



DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
National Health Physics Program
2200 Fort Roots Drive
North Little Rock, AR 72114

MAR 02 2010

In Reply Refer To: 598/115HP/NLR

Cassandra F. Frazier
Division of Nuclear Materials Safety
Region III, Nuclear Regulatory Commission (NRC)
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: NRC License 03-23853-01VA

Dear Ms Frazier:

Per your request for information regarding the prostate seed implant program, I am enclosing documents from the Hunter Holmes McGuire VA Medical Center, Richmond, Virginia.

Please contact Gary E. Williams at 501-257-1572, if you have any questions or comments.

Sincerely,

Lisa Maloy Offutt
Lisa Maloy Offutt

Administrative Officer, National Health Physics Program

Enclosure

RECEIVED MAR 05 2010

rw

NRC Request for Information (February 16, 2010)
Hunter Holmes McGuire VA Medical Center, Richmond, Virginia

1. Provide copies of policies and procedures for prostate implants to include the following:
 - a. Copies of policies and procedures current at the time of the on-site NRC inspection for the prostate implant program with the effective date indicated.
 - b. Copies of policies and procedures that were revised after the on-site NRC inspection or in response to NHPP recommendations with the effective date indicated.
2. Provide copies of any training records for calendar years 2007, 2008, and 2009 for medical physicists, dosimetrists, physician authorized users, and radiation safety staff involved in prostate implants.

From: Panos P Fatouros/HSC/VCU [ppfatouros@vcu.edu]
Sent: Wednesday, February 24, 2010 11:35 AM
To: Williams, Gary E
Cc: Leidholdt, Ed; Offutt, Lisa M; Hagan, Michael P., M.D., Ph.D. RICVAMC; Huston, Thomas E.; Kemp, Wendy H. RICVAMC; Burke, Timothy S. RICVAMC; Habeeb Saleh/FS/VCU; Jianqiao Luo/FS/VCU; John D Wilson/HSC/VCU
Subject: Additional information for NRC inspection
Attachments: AttendMar2009Brachy.pdf; AttendDec2007.pdf; AttendDec2008.pdf; AttendMar2009.pdf; Radiation Safety LectureRadOncMar2009.doc; BrachyLectureMar2009.docx; Radiation Safety LectureRadOncDec2007.docx; Radiation Safety LectureRadOncDec2008.docx; ProstateSeedImplantManual_April2009.doc; ProstateSeedImplantManual_Sept2008.doc

Mr. Williams,

As requested, I am attaching the following documents addressing NRC's questions:

1. Our current Prostate Seed Implant Procedures and QA Manual: file titled "ProstateSeedImplantManual_April2009". The procedures described were put into effect as per NHPP instructions by April 24, 2009.

Note: The NRC inspection of our facility was conducted in April 22-23, 2009.

2. Our previous "Prostate Seed Implant Procedures and QA" Manual: file titled "ProstateSeedImplantManual_Sept2008". The procedures described were in effect prior to April 24, 2009.

3. Training records for calendar years 2007, 2008 and 2009 including copies of attendance sheets. Specifically for 2009, two training sessions were held that were focused on brachytherapy procedures for medical physicists, dosimetrists, physician authorized users and radiation safety personnel involved in prostate implants.

I hope this additional information satisfies the NRC requirements. Please let me know if you need anything else.

Sincerely,

Panos P Fatouros, Ph.D., FACR
Radiation Safety Officer, Hunter Holmes McGuire Veterans Medical Center, Richmond, VA
Professor & Chair, Div. of Radiation Physics & Biology

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"Williams, Gary E" <Gary.Williams3@va.gov>

02/17/2010 04:03 PM

To <ppfatouros@vcu.edu>

cc <Edwin.Leidholdt@va.gov>, <Thomas.Huston2@va.gov>, "Offutt, Lisa M" <lisa.offutt@va.gov>, "Hagan, Michael P., M.D., Ph.D. RICVAMC" <Michael.Hagan@va.gov>

Subject additional information for NRC inspection

NRC requested additional information related to their on-site inspection at Richmond for the prostate seed implant program.

I am attaching the specific questions for which NRC has requested a response be received from NHPP by February 24, 2010.

Please review the questions and provide to NHPP an e-mail or facsimile response with the best possible response for the requested information or documents as soon as possible.

Some of the questions might not be applicable based on the current or past status for your prostate seed implant program.

If so, you should indicate which information or documents are not applicable.

As an example, training records might not be applicable for calendar year 2009, if your program was inactive during that calendar year.

If you have any questions, please contact Ed Leidholdt.

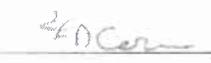
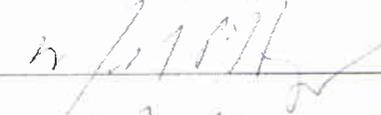
Gary E. Williams
National Health Physics Program
Veterans Health Administration
North Little Rock, Arkansas
W 501-257-1572; C 501-256-5331

**In-Service Training: Transperineal Permanent Implant Prostate Seed
Brachytherapy Program**

Hunter Holmes McGuire Veterans Medical Center

March 4, 2009

**Presenters: Panos P Fatouros, PhD, RSO
Habeeb H Saleh, PhD, Rad. Oncology**

NAME	SIGNATURE	TITLE/JOB FUNCTION
Jeremy Horn		Physicist
Frank Corwin		Physicist
JOHN WILSON	John D. Wilson	RSO Staff
Jiangqiao Luo		Physicist
JAMES GORDON		PHYSICIST
Vicki Skinner		Research Nurse
Rosemary Schaefer	Rosemary Schaefer	DOSIMETRIST
Habeeb Saleh	Habeeb H Saleh	Physicist
Michael Hagan		Physician
Panos Fatouros		RSO

Filename: AttendMar2009.pdf

Hunter Holmes McGuire VAMC, Richmond, Virginia
Department of Radiation Oncology
Annual Radiation Safety Refresher Training

Name	Signature	Title/Job Function
Glenda Campbell	Glenda Campbell	Chief Therapist
Donise Greaves	Donise Greaves	Rad. Therapist
Michaela Rosa	Michaela Rosa	Physicist
Kelly W. Warren	Kelly Warren	Therapist
Adel JACKSON	Adel Jackson	Therapist
Daniella Montejano	Daniella Montejano	Therapist
John Spindler	John Spindler	Dosimetrist


Signature:

Habeeb Saleh, Ph.D.
Radiation Therapy Physicist
3/16/2009

Radiation Safety Lecture
Radiation Oncology Services

March 16, 2009

Habeeb Saleh, Ph.D.

The following topics were covered:

1. General information and definitions of radiation sources.
2. NRC regulations
3. Survey meters
4. Signs, Labeling requirements for radiation devices and sources.
5. Radiation monitoring devices
6. Medical events definition and reporting
7. Patient discharging information.

Filename: BrachyLecture Mar 2009.docx

***In-Service Training: Transperineal Permanent Implant Prostate Seed
Brachytherapy Program***

Hunter Holmes McGuire Veterans Medical Center

Radiation Oncology Service

March 4, 2009

Panos P Fatouros PhD, RSO

This presentation focused specifically on discussing prostate seed implant procedures and QA at the Medical Center. The basis for this educational meeting was (a) the VAMC manual that we have prepared (attached) and (b) the VHA Standard procedures that were introduced at the national VA Radiation Oncology Conference in January 8-9, 2009 in Washington, DC. During this afternoon-long meeting an extensive Q&A session followed that covered all aspects of the brachytherapy program at our institution.

Radiation Safety Lecture
Radiation Oncology Service
Dec. 14, 2007
Jianqiao Luo, PhD

Presentation covered basic radiation safety topics including

- NRC Regulations,
- Dosimetry Records,
- Patient Surveys,
- Staff Safety Protection,
- Record Keeping
- ALARA Principles

Filename: Radiation Safety Lecture RadOncDec2008.docx

Radiation Safety Lecture
Radiation Oncology Service

Dec. 8, 2008

Jianqiao Luo, PhD

Presentation covered basic radiation safety topics including

- NRC Regulations
- Survey Meters
- Dosimetry Records
- Patient Surveys
- Staff Safety Protection
- Record Keeping
- ALARA Principles

**Hunter Holmes McGuire Veterans Medical
Center**

Radiation Oncology Service

Prostate Seed Implant Procedures and QA

**1201 Broad Rock Blvd
Richmond VA 23249**

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1.0 Goals

The plan aims to monitor and evaluate the brachytherapy application of radioactive materials and to resolve identified problems in order to ensure accurate radiation dose delivery, minimize risks to patients and personnel, and ensure compliance with applicable laws and regulations. In addition to other indicators defined in the quality assessment plan, specific indicators consistent with the aims mentioned above are:

- Dose integrity verification
- Assessment of radiation safety

2.0 Scope

The brachytherapy quality assessment plan is designed to monitor and evaluate the brachytherapy use of all radioactive materials by the Radiation Oncologists.

3.0 Procedures

3.1 Radiation Safety Procedures

The following are the steps followed from the point of seed order to the disposal of the seeds.

3.1.1 Pre-implant Procedures

1. Seeds for new cases are ordered by Radiation Oncology (Form A: Seed Order). These orders for I-125 or Pd-103 prostate seeds are received by Radiation Safety personnel from the Radiation Oncology Service (Form B: Permanent Prostate Implant Seed Inventory)

2. Seed packages are delivered by FedEx to the Medical Center warehouse loading dock and transferred immediately by warehouse personnel to the adjoining mailroom where they are placed in a padlocked cage.
3. Seed packages are picked up from the mailroom by Radiation Safety Office personnel or other individuals authorized by the Radiation Safety Office to receive radioactive material. A receipt log maintained in the mailroom is signed and dated by the person picking up the package.
4. The package is transported to the Nuclear Medicine Service where the exposure rate is measured using a survey meter and a wipe test is performed. The results of these tests are recorded on a standard radioactive package receipt form which is maintained in the Nuclear Medicine hot lab.
5. The package is opened in the Nuclear Medicine Service by Radiation Safety personnel and the inner box containing the seeds and the accompanying paperwork is removed. Patient and isotope information are verified. The date, number of seeds received, mean seed activity, and total activity received are recorded in the Shipment Receipt section of the Permanent Prostate Implant Seed Inventory Form (Form B). A copy of the completed form is retained in the Radiation Safety Office. Seed receipt information is also recorded in a seed inventory database maintained on the Radiation Safety Office computer.
6. Radiation Safety personnel then transports the seeds to the Radiation Oncology brachytherapy room (1Z-113) for storage until use (usually the following day). The patient name, isotope, number of seeds delivered, mean seed activity, and date and time of delivery are entered in the Brachytherapy Log Book which is maintained in 1Z-113. The brachytherapy room is locked at all times unless under direct surveillance by Radiation Oncology or Radiation Safety personnel. Unannounced security inspections of the brachytherapy room are conducted monthly by Radiation Safety personnel.
7. On the day of the procedure, the oncology physicist records the number of seeds transported to the OR for implantation in the Brachytherapy Log Book.

3.1.2 OR Procedures

1. Following implantation oncology physicist documents number of seeds implanted in the written directive (Form D, part II)
2. While patient is still supine in bed, oncology physicist surveys the OR. Survey includes bedside, 3 feet from bed, and door reading. Survey is

documented in Form E: Patient Survey Form. Copies of this form are placed in the patient hospital chart and in the radiation oncology chart. If patient exposure limits exceeds release limits, nurses would be instructed and given specific instruction for patient care.

