

**DEPARTMENT OF  
VETERANS AFFAIRS**

**Memorandum**

Date: **DEC 18 2008**

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

Subj: Radiation Safety Program Inspection and Notice of Violation - Inspection Report 688-08-I01

To: Director (688/00), VA Medical Center, Washington, DC

1. Edwin M. Leidholdt, Jr., Ph.D., Gary E. Williams, and Paul L. Yurko, VHA National Health Physics Program, inspected your radiation safety program on September 30-October 1, 2008, and again on November 12 and 14, 2008, with continuing review through December 2, 2008.

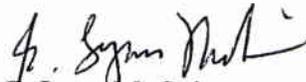
2. Attachment A to this memorandum is the inspection report. Attachment B is a Notice of Violation listing three violations. The violations represent deviations from Nuclear Regulatory Commission (NRC) requirements for radioactive material use and are cited at Severity Level IV.

3. These violations pertain to the transperineal permanent implant prostate seed brachytherapy program and were identified during a reactive inspection subsequent to a report of three medical events. Based on further review of the patient circumstances of the medical events, we retracted the medical events by notification to NRC Operations Center on December 2, 2008. However, your seed brachytherapy program must remain suspended and requires specific approval by the National Radiation Safety Committee before restart.

4. 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 in preparing the response.

5. For additional information, Attachment C has results for the audit checklist completed as part of the inspection.

6. Please contact Mr. Yurko at (410) 642-2411, extension 6288, if you have any questions about the inspection.

  
E. Lynn McGuire

Attachments

cc: Network Director, VISN 05 (10N05)

**RADIATION SAFETY PROGRAM INSPECTION**  
**Inspection Report Number 688-08-I01**  
**VA Medical Center, Washington, DC**  
**September 30 – December 2, 2008**

**1. Introduction:**

a. Edwin M. Leidholdt, Jr., Ph.D., Gary E. Williams, and Paul L. Yurko, VHA National Health Physics Program (NHPP), performed an announced reactive inspection of the radiation safety program for transperineal permanent implant prostate brachytherapy (hereafter referred to as prostate brachytherapy) at VA Medical Center, Washington, DC. Gary E. Williams and Paul L. Yurko performed the initial on-site visit on September 30 and October 1, 2008.

(1) The inspection focus was three possible medical events involving prostate brachytherapy that occurred after November 30, 2007, the effective date for which revised Nuclear Regulatory Commission (NRC) regulations became applicable for the Pd-103 used for patient treatments.

(2) The possible medical events were discovered during an external review process as part of VHA follow-up for medical events discovered at the VA Medical Center, Philadelphia, Pennsylvania. Four of the ten patient charts reviewed were for patient treatments conducted after November 30, 2007. Of the four patient treatments, three had inadequate seed distributions such that the D90 doses (the largest doses covering 90% of the volume of the prostate) were less than 80% of the prescribed dose.

(3) The inspectors presented their preliminary findings at a meeting with key medical center staff on October 1, 2008, including review of apparent violations.

b. Two inspectors performed a second on-site visit to the medical center on November 12 and 14, 2008, to further evaluate the possible medical events and corrective actions since the initial inspections. NRC staff accompanied the inspectors.

(1) NRC regulations in 10 CFR 35.3045 define a medical event. The inspectors used this definition as a basis to evaluate the possible medical events.

(2) The medical center provided information for the three patient treatments reported as having D90 doses that were less than 80% of the prescribed dose. Two patients had been asked to return for late follow-up CTs and the D90 doses were determined to be above the 80% threshold for both patients. For the third patient, after a review of the prostate volume in the post-treatment CT scan, the value of D90 was determined to be 82%. External review by VA Puget Sound Health Care System, Seattle, Washington, confirmed these revised D90 doses.

(3) The inspectors conducted an exit meeting for the second visit on November 14, 2008, and left the inspection open pending further review.

c. NHPP reviewed the possible medical events and agreed with the medical center position that, given confirmed D90 values exceeding the 80% dose threshold, the patient circumstances were not within the regulatory definition of a medical event.

