

**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 (523/00), VA Boston Healthcare System, Boston, Massachusetts

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 Jamaica Plain Campus of the VA Boston Healthcare System on September 9-10, 2008. The purpose of the visit was threefold: to assess regulatory compliance and technical quality assurance regarding permanent implant brachytherapy for prostate cancer; to assess the state of technical quality control and radiation safety regarding machine sources in radiation oncology; and to gather information for NHPP's project on machine sources in radiation oncology.

2. Attached is the site visit report outlining the radiation oncology 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 1 (10N1)
Director, VHA National Radiology Program
Director, VHA National Radiation Therapy Program

**Radiation Safety Program Site Visit
Jamaica Plain Campus, VA Boston Healthcare System, Boston, Massachusetts
September 9-10, 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 Jamaica Plain Campus, VA Boston Healthcare System, Boston, Massachusetts, on September 9-10, 2008. Dr. Leidholdt discussed the site visit results during a meeting with key healthcare system staff on September 10, 2008.

2. Scope of site visit:

The purpose of the visit was threefold: to assess regulatory compliance and technical quality assurance regarding permanent implant brachytherapy for prostate cancer; to assess the state of technical quality control and radiation safety regarding machine sources in radiation oncology; and to gather information for NHPP's project on machine sources in radiation oncology. 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) Nuclear Regulatory Commission (NRC) regulations (10 CFR 20.1906) require labeled packages of radioactive materials be surveyed for removable contamination. These surveys must be able to detect 3 nanocuries of radioactive material on a wipe sample. When packages of I-125 seeds are delivered to the healthcare system for brachytherapy, wipe samples for removable contamination are measured using a Standard Imaging well-geometry ambient air ionization chamber and electrometer. The facility should determine whether this system is able to detect 3 nanocuries of I-125 on a wipe sample. If it cannot, a detector system and counting protocol with minimum detectable activity less than 3 nanocuries should be used to measure such wipe samples.

(b) 10 CFR 35.41 states that written procedures for written directives must address verifying the identity of each patient or human research subject. The written directive form addresses this verification, but the written procedures do not. The healthcare system's written procedures required by 10 CFR 35.41 should be modified to explicitly address verifying the identity of the patient or human research subject. NHPP also recommends addressing verification that the seeds brought to the operating room were ordered for that specific patient.

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Boston, Massachusetts – September 9-10, 2008**

(c) Modify the written procedures required by 10 CFR 35.41 to explicitly address when the post-implant portion of the written directive should be signed by the authorized user physician.

(d) Review procedures for providing and documenting training of authorized user physicians, medical physicists, and other persons with significant involvement in the brachytherapy program. Such training should be provided initially, periodically thereafter, and as needed (for instance, after changes in regulations or procedures). Training topics should include NRC regulatory requirements related to brachytherapy, including adverse event (e.g., lost seeds and medical event) reporting requirements, and facility procedures.

(e) For each major acceptance test or commissioning, it is recommended that a report be prepared that summarizes testing dates, methods, standards used, equipment, results, a statement regarding readiness for clinical use, and signature of the chief medical physicist.

(f) Reports of the shielding calculations and shielding surveys for both Linac vaults, performed at the time of installation, could not be located. To remedy this deficiency, Mr. Naughton has made a great effort to repeat these calculations and surveys and documented them in well-written reports. However, it is recommended the reports of shielding surveys be reviewed to ensure that the correct use factors were applied to secondary barriers.

4. Persons contacted:

Michael Charness, M.D., Chief of Staff
Karen Acerra-Williams, Health Systems Specialist, Director's Office
Mia Powers, MHA, Staff Assistant to the Chief of Staff¹
James Pearlman, M.D., Radiation Oncology Physician, and Authorized User
John P. Naughton, M.S., Chief Therapeutic Medical Physicist¹
David Drum, M.D., Nuclear Medicine Physician, and Radiation Safety Officer¹
Irving Kaplan, M.D., Radiation Oncologist, Beth Israel Deaconess Medical Center
Nicole Flagg, RT(T), Dosimetrist

1. Individual(s) present at exit meeting

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

VA Boston Healthcare System, Boston, Massachusetts

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 delivered to the warehouse by FedEx. FedEx then delivers the packages directly to Radiation Oncology Service. Surveys appear to meet all NRC requirements with one exception: wipe samples used to detect removable contamination on the package surfaces are being assayed using a Standard Imaging ambient air well-geometry ion chamber and electrometer. It is unlikely that the MDA of this system meets NRC requirements in 10 CFR 20.1906. Recommend that the MDA of this system for I-125 be reviewed and, if not sufficiently low, establish a procedure on another detection system, such as a NaI scintillation well counter.