3. After patient is moved out of the OR, oncology physicist surveys OR and trash for any lost seed (Form E).
4. Oncology physicist fills in radioactive material label (Form G) and places it on patient's Hospital chart.
5. Upon arrival of the patient on the 2E Short Stay Surgery Unit, the nursing staff, or oncology physicist posts the door of the patient's room with a sign indicating that it is a radiation area and a second sign indicating that room items may not be removed until a radiation survey has been performed by the Radiation Safety Office following release of the patient.

3.1.3 Post-implant Procedures

1. Upon returning from the OR, the oncology physicist enters the number of unused seeds returned to the brachytherapy room in the Brachytherapy Log Book. The seeds are transferred to a lead pig identified with the patient's name, isotope, and number of seeds and stored on a shelf in the brachytherapy room.
2. Lead pigs containing unused seeds are periodically picked up by Radiation Safety Office personnel and transported to the Nuclear Medicine hot lab for decay in storage and ultimate disposal. The number of seeds returned to the Nuclear Medicine Service are entered in the Brachytherapy Log Book by Radiation Safety personnel and recorded in the Radiation Safety seed inventory database.

3.1.4 Survey of Patient's Room Following Release

1. Following release of the patient by the physician, Radiation Safety Office personnel conducts a survey of the room with a survey meter in order to determine that the room is clear of radioactivity. Any seeds that are recovered are returned to the Nuclear Medicine hot lab to be decayed in storage. The RSO staff conducting the clearance procedure enters the results of the survey in the Patient Room Survey section of the Permanent Prostate Implant Seed Inventory Form (Form B) which is subsequently filed in the Radiation Safety Office.
2. At the completion of the room survey, the radiation warning signs are removed from the door and a sign is posted to notify housekeeping and nursing staff that the room is clear of radioactivity and is available for normal use.

3.1.5 Storage and Disposal of Unused Seeds

1. All unused seeds returned to Nuclear Medicine Service are stored in shielded containers in the Nuclear Medicine hot lab or in a locked designated radiation waste disposal closet (BC-129) located in the research animal quarters in the basement of the VA Medical Center. Access to the animal quarters requires a proximity card issued by Medical Center police. The current activity of seeds in each storage container is available from the Radiation Safety seed inventory database.

3.1.6 Seed Return:

If implantation is cancelled, seeds must be returned to vendor. The following procedure is followed:

1. Oncology physicist contacts vendor (Theragenics Corporation) and request return authorization number and return kit.
2. Return kit is passed on to radiation safety along with seeds for return.
3. Brachytherapy Log book located in the Brachytherapy room is updated.

3.2 Clinical Medical Physics Procedures:

The following sections are intended for medical physics involved in the process of seed implant.

3.2.1 Volume Study preparation

1.1 Ultrasound (US) probe preparation

1. Put ultrasound gel into the probe balloon (the volume of gel used is about 10cc). Make sure the gel goes all the way to the tip of the balloon.
2. Place the balloon on the probe and make sure that the orientation of the balloon is correct (i.e. the plastic tube should be aligned with the transducer on the probe). Make sure that no air bubbles left between the balloon and the probe. Wipe off the excess gel that comes out from the open side.
3. Wrap around a piece of adhesive tape on the extension to fix the balloon on the probe.
4. Fill a 50-60cc syringe with water. Make sure that no air bubbles are left in the water filled into the syringe.
5. Connect the syringe to the tube and open the valve. Keep the probe-tube-syringe line vertical so that the air in the balloon can move into the syringe.

6. Inject about 20-30cc of water slowly. Once the balloon expands, tap onto the balloon to remove trapped air bubbles.
7. Retract water from the balloon and close the valve.
8. Place the probe on the stepper. If the old stepper is used (for Dr. Adessa), you will need the steel probe clamp to lock-in the probe into the stepper.
9. Check travel limits of all position adjustment knobs. They should be set to 50 % range of the maximum travel.
10. In some instances, MD may request the plastic stand-off and a condom on the probe rather than a balloon. If this is the case, put a small amount of gel into the stand-off and insert the probe into the stand-off. The thick part of the stand-off should align with the sensor on the probe. Put a lot of gel into the condom and place the condom on the standoff.

1.2 Computer Setup and Stepper Interface

1. Place the laptop on the ultrasound machine using the Velcro's.
2. Connect the video cable jack (from the ultrasound machine) to the video card channel 1 in the laptop.
3. A stepper interface is used to transmit stepper's position data to the laptop and it has to be set up for Dr. Hagan's patients.
4. Connect the serial cable coming from the stepper interface to the laptop.
5. Connect the cable coming from the stepper to the stepper interface. Make sure that port A and B are connected to the correct inlets.
6. The power cord of the interface is connected to the back panel of the ultrasound machine.
7. Power up the ultrasound machine and turn the grid on. The default grid spacing is 5mm.
8. At this point, you should be able to check if the US probe is working properly. Stick the probe into a pitcher of water and check the image quality. Dark streaks in the image may be due to air bubbles trapped between the balloon and the probe.
9. Power up the stepper interface. Make sure the display switch is set to linear and the green LED is on.
10. Start Variseed in the laptop. Create a new patient. Type in the patient's name, department ID (the number on the upper right corner of the chart cover). Patient ID is the last four digits of patient's SS number.
11. On the next page select "Pre-op Ultrasound Video Acquisition", type in the source type and the activity.

12. Set the distance between the images to 0.5 cm.
13. At this stage, you should be able to see the US image on the VariSeed window.
14. On the next page, click on "Automatic volume capture". If manual volume capturing is preferred by the MD, select "Acquire video image". Then, select template registration.
15. Match the VariSeed template to the ultrasound template using the screen panning tools. Accept the template registration. VariSeed is ready for image acquisition.
16. Place the stir-ups on the couch rails. Each MD prefers a different set of stir-ups and stir-up clamps. Make sure that you choose the correct set.
17. If needed, assist MD with locking the stepper.

1.3 Capturing Ultrasound Images

- A. MD will notify when ready to proceed with acquisition of images. At this stage, probe is superior to the base of prostate.
- B. If "automatic volume capture" is selected, press "Set superior extent and Start capture" button. As the MD moves the stepper in the inferior direction images will be captured automatically. Press "OK" when done.
- C. If images will be acquired manually, press "Acquire Video Image" button when MD indicates. Each acquisition will capture a single frame of image. This process is repeated until the whole volume is captured.

3.2.2 Post volume study procedures

1. Go to the contouring tab in VariSeed. Images are ready for contouring by the MD.
2. If the treatment plan is done, double check the source strength and prescription.
3. The standard prescriptions are: Pd-103 sole treatment 124 Gy, Pd-103 boost treatment: 85 Gy, I-125 sole treatment: 145 Gy, I-125 boost treatment: 90Gy. D90 is usually higher than the 90% of the prescribed dose.
4. **Planning Tips:**
 - a. Start with Pd-103 with activity between 2.0 and 2.4 U. Switch to I-125 if the plan approaches 30 needles and/or 100 seeds.
 - b. Start from the top of the prostate and go down in cascade steps
 - c. Choose either odd or even image slices to place either core or peripheral seeds. This is only a rule of thumb, but helps to prevent or cut down on the number of hot spots within the prostate.
 - d. The usual ratio of core to peripheral seeds is 1/3 to 2/3, respectively.

- e. Ensure posterior seeds are at least 5mm from rectum.
 - f. Carefully with anterior needles as the bladder neck abuts the prostate. Ensure seeds are not planned outside of the prostate in this region.
 - g. No needle with a single seed.
 - h. At each end of prostates, it is ok to have double seeds
 - i. Get rid of needles that has two seeds or replaces needles with two seeds by needle with 4 seeds when possible
 - j. D90: 80 – 130%
 - k. V150 prostate < 60% up to 66% is fine.
 - l. V100 prostate ~ 95%
 - m. V100 rectum < 1cc
 - n. V150 urethra < 1cc
 - o. Isodose line at the posterior edge of prostate should be wavy. If the isodose line is flat or straight then the area is too hot and seeds should be reorganized or removed.
5. Check whether needles with single seeds exist. If this is the case, bring this to senior physicist's attention.
 6. Print out the plan and place it in the patient's chart.

7. Physics Second Check:

- i. The computer generated plan is checked against a hand calculation method based on AAPM TG-43 and TG-64 formalisms. The seed positions and dose calculation points are imported from *Variseed*[™]. The spreadsheet compares point dose calculations for various points to those calculated by *Variseed*[™].
- ii. The double check must be done by an independent person (physicist who did not plan it). The percent deviation between VariSeed and second check should within $\pm 5\%$. If the 5% limits exceeded, choose different points, if the difference continue to be greater, a new plan must be generated.
- iii. Instruction on how to use the excel program for double check is shown on as part of Form F.
- iv. Plan must be signed before seed is ordered.

3.2.3 Ordering seeds and documentation

1. Go to VA Prostate Implants Excel sheet. Type in the required data from the plan print-out and patient's chart as instructed (Form A)
2. In addition to the planned seeds, order extra seeds of the same source type and strength. The needle loading plan for extra seeds can be obtained from the senior physicist.

3. The following forms are generated by the Excel sheet: seed order form, seed inventory form, written directive, radiation survey sheet.
4. Check all the check boxes in the seed order form. The seed delivery date is usually one day before the implant date. If extra empty needles are requested (usually two empty needles for Dr. Hagan), indicate this on the seed order form.
5. Fax the seed order form, the needle loading report for the planned seeds and the extra seeds to the seed manufacturer (Theragenics). Attach the send fax confirmation page to the patients chart.
6. Place the written directive and radiation survey sheet to patient's chart.
7. Place the seed inventory form (Form B) in the Radiation Safety pick-up box.
8. The seed manufacturer (Theragenics) will fax back an order confirmation report. Check the report and place in the patient's chart.
9. Seeds will be delivered to the Brachytherapy room by radiation safety personnel.
10. When the seeds arrive, check the patient name, source type, and strength. Compare the autoradiographs and the needle loading plan from the chart.
11. Check the seed assay certificate. The mean strength of the seeds should be within 5% of the prescribed strength. The strength deviation of individual seeds should be within 5% of the mean. Mark the appropriate check box in the inventory form if the seeds satisfy the given criteria.

3.2.4 Seed calibration

Because, pre-loaded needle approach is used for seed implant, **100% of the seed are calibrated by the manufacturer before they are loaded.**

1. Dosimetry System:
 - Standard Imaging Well Counter, Model HDR1000 Plus S/N A981807
 - Standard Imaging Electrometer Model: CDX-2000A S/N B981531
2. The chamber and electrometer are calibrated every two years by an ADCL. (Copies of the recent calibration certificates from University of Wisconsin Accredited laboratory are attached.
3. Calibrated seeds of I-125 and Pd-103.
4. Chamber constancy check is performed every three months. If the discrepancy between vender supplied seed strength is differs by more than 5%, the chamber constancy is checked immediately
5. The method used is similar to the one discussed by Mellenberg and Kline (*Verification of manufacture-supplied ¹²⁵I and ¹⁰³Pd air kerma strengths,*

Medical Physics 22(9), Sep 1995). Batch of 5 seeds assayed and the seed strength is calculated using an Excel® Spreadsheet (copies of the spreadsheet attached). The geometry/self-absorption factor is experimentally determined every year.