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(1) NHPP retracted the possible medical events on December 2, 2008, by notifying the NRC Operations Center.

(2) NHPP informed the medical center on December 2, 2008, about the retraction and noted the prostate brachytherapy program must remain suspended until the National Radiation Safety Committee approves restart.

(3) NHPP closed the inspection on December 2, 2008.

**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 and contract staff regarding the events,
- b. Review 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 a prostate brachytherapy program,
- f. Evaluation of root or basic causes for the events, and
- 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 5-6, 2003, cited one Severity Level IV violation for failure to perform adequate surveys. This was not prostate brachytherapy related. NHPP inspected the medical center on March 2, 2006, and did not cite any violations. A non-cited violation was identified but not prostate brachytherapy related.
- b. The medical center had not previously reported any medical events involving prostate brachytherapy.
- c. The inspectors gathered information about the history of the prostate brachytherapy program at the medical center and the workload.

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(1) The first prostate brachytherapy procedure was performed on December 15, 1998. Only Pd-103 seeds have been used. Since program inception, approximately 95 patients have been treated. In 2008 to date, five patient procedures were performed.

(2) In June 2002, a Varian VariSeed™ treatment planning system (TPS) was delivered. In July 2002, the TPS was used to create pre-plans using trans-rectal ultrasound system (TRUS) images. Prior to this, pre-plans were not performed.

(3) In January 2005, post-implant CTs were obtained and the TPS used to create post-plans. Prior to this, post-plans and post-implant dose assessments were not performed.

(4) On September 26, 2008, based on an external review by VA Puget Sound Health Care System, Seattle, Washington, NHPP notified NRC of three possible medical events. NHPP contacted the medical center Chief, Radiation Oncology Service who agreed to suspend the prostate brachytherapy program.

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

(1) The medical center has a Radiation Oncology Service with two radiation oncology physicians, both of whom are full-time VA employees. The permit lists the physicians as authorized user physicians for brachytherapy. There are two medical physicists, one a full-time VA employee and the other a contractor.

(2) The medical center obtains non-sterilized Pd-103 seeds in cartridges for the Mick applicator, from a commercial vendor.

(3) Within a few weeks before each patient procedure, an authorized user physician obtains TRUS images. The images are transferred to the TPS for a medical physicist 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 physician.

(4) The authorized user physician reviews the treatment plan prepared using the TPS, prepares, and signs a written directive. A medical physicist may assist the physician.

(a) 10 CFR 35.40 specifies that the part of the written directive completed before an implant procedure must state the treatment site, radionuclide, and dose.

(b) The medical center written directive procedures require preparation of a written directive form before each implant. This information includes the radionuclide, treatment site, planned number of seeds, strength per seed, and dose in cGy. The information is transcribed from the treatment plan and needle loading diagrams onto the written directive form.

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(5) The written directive and needle loading diagrams are provided to the Radiation Safety Officer (RSO). A medical physicist orders cartridges/magazines loaded with 15 seeds per cartridge from the seed vendor.

(6) The seed vendor ships a package of two containers; one contains the calibrated seed and the second has approximately 15 magazines of seeds for the applicator. The package is delivered to the mailroom; the mailroom staff stores the package in a secure area and notifies the RSO. The RSO takes the package of seeds and performs a package receipt survey. The seeds are then stored under RSO control until the prostate brachytherapy procedure. A medical physicist uses a well-type ionization chamber and electrometer to verify activity of the single, separately calibrated seed in the package.

(7) Seeds are implanted in patients in an operating room under TRUS guidance. Fluoroscopy is not used. The team for patient treatments includes an authorized user physician, a medical physicist, an anesthesiologist, and nurses.