- b. Security requirements (10 CFR 20.1801 and 20.1802) 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).

Conform to regulatory requirements.

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

Conform to regulatory requirements.

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

Facility stores unused seeds for decay and disposal as non-radioactive waste. Plans for disposal conform to regulatory requirements.

2. Preparations for seed implant procedures

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

Conform to regulatory requirements. The written directive form has a checklist for patient identity verification; however, patient identity verification is not specifically addressed in the text of the procedures. Recommend that the written procedures be revised to describe methods for verifying the identity of each patient.

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

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Based on performance-based interviews, conform to regulatory requirements.

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

Performed using CT, done about two months in advance of a procedure. Real-time planning is done for each procedure.

- d. Preplan preparation.

No preplan; real-time planning is performed in the OR.

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

Completed before first seed is implanted. Conforms to NRC regulations.

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

Based on performance-based interviews and review of available records, conform to regulatory requirements.

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

Based on performance-based interviews and review of available records, conform to regulatory requirements.

- 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.

According to the medical physicist, a Ludlum survey meter, equipped with a pancake GM probe, is used for these measurements. The survey meter readings are not being corrected for instrument energy response. According to the manufacturer's energy response curve, the system will over-respond by about a factor of two for the x-rays from I-125. Thus, the measurement errs in the conservative direction.

- i. Patient instructions (10 CFR 35.75).

Conform to regulatory requirements.

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

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Medical physicist performs calibration measurements of 10% of the seeds for each patient. A document from the seed vendor states that the vendor assays 100% of the seeds.

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

Based on performance-based interviews and review of available records, conform to regulatory requirements. However, it is recommended that the physicist prepare a summary memorandum describing the testing and the protocols followed, and summarizing the findings.

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

Based on performance-based interviews and review of available records, 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 medical physicist 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).

Broad-scope permittee. Radiation Safety Committee approval appeared to meet regulatory requirements.

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

Satisfactory.

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

Initial training for new physician authorized user was completed by informal discussions and procedures review. Recommend facility review methods and criteria for initial training to establish more explicit documentation.

- q. Usual type of anesthesia?

General anesthesia.

3. Performance-based interviews and observations

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a. Authorized user physicians.

Interviewed James Pearlman, M.D., Radiation Oncology Physician and recently approved Authorized User and also Irving Kaplan, M.D., of Beth Israel Deaconess, who is mentoring Dr. Pearlman in prostate brachytherapy.

Based on performance-based interviews, users have adequate and sufficient knowledge of regulatory requirements.

b. Medical physicists and dosimetrists.

Interviewed John Naughton, M.S.

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

c. Other physicians including urologists and/or residents.

None interviewed.

d. Radiation Safety Officer.

Interviewed David Drum, M.D., nuclear medicine physician and 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, this area did not have any deficiencies or deviations from regulatory requirements.

b. Package receipt areas.

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

c. Seed implant preparation areas.

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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.

Post-implant CT scans and post-plan using Pinnacle3 TPS.

b. Fluoroscopy used to supplement TRUS during procedure.

Yes.

c. Radiograph acquired after implant.

Yes.

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

Completed by AU physician in OR or in Radiation Oncology Service shortly afterwards.

e. Post implant CT scans: when completed?

For one AU physician, same week as procedure; for the other, approximately one month later. Both conform to ACR guideline.

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

Post-plans performed on day of post-implant CT.

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

Yes. Ten consecutive implants reviewed. Lowest D90 was approximately 90% of prescribed dose.

h. Clinical quality assurance, including peer review.

Being established.

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6. Workload data

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

Needles loaded in OR.

- b. Date of program inception.

Approximately 1998

- c. Number of patients implanted per year.

Approximately 30.

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

I-125. Use Oncura Model 6711 seed.