6. All seeds are assayed for each patient.
7. Criterion for agreement is $\pm 5\%$ with the vendor specified strength
8. The vendor specified seed strength is used for planning in *Variseed™*

3.2.5 OR and post-implant procedures

Before going to OR

1. Equipment to take to OR: Stir-ups and clamps, stepper, needle tray box, survey meters, source vial and tweezers (to collect dropped seeds), patient chart, balloons, ultrasound gel, grid template, sterilized empty needles, radiation warning label for the nurse chart. MD may want to acquire US images in the OR. Therefore, laptop may be needed. Sign the check-out chart when taking the seeds out of the storage room.
2. MD may want to see the needles in retraction order. Print out the needle loading "by retraction order. Select this option under printing, advance settings.
3. Prepare the probe as described in section 1.1. MD may prefer a plastic standoff and condom combination instead of balloon. Check with the senior physicist or MD. Place the stir-up and clamps on the table.

In the OR

1. After patient is taken into the OR, check patients name with two identifier: verbally ask the patient his name and date of birth, and patient wrist ID.
2. Hand the needle tray to the nurse. Also, hand the grid template if it is used by the MD.
3. Before starting the procedure, **complete Part I of the written directive (Form D)**
4. **After handing the needle tray to the nurse, take the empty tray outside the OR and survey it for possible seed leakage. If seed leakage is discovered:**
 - 3.1 Stop the procedure
 - 4.2 Notify radiation safety immediately

- 4.3 Survey all personnel in the OR for possible contamination including patient.
 - 4.4 Remove patient from room
 - 4.5 All personnel must evacuate the room
 - 4.6 If OR is contaminated, it must be decontaminated before it can be used again.
5. At the needle insertion stage, physicist scrubs in and hands the needles to the MD.
 6. At the conclusion of the implant procedure, the exposure around the patient is measured using a calibrated survey meter. Readings are taken next to the patient's pelvis, 3 feet from the pelvis and at the OR door and recorded in the patient's chart (Form E).

Post-implant phase

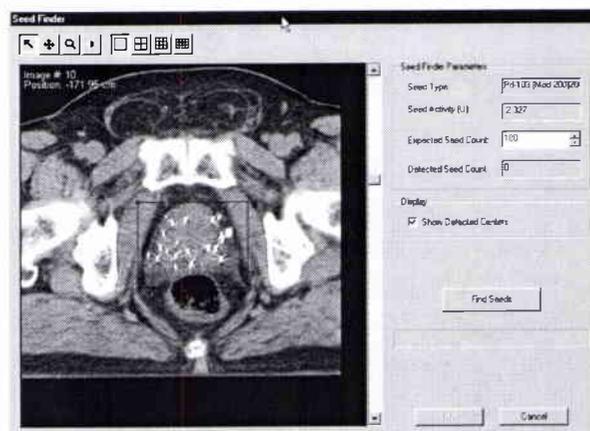
1. Complete the **Part II of the written directive** (Form D).
2. Fill in radiation warning label (Form G) and place on the nurse chart.
3. After patient leaves the OR, survey the operation room including trash and pitcher that holds the used needles.
4. Fill in the Patient Survey Form (Form E), make a copy of the form, and place the original in the patient's chart.
5. Return unused needles to the Radiation Oncology Brachytherapy room (1Z-113) and record the number of returned seeds in the Brachytherapy Log Book. Expel the unused seeds into a lead pig. Keep the Geiger counter on to check any accidentally dropped seeds on the counter. Following this, tape the pig cap and write patient's name and number of seeds on the pig. Pig will be picked up by the Radiation Safety Office.
6. Deface the patient's name, SSN, radioactivity sign from the boxes and trays. Remove the lead sheets on the needle trays and keep them in storage. Boxes and plastic trays can be discarded into trash after checking for seeds.

3.2.6 Source accounting

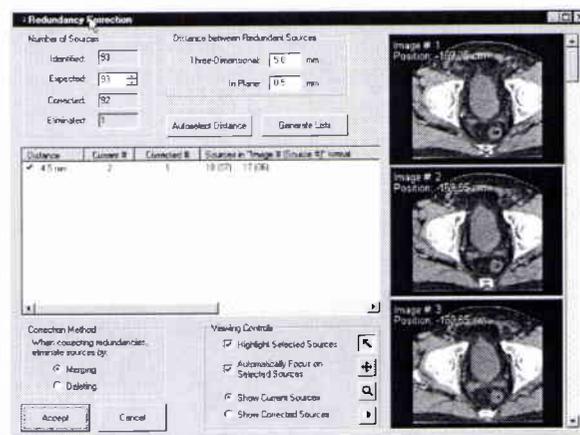
1. A Posterior to Anterior (PA) radiograph taken at the completion of the implant (shown is the picture)



2. A second physicist/dosimetrist keeps track of seed inventory of the implanted seeds and number of seeds remaining. If there is a discrepancy, seeds are counted from the Posterior to Anterior (PA) radiograph
3. Diagnostic quality Anterior to Posterior (AP) and Lateral radiograph used to count seeds, and then the found number of seeds is entered into *Variseed's*TM seed finder module (shown in picture).



4. The redundancy check is performed in *Variseed*TM by the redundancy module (shown in picture below). A manual slice-by-slice inspection performed by the planner after the *Variseed*TM redundancy check.



The discrepancy limit from the time the patient leaves the hospital to the time of the post implant is one seed. If more than one seed is missing from the implant to post implant study after multiple recounts of the radiographs, the patient is re-radiographed at different angles or stereo-shifted and seeds are counted again, if still there is more than one seed missing, the number of seeds missing is documented on the chart.

3.2.7 Post-implant CT scan and QA

1. Patient is CT scanned after the implant procedure. The images are transferred from the CT scanner to the local drive. The purpose of this

scan is to identify the true seed positions to calculate post-implant dose distribution.

2. Import the CT scan into VariSeed as a new study under patient's folder.
3. Contours are drawn by the MD as usual.
4. In the "source identification" tab, you can either manually mark the seeds or detect them automatically.
5. To detect seeds automatically press "seed finder" button. Adjust the size of the search area to the region of interest. Type in the expected number of seeds. After search is done, check the marked seeds visually. The software may double count, mark bone or calcifications as seeds, in this case you must correct the error manually. Also use the redundancy check button to identify suspicious seed locations. Number of marked seeds should match the implanted seeds.
6. Print out the plan and place it into patient's chart.
7. Snap images of the post plan and place it in the morning conference directory for presentation.
8. Back up patient plan to the snap server and delete patient from the active data base.
9. Complete the BrachyTherapy QA Excel sheet.

3.2.8 BrachyTherapy Review and QA

Both monthly and quarterly brachytherapy review are conducted. The monthly review is conducted by a medical physicist as part of the monthly quality assurance program. The monthly brachytherapy review consists of:

- a. Review each patient chart of previous months to ensure all forms are properly filled
- b. Complete the BrachyTherapy QA excel sheet
- c. Create morning conference images
- d. Backup patient plans delete that patient from the VARISeed active database.

The quarterly review is conducted by a medical physicist and the radiation safety officer. The purpose of quarterly review is to check for medical events. Report of the quarterly review is reported using Form F

4.0 Criteria and Tolerances

1. Quality control procedures which provide a data base for monitoring established indicators have been described. The following criteria with

their corresponding reported levels (tolerances) form the basis for assessing the effectiveness of the brachytherapy Quality Assessment plan. All of the following are to be reported to the QA Committee.

- a. Any occurrence of a misplaced or lost radioactive source, for any period of time.
- b. Failure to log source removal from storage or return to storage
- c. Failure to perform surveys as required by applicable polices and procedures
- d. Failure to wear appropriate exposure monitors as required by the radiation safety polices and procedures.
- e. Any treatment delivered without an appropriately written and signed prescription.
- f. Any treatment delivered without appropriate calculation checks.
- g. Any calculation errors and/or source application errors found to result in delivered tumor (or critical structure) dose errors in excess of 20% over the complete course of the implant. In such cases the radiation oncologist will be notified as soon as possible.
- h. Any calculation errors and/or source application errors found to result in delivered tumor (or critical structure) dose in excess of 10% over the complete course of the implant. IN such cases the radiation oncologist will be notified as soon as possible who will in turn inform the department chairman and the QA committee.

Appropriate steps will be taken to ensure that any relevant Stage Federal and/or institutional reporting requirements are followed.

- i. Changes in quality control procedures or frequencies.

5.0 Applicability of QA Standard

The quality assessment standards described in this document may be temporarily suspended under special circumstances by direct order of an attending Radiation Oncologist when such action is clearly in the patient's best interest. Such suspension must be reported as soon as possible to the department chairman and to the quality assessment committee as its next meeting.

6.0 Patient Discharge Instructions

After your implant, it is normal to experience some difficulty with your urination. You may experience a burning sensation when you pass urine the first few times and small or trace amounts of blood or clots may be present in the urine. This usually resolves in a day or two. Other common urinary side effects are a need to urinate more frequently and a strong need to urinate (urgency). You may also experience more difficulty in emptying your bladder. NOTE: On rare occasions, complete blockage of urination may occur. If this happens, you will need to see your physician or go to the hospital Emergency Room to have a catheter placed in the bladder. In most situations side effects are moderate. The following medications and recommendations can improve or lessen your symptoms.

MEDICATIONS

Antibiotics

Antibiotics are given after the implant to prevent infection. This may also help prevent symptoms of burning on urination. You should take the antibiotic as prescribed by your physician until the medication runs out. If

you develop an allergic reaction, such as a skin rash, stop the medication and contact your physician.

Anti-Inflammatory Pain Medication

Advil or Aleve -- These are anti-inflammatory drugs usually given for arthritis symptoms. They are over-the-counter medications, so you can buy it off the shelf at the pharmacy. These medications can help reduce the inflammation from the implant. They can be taken three to four times per day and should be taken with food. Since this medication is designed to relieve symptoms, if you feel it is not helping, you may discontinue it. Many people find that they can decrease the dose after about a week. You can change the dose to suit your needs.

NOTE: Advil and Aleve can worsen ulcer symptoms as well as the potential for minor bleeding. If your stomach becomes irritated, if you have dark black stools or experience increased bleeding after taking this medication, stop it and inform your doctor.

Tylenol Extra Strength or Tylenol PM. These are over-the-counter medications that you can obtain at any pharmacy. Use as directed as a minor analgesic to relieve pain and also to help you sleep. Of the above over-the-counter medications, Tylenol will have the least potential for causing side effects.

Anti-Spasm Agents - Hytrin

This medication has beneficial effects on the bladder and helps improve the flow of urine. At the doses prescribed, it relaxes the muscle of the urethra and bladder allowing for improved stream and complete emptying of the bladder. Typically the **starting dose** is 1.0 mg at bedtime.

Sometimes it is necessary to give 2 to 5 mg once or twice a day. This medication is a mild blood pressure medication and can interact with other blood pressure medications. A possible side effect is the lowering of the blood pressure causing some light-headedness or dizziness. To reduce this effect it is important to build up the dose slowly (see starting dose as noted above). If light-headedness or dizziness occurs, either sit or lie down until the sensation goes away. The dose may need to be lowered or the medication stopped. Discuss this with your doctor.

Stool Softeners and/or Anti-Diarrhea Agents

It is common to have inflammation or irritation of the rectum and anus after a prostate implant procedure. Caution should be taken to avoid constipation as this will worsen rectal irritation. Note that most pain medications can cause constipation. If constipation should occur the use of a mild stool softener such as Colace or Metamucil is recommended. If hemorrhoidal irritation of the rectum or anus occurs it is recommended that local anti-inflammatory agents be used generously. This includes: Preparation H with Hydrocortisone, Anusol cream or suppository (with or without cortisone), Tucks pads, and of course Sitz baths. If persistent pain

or bleeding is present you should contact your physician to discuss the symptoms.