(8) After the procedure, the patient recovers from the anesthesia in a post-surgical recovery room and remains overnight. On the second or third day after the prostate brachytherapy procedure, CT images are obtained of the patient's pelvic region. At some time thereafter, the CT images are transferred to the TPS, an authorized user physician contours the prostate, and a medical physicist creates a post-plan to assess the dose distribution. Indices of the dose distribution to the prostate, including V100 and D90, are calculated and given to the physician.

e. The inspectors confirmed regulatory compliance for the following:

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

(2) Stored sealed sources security before and after prostate brachytherapy procedures under 10 CFR 20.1801 and permit conditions.

**4. Findings and impressions (regulatory violations):**

a. The inspectors reviewed and evaluated information about the reported possible medical events and overall implementation of the prostate brachytherapy program.

b. The inspectors concluded three regulatory violations related to the circumstances for prostate brachytherapy procedures.

(1) The first violation was that, contrary to 10 CFR 35.41(a) and (b), the permittee did not develop, implement, and maintain written procedures for prostate brachytherapy to provide high confidence that each administration requiring a written directive is per the written directive and treatment plan.

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(a) During the initial on-site inspection, the only written procedures available for review were part of a Quality Management Program circa 1998. These procedures were outdated and did not reflect current regulations and practices.

(b) The inspectors concluded these written procedures were not adequate to ensure that each administration requiring a written directive would be administered per the written directive and the pre-treatment plan as required by the regulation.

(2) The second violation was that, contrary to 10 CFR 35.27, the permittee did not provide training to the Radiation Oncology Service staff regarding current NRC regulations on medical events or on medical center procedures for procedures requiring a written directive.

(a) Because the written procedures were outdated, any training on these procedures, even if completed, was not adequate and sufficient to include current NRC requirements, methods, and procedures being used by the medical center.

(b) The medical center did not have a record to document any training related to the written procedures.

(3) The third violation was that, contrary to 10 CFR 35.75, the release surveys for patients who had been administered radioactive materials did not determine that the total effective dose equivalent to any other individual from exposure to the released patient was not likely to exceed 5 mSv (0.5 rem).

(a) The medical center did not have a procedure for release surveys to specify an appropriate survey for patient measurements. The survey meter used for the release surveys was a Ludlum Model 19 Micro-R meter and this survey meter only has a documented energy response down to approximately 40 keV. The Pd-103 seeds used emit characteristic x-rays with average energies of about 21 keV. This meter is inadequate for such surveys.

(b) During the initial inspection, the medical center facility agreed to use either a Ludlum Model 3 with a thin-window NaI Model 44-3 detector, if the detector is properly calibrated for Pd-103, or a Ludlum Model 9 ion chamber for their release surveys, with correction of measurements for the meter's energy response.

c. The inspectors evaluated the root or basic causes for the first and second violations noted in Paragraph 4b above as the following:

(1) "Management System - Procedures - Need Improvement," in that an adequate written procedure for prostate brachytherapy was not available; and

(2) "Work Direction - Preparation - Needs Improvement," in that authorized user physicians and medical physicists with primary involvement in preparing the treatment plans, written directives, and dose analysis were not provided any training or briefing to ensure compliance with current NRC regulations.

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d. The inspectors evaluated the root or basic causes for the third violation noted in Paragraph 4b above as “Procedures - Need Improvement.” Procedures for release surveys did not specify use of an appropriate survey meter.

e. The inspectors confirmed during the second on-site inspection that the medical center had initiated corrective actions for the violations.

**7. Notice of Violation:** The inspection identified three violations of NRC regulations. The first violation was failure to have written procedures to provide high confidence each administration is per the written directive and the treatment plan. The second was failure to provide training in the specific procedures for prostate brachytherapy. The third violation was failure to complete an adequate release survey to comply with 10 CFR 35.75.

**8. Persons contacted:**

Fernando O. Rivera, FACHE, Medical Center Director  
Ross D. Fletcher, M.D., Chief of Staff  
Joann Manning, M.D., Chief, Radiation Oncology Service, and Authorized User Physician  
William Jackson, M.D., Radiation Oncology Physician, and Authorized User Physician  
Indravadan Patel, Ph.D., Therapy Physicist  
Mariana Guerrero, Ph.D., Therapy Physicist  
Michael Funkhouser, Radiation Safety Officer

**Notice of Violation (NOV)  
Inspection Report Number 688-08-I01**

VA Medical Center, Washington, DC

VHA Permit Number 08-00942-05

**1. Violation(s):**

a. Written procedures for written directives: 10 CFR 35.41(a) and (b) 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 and the written directive is per treatment plan.

