Radiation Safety Committee minutes for the meeting of January 1998.

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

Packaging is surveyed after seeds are removed. A written procedure is being prepared.

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

Training of the authorized user physician is not documented. Recommend that such training be documented.

q. Usual type of anesthesia? Local anesthesia.

3. Performance-based interviews and observations

a. Authorized user physicians.

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

b. Medical physicists and dosimetrists.

Based on performance-based interviews, medical physicists have adequate and sufficient knowledge of regulatory requirements. Dosimetrist was not interviewed.

c. Other physicians including urologists and/or residents.

Urologists do not participate in implants. Residents participate, but were not interviewed.

d. Radiation Safety Officer.

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

e. Support staff.

None interviewed.

4. Performance-based tours and observations

a. Radiation oncology areas.

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

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.

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

d. Seed storage areas.

Based on performance-based tour, this area 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.

A CT is performed immediately after each implant and a postplan is performed. Additional seeds are then implanted if necessary to obtain adequate dose coverage of the target volume.

b. Fluoroscopy used to supplement TRUS during procedure. Yes

c. Radiograph acquired after implant.

Radiographs from the C-arm fluoroscope cannot be transferred to the VAMC's computer network for printing or storage. As an interim measure, a medical physicist places a plastic sheet over the video monitor of the C-arm fluoroscope and makes a tracing. A recommendation is made in the report of the site visit that the VAMC take action to remedy this deficiency.

c. Written directive, Part 2: when completed and how.

Immediately after each implant. Authorized user physician and medical physicist sign it.

d. Post implant CT scans: when completed?

A CT is performed immediately after each implant on the day of the procedure and a postplan is performed.

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

A postplan is performed immediately after the post-implant CT is performed.

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

Yes. The D90s of hundreds of procedures exceed 80% of the prescribed doses.

g. Clinical quality assurance, including peer review.

6. Workload data

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

Mick applicator.

b. Date of program inception. February 1998.

c. Number of patients implanted per year.

Approximately 400 patients per year. Typically, 2 to 3 patients are implanted a day on 4 days of each week. About 8 to 12 patients are implanted in a typical week. The department typically performs no implants for one month in late summer when the authorized user physician is not in the department.

d. Radionuclides (I-125, Pd-103, Cs-131).

All have been used. Currently, I-125 is being used on most patients, but Pd-103 is used on a few patients to provide training for residents. Cs-131 is not currently being used. I-125 seeds are Oncura Model 6711 and the Pd-103 seeds are from Theragenics.