Foods

Some foods and liquids (acidic food or certain proteins) can be slightly irritating to the bladder, causing increased urinary frequency, discomfort and a slower urinary stream. Generally it is not necessary to completely eliminate these foods from your diet, but you may wish to decrease their amount, particularly if you are experiencing frequent or excessive symptoms.

Acidic Foods

Alcoholic beverages	Cranberries and juice
Grapes/grape juice	Coffee including decaf
Carbonated beverages	Pineapple
Chilies/spicy foods	Plums
Citrus fruits and drinks	Tea
Tomatoes	Strawberries
Chocolate	Vinegar

Special Instructions Related to the Seeds:

1. Children and pets should not sit on the patient's lap for the first two months after the procedure
2. Pregnant (or possibly pregnant) women should avoid prolonged close contact with the patient for the first two months after the procedure (She can greet the patient briefly and then move to a distance of three feet or more away. At a six foot distance, there is no limit to the length of time she can be in the same room with the patient.)
3. Iodine and palladium are low energy radioactive materials. The emitted radiation is not deeply penetrating and loses energy at short distances. Your prostate will absorb most of the radiation. Objects that are touched or used by the patient ***do not become radioactive.***
4. Body wastes (urine and stool) or body fluids (saliva, tears, semen or blood) are ***not radioactive.***
5. You ***may resume sexual relations two weeks after the procedure. A condom should be used for the first two weeks.*** Your semen may be dark brown or black; this is normal and is related bleeding that may have occurred during the implant. After two months, condom use should return to normal public health recommendations.

After two (2) months, no further precautions are necessary. If you have any questions, please call the Radiation Oncology Department at (804) 675-5000 ext: 5105

It is unlikely that you will pass an Iodine-125 seed in your urine. However, as a precaution, for the next week, urinate through the strainer that you received when you left the hospital. The seeds are silver in color and are about as large as a grain of rice. If you find a seed, pick it up with a tweezers and flush into the toilet.

7.0 Imaging QA

7.1 CT QA

Physicist: _____ Monthly QA Review for _____, _____
 (month) (year)

CT scanner start-up procedure:

1. Turn on the reconstruction hardware (rightmost black box), then the scanner's PC.
2. After boot-up, turn the scanner's key clockwise momentarily (about 120 degrees), and release.
3. To use wall lasers, make sure that the LAP software is turned off.

A. Electromechanical Checks

1. Couch Digital Accuracy (tolerance ± 1 mm)

Vertical (Z)	Digital Reading (mm)	Digital Distance (mm)	Mechanical Reading (mm)	Mechanical Distance (mm)	Sat.	Unsat.
Initial position		0.0		0.0		
Lowered 200 mm					<input type="checkbox"/>	<input type="checkbox"/>

Longitudinal (Y)	Digital Reading (mm)	Digital Distance (mm)	Mechanical Reading (mm)	Mechanical Distance (mm)	Sat.	Unsat.

Aligned with scanning plane		0.0		0.0		
Out 500 mm					<input type="checkbox"/>	<input type="checkbox"/>

2. Laser Digital Accuracy (tolerance $\pm 1\text{mm}$)

Right Laser (a)

Vertical (a)	Digital Reading (mm)	Digital Distance (mm)	Mechanical Reading (mm)	Mechanical Distance (mm)	Sat.	Unsat.
Zero		0.0		0.0		
-200 mm					<input type="checkbox"/>	<input type="checkbox"/>

Left Laser (b)

Vertical (b)	Digital Reading (mm)	Digital Distance (mm)	Mechanical Reading (mm)	Mechanical Distance (mm)	Sat.	Unsat.
Zero		0.0		0.0		
-200 mm					<input type="checkbox"/>	<input type="checkbox"/>

Lateral (X)	Left (-125mm)	Center (0 mm)	Right (+125 mm)	Sat.	Unsat.
Alignment with Laser QA Device				<input type="checkbox"/>	<input type="checkbox"/>

3. Laser tracking (tolerance $\pm 1\text{mm}$)

Laser alignment accuracy: Use the Laser QA peg tool for the tracking test. Align the wall and ceiling lasers with the grooves on the pegs. As the lasers are moved laterally and vertically they should be within 1 mm of pegs' grooves. The laser tracking test range is 200mm vertically, 250mm laterally, and 600 mm longitudinally.

Lateral (X)	Longitudinal (Y)	Vertical (Z)
-------------	------------------	--------------

	<u>Sat.</u>	<u>Unsat</u>	<u>Sat.</u>	<u>Unsat.</u>	<u>Sat.</u>	<u>Unsa</u> <u>t.</u>
Wall Lasers	<input type="checkbox"/>					
Ceiling Lasers	<input type="checkbox"/>					

B. Radiographic Checks (Use manufacturer's phantom)

1. Slice Thickness (Protocol: Misc menu, Slice Width, protocol varies with thickness)

Note: 0.75 mm slice thickness cannot be measured by the manufacturer's QA phantom.

Slice Thickness (mm)				
Set	Measured	Tolerance	Sat.	Unsat.
0.75 (optional)		± 0.5 mm	<input type="checkbox"/>	<input type="checkbox"/>
1.5		± 0.5 mm	<input type="checkbox"/>	<input type="checkbox"/>
3.0		± 0.5 mm	<input type="checkbox"/>	<input type="checkbox"/>

2. Modulation Transfer Function (MTF) Protocol: MTF measurement tool is on the right screen. Misc. enu, Impulse Response using Head STD-QA protocol, **but with FOV = 100 mm**. FWHM (50%) should be 1.45 mm ± 0.1 mm.)

FWHM (50%) (mm)	FWTM (10%) (mm)	MTF (50%) (lp/cm)	MTF (10%) (lp/cm)

3. Uniformity and Noise (Protocol Head STD-QA protocol, ROI = 1000 mm²; Tolerance: CT # = 0 ± 4, Std Dev = 4.5 ± 0.5)

120 kVp	Center	3	6	9	12	Sat.	Unsat.
CT # Std. Dev.						<input type="checkbox"/>	<input type="checkbox"/>

140 kVp	Center	3	6	9	12	Sat.	Unsat.
CT #						<input type="checkbox"/>	<input type="checkbox"/>
Std. Dev.						<input type="checkbox"/>	<input type="checkbox"/>

4. Resolution and CT Numbers (Protocol : Head STD-QA protocol, ROI = 20 mm²)

Item	Measured	Tolerance	Sat.	Unsat
Spatial Resolution		Resolve all 7 rows	<input type="checkbox"/>	<input type="checkbox"/>
Contrast Resolution		Resolve 5 of 6 pins	<input type="checkbox"/>	<input type="checkbox"/>
Aculon CT #		+100 ± 15	<input type="checkbox"/>	<input type="checkbox"/>
Polyethylene CT #		-70 ± 15	<input type="checkbox"/>	<input type="checkbox"/>
Teflon CT #		+1016 ± 50	<input type="checkbox"/>	<input type="checkbox"/>
Perspex CT #		+140 ± 15	<input type="checkbox"/>	<input type="checkbox"/>
Lexan CT #		+116 ± 15	<input type="checkbox"/>	<input type="checkbox"/>
Water CT #		0 ± 2	<input type="checkbox"/>	<input type="checkbox"/>
Air CT #		-1000 ± 50	<input type="checkbox"/>	<input type="checkbox"/>

5. Scan plane – laser plane alignment tests

Align ceiling, A and B LAP lasers with PEG cross hairs. A and B wall lasers should be centered at 0mm. Then, shift the table 600mm into the gantry. Use standard head QA protocol, 0.75 mm slice thickness, 600mm FOV. All cross hairs should appear within ± 1 mm in axial images slices.

Item	Measured	Tolerance	Sat.	Unsat
Center PEG cross hair (lateral position)		0 mm ± 2 mm	<input type="checkbox"/>	<input type="checkbox"/>
Left/right peg cross hair lateral distance		250 mm ± 2 mm	<input type="checkbox"/>	<input type="checkbox"/>
Left PEG crosshair				

(longitudinal position)		600 mm ± 2 mm	<input type="checkbox"/>	<input type="checkbox"/>
Center PEG crosshair (longitudinal position)		600 mm ± 2 mm	<input type="checkbox"/>	<input type="checkbox"/>
Right PEG crosshair (longitudinal position)		600 mm ± 2 mm	<input type="checkbox"/>	<input type="checkbox"/>

6. Image Transfer Accuracy:

Use images obtained in step 5 to measure distance between centers of PEG cross hairs.

Item	Simulator	VariSeed	Pinnacle	BrainLab	Tolerance	Sat.	Unsat
Let peg cross hair (lateral position)					125 mm ± 2 mm	<input type="checkbox"/>	<input type="checkbox"/>
Right PEG cross hair distance					125 mm ± 2 mm	<input type="checkbox"/>	<input type="checkbox"/>

C. RECOMMENDATIONS/ACTION TAKEN:

1. _____
2. _____
3. _____

7.2 Ultrasound QA:

Complete QA procedure is available with the phantom manufacturer manual

Ultrasound Quality Assurance

Physicist: _____
 Date: 12/10/2008
 Date of Last QA _____

Phantom Info: CIRS Brachytherapy QA Phantom
 Model: 45
 Serial #: 8032

System Settings:
 Gain: 39%
 FR: 23
 MI: 1.4

Parameter	Actual Value(cc)	Measured Value(cc) {Variseed}	% Difference	TG-128 Action Level	Pass/Fail	Action Taken/ Comments
Small Volume	3.6	3.6	0.0	>5%	Pass	
Medium Volume	8.9	8.9	0.0	>5%	Pass	
Large Volume	20.7	20.7	0.0	>5%	Pass	
Lateral Distance			#DIV/0!	3mm or 3%	#DIV/0!	
Vertical Distance			#DIV/0!	3mm or 3%	#DIV/0!	
Axial Distance			#DIV/0!	2mm or 2%	#DIV/0!	
Depth of Penetration			#DIV/0!	2mm or 2%	#DIV/0!	
Stepping Mechanism						
Volume	Steps taken	Steps Expected			Pass/Fail	
Small						
Medium						
Large						
Pass/Fail Parameters:					Pass/Fail	
Grid Alignment:						
Uniformity:						
Damage to:						
Transducer						
Keyboard						
Knobs/Controls						
Display						

NOTES:

7.3 Treatment Planning QA:

Whenever new version of the software is installed, a complete commissioning is performed.