Violation: Contrary to the above, for prostate brachytherapy procedures performed since November 30, 2007, the permittee did not have adequate written procedures to provide high confidence that each administration was per the written directive and the written directive per the treatment plan.

This is a Severity Level IV violation.

b. Instruction of supervised individuals: 10 CFR 35.27(a)(1) requires a permittee to instruct any supervised individuals, *inter alia*, in the written directive procedures, Nuclear Regulatory Commission (NRC) regulations, and permit conditions for use of radioactive materials.

Violation: Contrary to the above, the permittee's current written procedures for the prostate brachytherapy program were dated December 1998, did not define a medical event, and were not up-to-date with current NRC regulations. Furthermore, additional training was not provided to the supervised individuals in the Radiation Oncology Service for prostate brachytherapy program requirements or current NRC requirements.

This is a Severity Level IV violation.

c. Release surveys: 10 CFR 35.75 allows a permittee to release from permittee control any individual who has been administered implants with radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

Violation: Contrary to the above, for prostate brachytherapy procedures performed since November 30, 2007, the permittee made surveys to comply with 10 CFR 35.75 with a survey meter not adequate to detect the type and energy of the radiation released by Pd-103.

This is a Severity Level IV violation.

**2. Required action:**

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

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b. The medical center must submit a written statement to National Health Physics Program (NHPP) within 30 days of the date of the memorandum transmitting this NOV. For each of the violations, the medical center 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, NHPP will consider extending the response time.

d. The medical center must continue the prostate brachytherapy program suspension and not take any corrective actions that involve a patient treatment unless specifically approved by the National Radiation Safety Committee for restart.

## Attachment C

### Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

**VA Medical Center, Washington, DC**

**October 30-December 2, 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 are received during normal working hours in the mailroom and held until the Radiation Safety Officer (RSO) retrieves the packages. Receipt surveys are performed in the radiation safety laboratory within three hours of receipt.

- 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).

Source accountability and records conform to NRC regulations. For the inspection, the inspectors recommended the source accountability records be consolidated into a single document or computer record.

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

Conforms to NRC requirements.

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

Unused seeds are shipped to vendor.

#### 2. Preparations for seed implant procedures

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

The written procedures were outdated as evaluated during the initial on-site inspection. The inspectors recommended the RSO update the procedures to conform to current NRC regulations. At the second on-site inspection, the RSO provided revised procedures for review. The revised procedures appeared to conform to current NRC regulations.

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

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Reviewed written directive, patient identification verification, and treatment plans since November 2007. Conform to NRC regulations.

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

Pre-implant imaging is by ultrasound only. Images are obtained 1 week to 3 months before procedure.

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

Patients are selected based on age, condition, size of prostate. Determination made 1 week to 3 months before procedure. An authorized user physician draws the contours of the prostate.

- 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 35.2404).

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

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

The RSO performs the release surveys. The survey meter utilized in the past, a Ludlum Model 19, is inappropriate for the survey. Published energy response curves are not available below 40 keV. After the first on-site visit of this inspection, the facility decided to utilize either a thin-crystal NaI probe (Model 44-3) attached to Ludlum Model 3 if it can be properly calibrated or a Ludlum Model 9 ion chamber. Both detectors have an energy response at the low level of Pd-103.

- 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.

Measurements are not being corrected for energy response of the survey meter. Survey meter used for measurements is inappropriate for the type of energy. According to the RSO, measurements henceforth will be corrected for the energy response of the meter.

- i. Patient instructions (10 CFR 35.75).

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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. Measurement on one calibration seed, pre-loaded seeds utilized for procedures.

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

No documentation of acceptance testing could be found during the visit on September 30 and October 1, 2008. During the second on-site visit, the medical physicists showed a report documenting such acceptance testing. The testing appears to conform to 10 CFR 35.457.

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

No quality assurance testing was being performed on the TRUS. Since the first on-site visit of this inspection, the facility has implemented a QA program for the TRUS.

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

Authorized users and medical physicists were knowledgeable about the definition of medical events, but did not interpret the definition to require use of post-treatment dose analysis as a basis to discover a medical event. The possible medical events with initial D90 doses less than 80% were not identified and reported.

For the NHPP notification and coordination with the facility when the possible medical events were reported to NRC, contacting the RSO after normal working hours was difficult.

Prior to the second on-site visit of this inspection, the RSO had been required to carry a cell phone after normal working hours.

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

Both authorized users are named on the current permit. Approval of the second authorized user was documented in Radiation Safety Committee minutes. Approval by NHPP was part of the most recent permit renewal. The first authorized user was named on NRC license in effect before the master materials license.

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

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Packaging is surveyed after seeds are removed but this procedural step is not part of a written procedure. The inspectors recommended preparation of a written procedure.

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

The facility did not have any documented training for medical physicists or authorized users during the first on-site visit.

Prior to the second on-site visit of this inspection, the facility had implemented a training program for all staff involved in prostate brachytherapy. Training on the new procedures and medical events was completed and attendance records were filed by the RSO. The inspectors reviewed these training records during the second on-site visit.

- q. Usual type of anesthesia?

General anesthesia.

- r. Prescribed dose for each radionuclide used?

125 gray

- 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 the images retained?

PACS

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

Yes, from June 2002 until January 2005, post-plans were not performed because CT images could not be transferred to the VariSeed treatment planning system.

### 3. Performance-based interviews and observations

- a. Authorized user physicians.

Based on performance-based interviews, the authorized user physicians had adequate and sufficient knowledge of regulatory requirements, except for implementation of NARM and post-treatment dose analysis as a basis to discover a medical event.

This training deficiency was corrected during the training described in Item 2p above.

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b. Medical physicists and dosimetrists.

Based on performance-based interviews, medical physicists have adequate and sufficient knowledge of regulatory requirements, except for implementation of NARM and post-treatment dose analysis as a basis to discover a medical event.

This training deficiency was corrected during the training described in Item 2p above.

c. Other physicians including urologists and/or residents.

Urologists do not participate in prostate brachytherapy procedures.

d. Radiation Safety Officer.

Based on performance-based interviews, the Radiation Safety Officer had adequate and sufficient knowledge of regulatory requirements, except for implementation of NARM and post-treatment dose analysis as a basis to discover a medical event.

This training deficiency was corrected during the training described in Item 2p above with the RSO as the instructor.

e. Support staff.

The inspectors did not interview support staff.

4. Performance-based tours and observations

a. Radiation oncology areas.

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

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

d. Seed storage areas.

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Based on a 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.

No post-plans were performed for implants before January 2005. Since that date a CT is performed 3 days to 2 weeks post-implantation and a post-plan is performed.

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

No

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

No

- d. Written Directive Part 2: when completed and how.

After implantation, but before completion of procedure, Written Directive Part 2 is completed and signed by an authorized user.

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

A post-implantation CT is performed 3 days to 2 weeks after implantation.

- 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?

A post-plan is performed approximately 1 week after CT is contoured. The authorized user performs contours. No dose indices are calculated for the rectum.

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

Figure of merit is the D90; no post-plans were performed for implants before January 2005.

- h. Clinical quality assurance, including peer review.

Peer review was performed, but did not follow up on low doses.

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6. Workload data

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

Mick applicator

- b. Date of program inception.

December 15, 1998

- c. Number of patients implanted per year.

Approximately 95 patients have been implanted since the prostate brachytherapy program inception. Currently, approximately 4 to 6 patients are implanted per year.

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

Only Pd-103 has been used, Theragenics Model 200.