8.0 FORMS

Form A: Seed Order

Hunter Holmes McGuire V.A. Medical Center
Department of Radiation Oncology
 Permanent Prostate Implant Seed Order Form

Patient Name:	0	RT Number:	00-0000
Order Date:	2/9/09	P.O. Number:	652-C90041
Radiation Oncologist:	Oncologist	Physicist/Dosimetrist:	Planner
Isotope:	Isotope	Plan Activity / Seed:	Unit
Reference Date:	1/0/1900	Reference Activity:	0.000 Unit
Number of Seeds:	10	Delivery Method:	Pre-loaded
Implant Date:	01/00/00	Delivery Date:	
Theragenics Phone Number: 1-877-444-7333			
Theragenics Fax Number: 1-800-458-4303			
For Pre-loaded needles: (Variseed needle loading report attached)			
<input type="checkbox"/> Use square hub needles			
<input type="checkbox"/> Load manual Retraction			
<input type="checkbox"/> Use trailing Spacers			
<input type="checkbox"/> Send 5 extra loose seeds			
<input type="checkbox"/> Assay 100% of Seeds			
<input type="checkbox"/> Sterilization required			
<input type="checkbox"/> Fax order confirmation to 804-675-5287			
Ordered By:		Total Pages Faxed	

Form B: Implant Seed Inventory

Hunter Holmes McGuire VA. Medical Center
Department of Radiation Oncology
 Permanent Prostate Implant Seed Inventory and Survey Form

Seed Order (To Be Completed By Dosimetrist / Physicist)			
Patient Name:	0.00	RT Number:	00-0000
Social Security Num:	000-00-0000	Rad. Oncologist	0.00
Dosimetrist/Physicist:	Planner	Isotope:	Isotope
Number of Seeds:	10	Plan Activity / Seed:	U
Activity Reference Date:	1/0/1900	Reference Activity:	0
Delivery Method:	Pre-loaded	Total Ref. Activity:	0
Implant Date:	01/00/00	Delivery Date:	

Shipment Receipt (To Be Completed Out By RSO)	
Patient Name: _____	Isotope: <input type="checkbox"/> I-125 <input type="checkbox"/> Pd-103
Date Received: _____	Activity Reference Date: _____
Mean Seed Act. (mCi): _____	Total Act. Received (mCi): _____
Seed Count: _____	Received By: _____

Room Survey After Patient Discharge (To Be Completed By RSO)	
Survey Date: _____	Survey Time: _____
Room No. _____	Survey Meter: _____
Results: <input type="checkbox"/> Room clear of Activity	<input type="checkbox"/> Seeds found # _____
Surveyed By: _____	

Form C Seed Calibration

Hunter Holmes McGuire VA Medical Center
 Department of Radiation Oncology
 Seed Calibration Form

Patient Name	Roundtree, Cleophas	
Implant Date	4/14/2009	
Number of Seeds	66	
Isotope	Pd-103	
Today's Date	3/27/2009	
Days Till Implant	18	
Reading	Activity (nC)	Temperature °C
Seed1		21.5
Seed2		
Seed3		Pressure (mm Hg)
Seed4		774
Seed5		
Average Reading	#DIV/0!	<u>Ctp</u>
		0.980
Today's Activity	#DIV/0!	
Implant Day Activity	2.463	
Planned Activity		
Percent Difference	#DIV/0!	
Calibrated By:	HS	

**For I-125 Seeds: Calibration Factor is: 2.13 E 11 uGy*m²/hr/A
 Decay factors for I-125: 1: 0.9886, 2: 0.9772, 3: 0.9661, 4: 0.9550**

**For Pd-103 Seeds: Calibration Factor is: 4.565 E 11 uGy*m²/hr/A
 Decay factors for Pd-103: 1: 0.9605, 2: 0.9226, 3: 0.8861, 4: 0.8511**

Form F: QA Checklist

Hunter Holmes McGuire VA Medical Center
Richmond, Virginia

Prostate Implant QA Checklist

Patient Name: New, sheet

Social Sec. Number: 111-22-3344

<u>ITEM</u>	<u>INITIAL</u>	<u>DATE</u>
<input type="checkbox"/> Script Signed by Attending		
<input type="checkbox"/> Pre-implant contours approved by Attending		
<input type="checkbox"/> Treatment Plan Approved by MD (Resident or Attending)		
<input type="checkbox"/> Dose Calculation Double Check Performed by Physics		
<input type="checkbox"/> CT images loaded into VariSeed		
<input type="checkbox"/> Post Implant CT contours approved by Attending		
<input type="checkbox"/> Post Implant CT analysis (D90) performed by physics		
<input type="checkbox"/> Post Implant CT plan printed, filed, morning conference		
<input type="checkbox"/> Patient backed up and deleted		

Read this before proceeding!

The tabs titled "I-125-parameter" and "Pd-103-Parameters" are used for the Prostate Double Check procedure. These worksheets contain a print-formatted section where the user must enter the "Dose Point Coordinate and Variseed Calculated Dose in order for the double check calculations to take place. In addition, the user must manually import external data that contains the source location information from Variseed. The following details the appropriate steps to easily and correctly import external data and place it in the appropriate location.

Import External Data Instructions:

Navigate to the tab titled "Import". This is simply a temporary worksheet to import and copy the necessary data to perform the seed dose double check.

Select the "Data" menu from the menu bar.

Then select **Import External Data**. Then navigate to the desired Variseed text file.

Next (for Step 1), enter the number **38** for "Start import at row" value. Then click **Next**. This will cut out unneeded header data generated by Variseed.

Then for Step 2, ensure that "Semicolon" is checked. Click Next

Step 3, Click Next.

At this point the data should have been imported correctly. If it doesn't then select the Edit menu and select undo import data. Then start over.

Now we need to copy the needed data from this worksheet and paste it in the appropriate worksheet (eg If Isotope Type is I-125, then we paste the copied data on the "I-125 parameters" worksheet.

Form G: Radioactive Label



CAUTION RADIOACTIVE MATERIAL



PERMANENT PROSTATE SEED

Patient _____ Room _____

Radionuclide _____ mCi _____ Administered _____

Exposure at 1 meter _____ mR/h at Date _____ Time _____

Radiation Safety Office Signature

In case of emergency or for further information contact:

**John Wilson MCV 828-7225, Home 598-7682, Beeper 828-4999 3253
Panos Fatouros (RSO) MCV 828-8282, Beeper 828-4999 3265**

**VA Radiation Safety Office 1H-126 Ext. 3495
Located in Nuclear Medicine Service 675-5115**



Form F BrachyTherapy Quarterly Review Form

Hunter Holmes McGuire V.A. Medical Center
 Department of Radiation Oncology
 BrachyTherapy Quarterly Report

OCTOBER - DECEMBER 2008

Patient Name	RT#	Implant Date	Isotope	Pre Implant Signed	Post Implant Signed	D90 Analysis	Medical Events
OCTOBER							
Mc Comsey, Herbert	08-0154	10/07/08	I-125	X	X	112.80%	NO
Jones, Clarence	08-0149	10/07/08	I-125	X	X	95.81%	NO
Mc Peake, Douglas	08-0163	10/14/08	Pd-103	X	X	109.91%	NO
Lego, Larry	08-0171	10/14/08	Pd-103	X	X	94.93%	NO
Neville, James	08-0158	10/21/08	I-125	X	X	93.60%	NO
Baker, Marlon	08-0159	10/21/08	I-125	X	X	91.80%	NO
Gelacio, Pedro	08-0168	10/28/08	I-125	X	X	100.88%	NO
Weaver, James	08-0138	10/28/08	I-125	X	X	97.75%	NO
NOVEMBER							
Mitchell, Thomas	08-0220	11/04/08	Pd-103	X	X	94.2	NO
Brown, William	07-0300	11/04/08	I-125	X	X	117.40%	NO
Evans, Edward	08-0134	11/18/08	Pd-103	X	X		TBD
Choice, Samuel	08-0210	11/18/08	I-125	X	X	102.90%	NO
Humphrey, Leonard	08-0205	11/25/08	Pd-103	X	X		TBD
Ferguson, Norman	00-0186	11/25/08	Pd-103	X	X		TBD
DECEMBER							
Redd, Coleman	08-0207	12/02/08	Pd-103	X	X		TBD
Wyatt, Herman	08-0233	12/02/08	Pd-103	X	X		TBD
Hughes, Richard	08-0151	12/09/08	I-125	X	X		TBD
Hackney, Arlin	08-0218	12/16/08	I-125	X	X	99.97	NO
Vance, Theodore	08-0228	12/16/08	I-125	X	X	97.81	NO
Cunningham, Mann	08-0237	12/23/08	Pd-103	X	X		TBD

NOTES:

1. Cases marked "NO" under medical events means cases were completely evaluated and no medical events were found.
2. Cases marked "TBD" under medical events means patients' post implant analyses "D90" are yet to be completed. Status will be reported in the next quarter report.

 Signature:
 Authorized Medical Physicist

 Signature:
 Radiation Safety Officer

 Date:

 Date:

9. VHA Standard Procedures

TRAINING

1. VHA facilities with prostate brachytherapy programs must complete initial and periodic training for the staff involved in, or supporting, the prostate brachytherapy program.
2. Training must be provided to physician authorized users, medical physicists, dosimetrists, participating urologists, and Radiation Safety Officers and staff. Other workers who participate in the procedures (e.g., anesthesiologists or anesthesiologists, nursing staff, and resident physicians) must receive training, as needed. The Radiation Safety Committee normally tasks the Radiation Safety Officer to develop, present, and/or coordinate training. Each individual facility must determine the type and extent of training, if any, that the Radiation Safety Officer is to receive by other staff or external to the facility.
3. The training must be commensurate with duties. A separate VHA standard procedure has more details for training for medical events.
4. The training topics to consider are listed below. The facility must document training completion and evaluate effectiveness of training by various methods such as group and one-on-one discussions, written or computer-based tests, and during audits.

Training Topics

1. Basic radiation biology, including risk estimates.
2. Radiation protection to include concepts of time, distance, and shielding.
3. Concept of maintaining radiation exposure ALARA (10 CFR 20.1101).
4. Posting requirements (10 CFR 20.1902).
5. Proper use of dosimetry (if applicable).
6. Access control procedures and security (10 CFR 20.1601 and 20.1801/.1802) and two delay methods if stored.
7. Proper use of radiation shielding, if used.
8. Patient release instructions, procedures, surveys, and records (10 CFR 35.75 and 35.2075).
9. Instruction in procedures for notification of the Radiation Safety Officer and physician authorized user, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. Note: The intent of these

procedures should not interfere with or be in lieu of appropriate patient care (10 CFR 19.12, 35.310, 35.410, and 35.610).

10. Occupational dose limits (10 CFR 20.1201).
11. Worker's right to be informed of occupational radiation exposure (10 CFR 19.13).
12. Worker's obligation to report unsafe conditions to the Radiation Safety Officer (10 CFR 19.12) and have a safety focus to ensure regulatory compliance. Methods and procedures for management oversight for use of radioactive materials.
13. Applicable regulations, licenses, permits, and notices (10 CFR 19.12).
14. Location and availability of applicable regulations, licenses, permits, notices, and Web sites (10 CFR 19.12).
15. Recordkeeping requirements (10 CFR 19.12), and documents and records for prostate brachytherapy procedures.
16. Radiation surveys to be completed (10 CFR 20.1501).
17. Proper calibration of survey instruments (10 CFR 20.1501).
18. Emergency procedures such as for a damaged or leaking seed, a leaking or damaged seed implanted in a patient, and a lost seed or seeds.
19. Decontamination and release of facilities and equipment (10 CFR 20.1406).
20. Dose to members of the public (10 CFR 20.1301).
21. Facility written procedures, protocols, and practices for prostate brachytherapy procedures.

Handling and security of sealed sources

- a. Radioactive material package receipt surveys and records (10 CFR 20.1906).
- b. Source accountability (10 CFR 35.406) and records of accountability (10 CFR 35.2406).
- c. Physical inventory (10 CFR 35.67(g)).
- d. Source disposal (i.e., ship to vendor or decay on site) (10 CFR 35.92 and 35.3092).

Preparations for seed implant procedures

- e. Written procedures and checklists (10 CFR 35.40 and 35.41).
- f. Patient identity verification, written directive, and treatment plan checking procedures (10 CFR 35.40 and 35.41).

- g. Pre-implant imaging (volume study), modality (TRUS, CT)
- h. Pre-plan preparation.
- i. Written directive, pre-implant part preparation, including prescribed dose.
- j. Surveys after source implant for misplaced seeds and records (10 CFR 35.404 and 35.2404).
- k. Calibration measurements of sources (10 CFR 35.432).
- l. Acceptance testing of treatment planning system (10 CFR 35.457).
- m. Quality assurance of imaging (i.e., TRUS, CT, and accuracy of image transfer).
- n. Possible problems, precautions to prevent, and follow-up actions for the following:
 - (1) Lost seeds.
 - (2) Seeds damaged during procedure.
 - (3) Leaking seeds, including leaking seeds implanted in patient.
- 22. Medical event definitions and roles and responsibilities to include what is a medical event, how to identify a medical event, criteria to determine if specific patient circumstances are a medical event, and reporting requirements for a medical event. Procedures for after-hours recall or notifications (10 CFR 35.3045).
- 23. Methods and procedures to verify seed placement is correct and determine proper needle placements during prostate brachytherapy procedures, including appropriate imaging modality verifications.
- 24. Preparation and completion of written directives (pre- and post-implant parts).
- 25. Methods and procedures for pre-implant treatment planning, post-implant treatment planning, and post-treatment dose analysis.

MEDICAL EVENTS

1. VHA facilities performing permanent implant prostate brachytherapy must provide initial and periodic training to the staff involved in, or supporting, the prostate brachytherapy program. The training must be provided to physician authorized users, medical physicists, urologists participating in these procedures, dosimetrists, and the Radiation Safety Officer (RSO) and staff.
2. A specific training topic is medical events to include specific details for NRC definition of a medical event, how to recognize a medical event, and actions to be taken if a medical event is discovered. The training should be provided by the RSO or by a qualified person, such as a therapeutic medical physicist, designated by the facility Radiation Safety Committee or RSO.
3. The guidelines for this training are listed below and consist of questions and answers to be addressed at the facility level. Training must be commensurate with duties. Also, facilities must incorporate these guidelines into other facility procedures, as needed, to ensure requirements for medical events are made known to the staff.

Training for Medical Events

What is the regulatory definition of a medical event?

NRC defines a medical event in 10 CFR 35.3045. A link to the NRC Web site with the definition is:

<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-3045.html>

The definition of a medical event is listed below.

“A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in.

1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and
 - a. The total dose delivered differs from the prescribed dose by 20% or more,
 - b. The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range, or
 - c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.
2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following.

- a. An administration of a wrong radioactive drug containing byproduct material,
 - b. An administration of a radioactive drug containing byproduct material by the wrong route of administration,
 - c. An administration of a dose or dosage to the wrong individual or human research subject,
 - d. An administration of a dose or dosage delivered by the wrong mode of treatment, or
 - e. A leaking sealed source.
3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Vs. (50 ram) to an organ or tissue and 50% or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.”

What are roles and responsibilities related to medical events?

The Radiation Safety Committee provides oversight of the safe use of radioactive materials and requires initial and periodic training for staff commensurate with their duties.

The RSO or a designee normally provides or coordinates staff training, including the training for medical events, and maintains training records. The RSO has primary responsibility for identifying and reporting medical events. If a medical event is discovered, the RSO makes required notifications to NHPP (to be reported to the NRC Operations Center by the next calendar day after discovery) and prepares the 15-day written report to send to NHPP.

Physician authorized users, medical physicists, dosimetrists, and other staff involved in prostate brachytherapy procedures must be aware of patient circumstances that might be a medical event and the requirement to report those circumstances to the RSO promptly upon identification.

Staff must be aware of the significance of the written directive, both the pre-implant part, which documents the prescribed dose, and the post-implant part, which documents the administered activity.

What is a medical event?

A medical event is patient circumstances that are within the NRC definition in 10 CFR 35.3045.

For prostate brachytherapy procedures, the figure of merit to identify a medical event during the post-treatment dose analysis is D90. The D90 must be 80% or greater of the prescribed dose in the written directive.

A medical event may also result from an overly large dose to tissue outside the prostate. A cause would be a seed or seeds outside the prostate. Note: Some physicians deliberately implant seeds just outside the prostate to treat a margin around the prostate.

An implanted leaking seed is a medical event if the seed will cause a dose exceeding 0.5 gray (50 rad) to an organ or tissue. For I-125 seeds, the primary organ of concern is the thyroid.

How to identify a medical event including the criteria for a medical event?

A medical event is identified by comparing the results of the treatment, particularly the post-treatment images and dose indices such as the D90; the authorized user's intent, as defined in the written directive and approved pre-plan; and the NRC definition of a medical event. Deviations or discrepancies are determined to help identify if a medical event occurred.

The post-implant dose analysis produces the D90. The D90 is a figure of merit for determining whether the prescribed dose was achieved. The D90 must exceed 80% of the prescribed dose in the written directive or a medical event has occurred.

Identification of a medical event resulting from seed(s) outside of the prostate is determined on a case-by-case basis in consultation with NHPP. Circumstances to consider include: a seed or seeds distant from the prostate, unless the seed(s) migrated; a seed or seeds in the rectum or very close to the rectum; and a volume of the rectum exceeding 160 gray that is more than about 1.5 cc.

What are the notification and reporting requirements for a medical event?

10 CFR 35.3045 requires:

- Notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a medical event.
- Submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the medical event.
- Notify the referring physician and the patient.

Under the master materials license issued to VHA, NHPP makes notifications to the NRC Operations Center. The facility must contact NHPP as soon as possible about any patient circumstances that might be a medical event. The telephone information is noted below.

- Normal business hours for Central Time Zone at 501-257-1571.
- After normal business hours for Central Time Zone at 800-815-1016.

- Intranet Web page for information to contact individual NHPP staff at the following URL.

<http://nhpp.med.va.gov/emergency.asp>

For notification of, or contact with, NHPP, voice mail or e-mail must NOT be substituted for a direct discussion with NHPP staff, preferably a technical staff member. This is particularly important if an immediate or next day notification is required to NRC.

The RSO must have a recall list with contact information for the physician authorized users, referring physicians if possible, and NHPP. The list should have the office and cellular telephone numbers so key staff can be contacted and consulted in a medical event situation, both during and outside normal working hours.

The after-hours recall information is especially important for a weekend recall when a patient therapy procedure or post-implant dose analysis might have been completed late in the week, such as on a Friday, and notification is required within a specific time period.

This recall list should also include vendor telephone numbers if sealed sources are used in the patient therapy procedure.

WRITTEN DIRECTIVE

1. VHA facilities that perform permanent implant prostate brachytherapy must prepare and complete a written directive for each patient treatment. The Nuclear Regulatory Commission (NRC) has regulatory requirements for written directives. This standard procedure provides specific guidelines to be followed by VHA facilities.

2. Current regulatory information is available on the NRC Web site at the following address.

<http://www.nrc.gov/materials/miau/med-use-toolkit.html>

3. NRC defines a written directive, in 10 CFR 35.2, as:

Written directive means an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in 10 CFR 35.40.

4. For permanent implant prostate brachytherapy, the NRC requirements for a written directive in 10 CFR 35.40 are:

a. A written directive must be dated and signed by an authorized user before the administration any therapeutic dose of radiation from byproduct material.

b. The written directive must contain the patient or human research subject's name and the following information:

(1) Before implantation: treatment site, the radionuclide, and dose; and

(2) 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).

c. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

d. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

5. NRC requirements to retain a copy of the written directive are in 10 CFR 35.2040 as follows:

A licensee shall retain a copy of each written directive as required by 10 CFR 35.40 for 3 years.

6. VHA facilities must comply with NRC requirements. In addition, VHA facilities must follow these additional guidelines for prostate brachytherapy procedures.

a. Ensure initial and periodic training for prostate brachytherapy programs includes the requirements in this standard procedure and is provided to, as a minimum, physician authorized users, medical physicists, dosimetrists, participating urologists, and Radiation Safety Officers and staff.

b. Complete and document quarterly audits of written directives to ensure NRC and VHA requirements have been met.

c. Use the standard procedure for training for medical events as criteria to evaluate written directives and to determine if a medical event has occurred.

d. For the pre-implant portion of the written directive, provide the following information per 10 CFR 35.40: treatment site, the radionuclide, and dose.

e. For the post-implant part of the written directive, provide the following information per 10 CFR 35.40: radionuclide, treatment site, number of sources, total source strength, and the word "permanent."

f. At the bottom of the written directive, after the post-implant part, or on a separate review worksheet for written directives provide the following information.

(1) Name, date, and signature for medical physicist review to determine if a medical event occurred. (If possible, the reviewing medical physicist should be a reviewer other than the medical physicist who prepared the treatment plan.)

(2) Name, date, and signature for Radiation Safety Officer review to determine if a medical event occurred.

CLINICAL REQUIREMENTS

1. This VHA standard procedure has requirements for technical quality assurance (QA), pre-implant or intraoperative treatment planning, post-implant treatment planning, post-treatment dose analysis, and seed placement and verification.

2. VHA facilities performing permanent implant prostate brachytherapy must develop, maintain, and implement written procedures for the clinical requirements listed above. The facilities must also develop, maintain, and implement written procedures for written directives per 10 CFR 35.41. A facility has the option to combine written procedures into a single document. The items below are specific guidelines to be followed by VHA facilities performing permanent implant prostate brachytherapy.

3. The guidelines are based on the American College of Radiology *Practice Guideline for Transperineal Permanent Brachytherapy of Prostate Cancer* and publications by the American Association of Physicists in Medicine (AAPM).

4. The facility must have a QA program for each device used for planning, performing, and assessing the implant procedures; these devices include the stepper/stabilizer, transrectal ultrasound system (TRUS), treatment planning system, and CT or MRI system. A therapeutic medical physicist experienced in prostate brachytherapy procedures must approve the QA program and periodically review the program. QA for the TRUS should substantially conform to the AAPM TG 128 report. Medical physicists and physicians should pay attention to spatial resolution, grey scale contrast, geometric accuracy, and distance measurement. The correspondence between the electronic grid pattern on the ultrasound image and the template grid pattern should be verified. For the CT system used for imaging for post-implant dose assessment, the QA program must address image quality, accuracy of the transfer of geometric parameters to the treatment planning system, and dose to the patient.

5. Computerized treatment planning system requirements are as follows.

a. Complete acceptance testing of the treatment planning system per 10 CFR 35.457 before the first patient treatment use and after software revisions or upgrades and commissioning other models of seeds. The acceptance testing methods and results should be reviewed and approved by a therapeutic medical physicist experienced in prostate brachytherapy procedures. The acceptance testing and seed commissioning must be documented in a written report describing references, methods, and results. The testing must assess:

(1) Geometric accuracy of image information transferred from imaging modalities used for pre- and post-plans,

(2) Source specific input parameters required by the dose calculation algorithm, and

(3) Accuracy of calculated doses and displays of dose distributions, such as dose plots and graphical displays, at representative points.

b. Compare dose rate values from the planning system for applicable seed models to current values listed in the appropriate AAPM report: Report No. 51 (TG-43), Report No. 84, Report No. 84s, or its successor.

c. Ensure medical physics staff is aware of and uses technical guidelines in AAPM Report No. 68 (TG-64).

6. Seed strength calibration requirements are as follows.

a. The source output or activity of each seed must be determined before implantation as required by 10 CFR 35.432. A record of each calibration must be maintained.

b. The output or activity of the seeds may be determined by a commercial vendor such as the seed manufacturer or a vendor that loads the seeds into needles or cartridges or places them in suture material. If the facility does not measure every seed, the facility must maintain written documentation that the seed manufacturer or vendor assays every seed and the measurements conform to 10 CFR 35.432.

c. In addition to the above, the facility may choose to assay seeds from each shipment on site. AAPM Report No. 98 provides guidance on such assays and should be followed.

7. Pre-implant or intraoperative treatment planning requirements are as follows.

a. Complete treatment planning for each patient before or during seed implantation.

b. Use appropriate imaging modalities such as TRUS, CT scanning, or MRI to assist in the treatment planning process.

c. Checking of the treatment plan must be performed as required by 10 CFR 35.41(b)(3). The written procedures should specify how this check is to be performed.

d. Before implantation of the first seed, complete the pre-implantation portion of the written directive, which must include the NRC required information in 10 CFR 35.40 (treatment site, radionuclide, and dose).

e. Before implantation of the first seed, verify the ultrasound images of the prostate are of adequate quality to perform the implant. Verify the prostate dimensions match those of the pre-plan. If they differ excessively, another pre-plan should be created.

8. At the end of each procedure, obtain a radiographic or fluorographic image depicting seed positions in the patient. Fluoroscopic imaging should be immediately available during the

procedure, to serve as a check that seeds are not being inadvertently placed away from the intended region.

9. After completion of the implant procedure, complete the post-implant portion of the written directive to record the information required in 10 CFR 35.40 (treatment site, radionuclide, number of sources implanted, total source strength implanted, and the word "permanent").

10. Immediately after the completion of each implant, perform a survey of the room using a portable radiation survey meter to locate any misplaced sources, as required by 10 CFR 35.404. The survey should include the floor, linens, waste material, applicators, and empty needles and cartridges. A record of the survey must be made as required by 10 CFR 35.2404. The survey should include the feet of people leaving the room.

11. Before releasing the patient, perform a release survey as required by 10 CFR 35.75 and document the survey as required by 10 CFR 35.2075(a). The survey should include measurement of the exposure rate, air kerma rate, dose rate, or dose equivalent rate at a distance of 1 meter from the patient. The survey must be made with a radiation survey meter calibrated for the energy of the radiation emitted from the seeds, or the measurement must be corrected for energy using the energy response curve of the meter and any attached detector. The patient must also be given instructions, both in writing and verbally, on actions recommended to keep doses to others as low as reasonably achievable. The instructions must include actions to take if a seed is passed in the urine.

12. Post-treatment planning requirements are as follows.

a. Post-implant imaging and dosimetric analysis is mandatory and must be completed for each implant procedure, unless the patient refuses post-implant imaging.

b. Complete post-treatment planning of each patient using post-implant CT or MRI imaging.

c. Determine the actual dose distribution delivered and identify any variances or deviations from the original treatment plan.

d. The post-treatment planning must evaluate the relationship of the implanted seeds to the prostate, rectum, and other extra prostatic tissues.

e. Establishment of a consistent post-implant image acquisition time frame. Examples:

(1) Obtain CT images at approximately 2 to 3 weeks post-implantation for Pd-103 and approximately 4 weeks post-implantation for I-125, or

(2) Obtain post-implant CT images on the day of the procedure or during the next 2 days. If the post-implant dose distribution is unacceptably low, obtain repeat CT images at approximately 2 to 3 weeks post-implantation for Pd-103 and approximately 4 weeks post-implantation for I-125, and create another post-plan.

f. Report the following parameters in a reviewable document, such as a quarterly report:

(1) Date of implant procedure and date of post-implant CT imaging.

(2) Prescribed dose.

(3) D90, defined as the minimum dose received by 90% of the target volume as delineated on the post-implant CT. According to AAPM Report No. 68 (TG-64), "An implant with good coverage is characterized by D90 equal to or greater than the prescribed dose."

(4) V100, defined as the percentage of the target volume delineated on the post-implant CT receiving 100% of the prescribed dose. A V100 equal to 90% (of the prostate volume) is equivalent to a D90 equal to the prescription dose.

(5) Rectal dose index, such as the R100 (volume of the rectum in cm³ that receives 100% or more of the prescribed dose).

(6) Evaluation of seeds outside the intended treatment volume.

13. Post-treatment dose analysis requirements are as follows.

a. Review dose indices including D90, V100, and rectal dose index, and evaluate seeds significantly outside the intended treatment volume. Note: Seeds may be deliberately implanted at the boundary of or just outside the prostate to provide adequate treatment margins.

b. Compare the results to the prescribed dose to determine if a medical event occurred, including whether the D90 is less than 80% of the prescription dose (10 CFR 35.3045(a)(1)(i)).

c. Notify the patient and determine whether corrective action, such as implantation of additional seeds, is warranted, if the dose distribution for a specific patient is inadequate.

14. Perform physician peer review to reduce intra-observer variability in the contouring of prostate volumes from post-implant CT scans and definition of rectal volumes and to assess quality of care. This should include ongoing within-department peer review. In addition, five cases each year should receive external peer review as specified by the Director, National Radiation Oncology Program, or as required by a VHA Handbook or Directive.

10.0 Appendix 1: Prostate Treatment Guidelines:

**Prostate Carcinoma
Treatment Guidelines
Department of Radiation Oncology
MCV Hospitals, VCU
(Revised 3/05)**

I. General.

These technical guidelines, meant as aids in treatment planning, should not be construed as rigorous requirements.

II. Treatment Schedule:

A. Irradiation.

All N0,X M0:

Low-risk: T1 with PSA \leq 10ng/ml and Gleason score \leq 6:

External beam radiotherapy (EBRT) to the prostate and peri-prostatic soft tissues.
IMRT or brachytherapy may be used as indicated below
See brachytherapy guidelines.

T-stage \geq T2b

or PSA \geq 15ng/ml:

EBRT should be delivered in the IMRT setting.
Neoadjuvant androgen suppression should be included.

N1,2:

Treatment should be individualized for patients with involved regional lymphnodes. Those patients with low volume disease should receive multimodality therapy including androgen suppression, and EBRT to the pelvis and prostate. A limited field boost should be delivered to radiographically visible lymphnodes.

B. Combined Irradiation and androgen ablation.

Radiation therapy should be accompanied by androgen ablation patient with any one of the following poor prognostic indicators:

T-stage: \geq T2B,*

PSA: ≥ 15 ng/ml,
Gleason score: ≥ 8 .

In addition, patients with two or more of the following parameters should be strongly considered for neoadjuvant plus concomitant hormone therapy.

T-stage: $\geq T2$,
PSA: ≥ 10 ng/ml,
Gleason score: ≥ 7 .

* This group also includes T2a patients whose nodule is greater than 1 cm and post prostatectomy patients with PSA > 1.0 ng/ml.

III. Treatment Techniques:

A. EBRT (prostate and modified whole pelvis):

Treatment limited to low-risk presentations or patients deemed at medical risk for standard dose treatment.

Four-field pelvis to 50.4 Gy* followed by coned down boost to the prostate only. Total dose will be in the range 70-74Gy.

When EBRT is incorporated with brachytherapy, when prior surgery makes fixed loops of bowel likely, or when the pelvis fields are larger than those described below, the pelvic dose should be limited to 45 Gy. Total dose may also be reduced to 64.8 Gy for patients unlikely to tolerate full dose therapy.

APPA port: Superior border: 2cm above the inferior aspect of the SI joints.
Inferior border: 2 cm below the prostatic apex determined by retrograde urethrogram.
Lateral borders: 1.5 cm outside the bony pelvis.

Lateral port: Anterior border: at the pubic synthesis
Posterior border: 1.5 cm posterior to the seminal vesicle or prostate margin.

Boost volume: at least a 1.5 cm margin on the prostate (GTV). The boost volume should make no attempt to include the entire volume of the seminal vesicles.

When possible, the prostate volume should be radiographically determined at the time of the simulation via direct fluoroscopy with contrast in the bladder, rectum and following retrograde urethrogram. For patients simulated fluoroscopically the bladder should contain no more than 60 cc of contrast. Patients should be instructed to void prior to therapy each day. Virtual simulation via CT with a maximum slice thickness of 0.5 cm is an acceptable alternative. Retrograde urethrogram is required at the CT for virtual simulation. Usually, no other contrast is necessary.

Routinely, external beam treatment of the pelvis should employ photon energies greater than 10 MV. The AP port for the modified whole pelvis field, however, may require a lesser energy to optimize coverage of the external iliac lymphnode chains.

B. EBRT (prostate plus periprostatic soft tissue):

Four-field pelvis to 50.4 Gy followed by coned down boost to the prostate only. Total dose will be in the range 70-74 Gy.

Total dose may be reduced to 64.8 Gy for patients unlikely to tolerate full dose therapy.

APPA port: Superior border: 2 cm above the *superior margin of the bladder*.
Inferior border: 2 cm below the prostatic apex determined by retrograde urethrogram.
Lateral borders: 1.5 cm outside the bony pelvis.

Lateral port: Anterior border: at the pubic synthesis
Posterior border: 1.5 cm posterior to the seminal vesicle or prostate margin.

Boost volume: at least a 1.5 cm margin on the prostate (GTV). The boost volume should make no attempt to include the entire volume of the seminal vesicles.

* Per department standards, the dose indicated is prescribed as a **minimum target dose**.

C. Androgen ablation.

Combined androgen ablation and irradiation. Androgen ablation use in the neoadjuvant and concomitant setting should be initiated with an antiandrogen for a minimum of 7 days, followed by LHRH agonist administration combined with the antiandrogen for an additional 14 days. Thereafter, the LHRH agonist will be continued through the course of external beam therapy or the first 2 months of seed implantation.

IV. Brachytherapy Guidelines:

A. Indications:

- a. Only the following patients may be treated with interstitial implantation alone as **definitive treatment T1-T2a, volume \leq 60cc, and with PSA \leq 10ng/ml and Gleason score \leq 6; patients meeting these criteria with the addition of GI 7 (3+4) adenocarcinoma involving less than 10% of a single biopsy core.**
- b. **T1-T2a, volume $>$ 60cc with PSA \leq 10ng/ml and Gleason score \leq 6.** Following downsizing by androgen suppression external beam treatment to 45 Gy will be included (prostate, periprostatic tissues and the proximal seminal vesicles) and **the implant used as a boost** (the final prostate volume should be less than 70 cc)
- c. or as **boost treatment when combined with androgen suppression and following 45Gy EBRT (modified whole pelvis) T1c or T2, volume \leq 60cc with PSA $>$ 10ng/ml, but \leq 30ng/ml, or Gleason score $>$ 6;**

A. Contraindications:

Medically unfit (Urologist's determination)

Prior hx/o TURP (unless the TURP defect is smaller than 1 cm in diameter on each CT scan image).

Interference by the pubic arch

Median lobe protrudes into the bladder (greater than 1 cm).

Prostate volume greater than 70cc after "downsizing."

B. Brachytherapy alone: (note that the reference dose structure below is intended for patients treated "off-protocol." Brachytherapy as a part of an IRB-approved protocol will follow protocol constraints)

Reference doses listed below are to be used as the written directive (WD) dose

125I: 145 Gy MPD (defined 0-5mm outside of the capsule with the exception of the rectal margin where the 145 Gy contour is at the capsule. Lateral margins are widened superiorly to include the SV takeoff).

103Pd: 124 Gy MPD (isodose coverage defined as above)

C. EBRT (45 Gy) + implant:

125I: 100 Gy MPD (isodose coverage defined as above)

103Pd: 85 Gy MPD (isodose coverage defined as above)

D. Quality control: The assessment of the delivered dose described below will be used to verify that the delivered dose is in accordance with the WD dose.

- a. Dose reconstruction (post-planning) will be done either within 24hr of the implant or between 4 and 6 weeks following the date of the implant. Seeds will be counted, localized individually and the delivered dose analyzed per physics protocol. A commissioned brachytherapy planning system will be used for this assessment.
- b. Permanent implants are designed to deliver 90% of the reference (WD) dose to 90% of the prostate volume ($D_{90_{CT}}$) **as determined from CT images obtained at the time of the dose reconstruction**. The dose delivered will be deemed **satisfactory as planned** when the $D_{90_{CT}}$ receives $\geq 80\%$, but $\leq 130\%$ of the reference (WD) dose.
- c. Doses to the urethra and rectum should be recorded as the maximum dose to 1cc of the contoured volume. Planned $D_{Urethra, 1cc}$ is satisfactory when $\leq 150\%$ and acceptable when $< 200\%$ of the reference dose. Planned $D_{Rectum, 1cc}$ is satisfactory when $\leq 100\%$ and acceptable when $< 120\%$ of the reference dose.
- d. Prostate implants will be revised (supplemented) when the $D_{90_{CT}}$ falls below 80%. Implants delivering $D_{90_{CT}} \leq 72\%$ (i.e., $\leq 80\%$ of $D_{90_{CT}} = 90\%$) or $\geq 150\%$ (i.e., 20% greater than the satisfactory RTOG upper limit) will be reported as **medical events**.

V. EBRT in the post-operative setting:

Indications:

Post-operative PSA ≥ 0.2 ng/ml.

Positive post-operative surgical margins (not merely focal capsular penetration)

Positive seminal vesicles

Positive regional lymphnodes

Treatment volume:

Initial volume:

After a negative pelvic lymphnode dissection (PLND), the clinical treatment volume (CTV) should include a 1.0 cm margin on perirectal and perivesicular vascular clips. Additionally, the CTV will include, when available, the pre-operative CT volume (prostate and seminal vesicles) with a 1.0 cm margin.

In the absence of PLND or after lymphnode sampling only, the initial treatment volume should include the modified whole pelvis field described above.

Boost volume:

After delivery of 50.4 Gy, the coned-down volume (CTV) will include only the prostate bed plus a 1.0 cm margin.

Treatment Dose:

The total dose delivered to the prostate bed will vary with the indications for treatment.

- i. When the post-operative PSA ≤ 1.0 ng/ml and/or there is a single microscopically involved margin the final dose will be 64.8-68.4 Gy.
- ii. When the post-operative PSA > 1.0 ng/ml, seminal vesicles are involved, or multiple surgical margins are involved with disease, the final dose will be at least 64.8 Gy and no greater than 72 Gy. In these cases radiation treatment should include 4 months of androgen suppression, two months of which are given in the neoadjuvant setting.

N.B. Each post-operative treatment volume has been given as a CTV. The planning treatment volume (PTV), equivalent to the "light-field" constructed at simulation, includes the CTV plus allowances for patient set-up error and beam characteristics. Thus, the volume shell for the PTV will normally be 1.0-1.5 cm greater than the CTV values given.

VI. IMRT guidelines for the prostate

A. General. IMRT should be planned for the prostate when (a) treatment involves a central axis dose of ≥ 75 Gy (bioequivalent dose [BED] if appropriate), (b) patient's medical condition requires greater avoidance of non-target tissues within the pelvis (such as a patient with inflammatory bowel disease or previous bowel surgery) (c) the prostate size requires a greater volume of the bladder to be included in the PTV_{pp}.

Due to daily variability in the prostate position, IMRT of the prostate requires the placement of internal markers capable of being easily imaged via real-time portal imaging. For this purpose three independent markers will be placed 1-3cm lateral to the midline, one each in the anterior

aspect of the base on the right and left and another near the apex of the prostate. These should be placed prior to the initial simulation. When marker placement results in noticeable prostate edema, simulation is postponed until the edema resolves.

IMRT should be planned and delivered as a single course of treatment with separate doses indicated for the involved region of the prostate (GTV_{HD}), remainder of the prostate and proximal seminal vesicles (PTV_{PP}), and pelvic lymph nodes (PTV_{LN}). IMRT can be used as a sole method of irradiation when the entire prostate is to receive 72Gy[BED]. Whole prostate doses above 72Gy[BED] will be achieved by the addition of brachytherapy boosting.

B. IMRT dosing. IMRT dose planning takes advantage of its inherent multiple dose-rate capability to deliver the following dose scheme to the planned PTVs:

<u>Target</u>	<u>physical dose</u>	<u>bio-equivalent dose</u>	<u>#</u>
<u>fractions/dose/fraction</u>			
GTV_{HD}	72Gy	77.8-80.2Gy	30/ 2.4Gy
PTV_{PP}	60Gy	60Gy	30/ 2.0Gy
PTV_{LN}	50Gy	50Gy	30/ 1.67Gy

Using the doses listed above, DVHs for non-target tissues should be constrained as follows (physical dose):

<u>Structure</u>	<u>50% criteria</u>	<u>10% criteria</u>	<u>2% criteria</u>	<u># fractions</u>
Skin	30Gy	35Gy	45Gy	30
Small bowel	25Gy	45Gy	50Gy	30
Bladder	30Gy	60Gy	65Gy	30
Non-PTV				
Periprostatic rectum	55Gy	63Gy	65Gy	30
Remaining rectum	45Gy	55Gy	60Gy	30
Femoral heads	35Gy	40Gy	45Gy	30

C. Defining target structures.

1. Contouring the involved prostate volume GTV_{HD} (white): A GTV_{HD} may be constructed at the discretion of the attending physician.

Contour expansion: none. This volume without expansions will be entirely contained within the prostate/peri-prostate GTV. Therefore, the $PTV_{HD} = CTV_{HD} = GTV_{HD}$.

It is the purpose of this volume to afford a 5-10% "hot spot(s)" to be planned regionally over areas of known disease, WITH NO COMPROMISE ON ANY OTHER DOSE CONSTRAINT. The GTV_{HD} will be modified if its inclusion causes the failure of any planned DVH constraint.

High dose volume(s), GTV_{HD} , will be individualized for each patient. The GTV_{HD} will be limited to the prostate or prostate bed and not exceed 115% of the planned physical dose to the prostate/peri-prostate CTV_{PP} .

2. Contouring the prostate/peri-prostate GTV_{pp} (red): The GTV_{pp} consists of the prostate (GTV_p) and the proximal 2cm of the seminal vesicles (GTV_{SV}).

Contour expansions: The CTV_{pp} is created by expanding GTV_p by 0.5 cm in all directions **except posteriorly**. The GTV_{SV} will not be expanded.

For the PTV_{pp}, the CTV_{pp} is expanded by 0.5cm in all directions.

3. Boost contours for second course treatment of the prostate GTV_{boost} (red): The GTV_{boost} is limited by the prostate (GTV_p). The boost volume may include any or all of the original GTV_p but may not be expanded beyond this volume. A separate GTV_{HD} may be included with the same limitations described above.

Contour expansions: The CTV_{boost} is the GTV_{boost}. No separate CTV expansion is allowed, created by expanding GTV_p by 0.5 cm in all directions **except posteriorly**.

For the PTV_{boost}, the GTV/CTV_{boost} is expanded by 0.5cm in all directions.

4. Contouring the LN volumes (light blue): The GTV_{LN} includes internal and external iliac vessels traced from the inferior aspect of the SI joints to the inferior aspect of the obturator foramina (internal iliac), and 2.5cm superior to the pubic symphysis (external iliac), respectively. Note that these LN regions have been shown to harbor prostate carcinoma both in extended LN dissections and by Combidex imaging.

Contour expansions: The CTV_{LN} is formed by a 1cm expansion of the GTV_{LN} in two dimensions (AP-PA and R-L), on each CT slice. The cephalad and caudal most contours are repeated for two additional CT slices (6mm). CTV does not expand over bowel, bladder, bone, skin (defined as a 1cm shell) or the prostate PTV.

The PTV_{LN} is formed by expanding the CTV_{LN} by 0.5cm in all directions with only the skin and prostate PTV as limiting objects.

5. Contouring other structures

Entire urinary bladder— yellow

Peri-prostatic rectum (defined from most inferior prostate contour to upper SV contour)— blue-green

Remaining rectum and anal canal --- blue

Small bowel (surround with a single contour where possible) --- brown

Skin (1cm shell defined by the dosimetrist using the CT image) --- green

VII. Androgen Ablation in the Adjuvant or Salvage Settings.

Androgen ablation represents a primary therapy for patients who experience recurrence following local irradiation. Failure is typically indicated by PSA elevation in the patient who is otherwise asymptomatic. The timing for the initiation of hormone therapy (castration or androgen suppression) is uncertain. Therefore, maximal efforts should be made to place these patients on existing protocols. The following indications, however, are associated with a greater than 50% likelihood for the development of distant metastases. Therefore, regardless of available protocols the following prognostic indicators should elicit a strong recommendation to begin hormone therapy:

- a. Salvage: PSA doubling time (above an absolute value of 1.0 ng/ml) of less than 1 year;
- b. Salvage: PSA after irradiation (either in the definitive setting or post-prostatectomy) which is greater than 10.0 ng/ml (or ≥ 5 ng/ml for patients on finasteride therapy);
- c. Adjuvant: Pre-irradiation PSA >20 ng/ml **and** T-stage \geq T2C **and** Gleason score ≥ 8 .

Androgen ablation, initiated as described above for salvage, will be given continuously unless patients are placed on protocol for intermittent or shorter duration therapy therapy. Androgen ablation administered adjuvantly will be continued for a minimum of two years.

References

American College of Radiology *Practice Guideline for Transperineal Permanent Brachytherapy of Prostate Cancer*

AAPM Report No. 68 (TG-64), *Permanent Prostate Seed Implant Brachytherapy*, October 1999

AAPM Report No. 51 (TG-43), *Dosimetry of Interstitial Brachytherapy Sources*, March 1995

AAPM Report No. 84, *Update of AAPM Task Group No. 43 Report: A revised AAPM protocol for brachytherapy dose calculations*, February 2004

AAPM Report No. 84s, *Supplement to the 2004 update of the AAPM Task Group No. 43 Report*, June 2007

AAPM Report No. 89, *Recommendations of the American Association of Physicists in Medicine regarding the Impact of Implementing the 2004 Task Group 43 Report on Dose Specification for ¹⁰³Pd and ¹²⁵I Interstitial Brachytherapy*, April 2005

AAPM Report No. 98, *Third-party Brachytherapy Source Calibrations and Physicist Responsibilities*

AAPM TG 128, *Quality Assurance Tests for Prostate Brachytherapy Ultrasound Systems*

NRC Regulations – 10 CFR 35, *Medical Use of Byproduct Material*

Filename: Prostate Seed Implant Manual - Sept 2008.
doc

Hunter Holmes McGuire Veterans Medical Center

Department of Radiation Oncology

Prostate Seed Implant QA

**1201 Broad Rock Blvd
Richmond VA 23249**

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1.0 Goals

The plan aims to monitor and evaluate the brachytherapy application of radioactive materials and to resolve identified problems in order to ensure accurate radiation dose delivery, minimize risks to patients and personnel, and ensure compliance with applicable laws and regulations. In addition to other indicators defined in the quality assessment plan specific indicators consistent with the aims mentioned above are:

- Dose integrity verification
- Assessment of radiation safety.

2.0 Scope

The brachytherapy Quality assessment plan is designed to monitor and evaluate the brachytherapy use of all radioactive materials by the department's radiation oncologists.

3.0 Procedures:

1. Receipt, temporary storage and disposal of sources
 - a. Brachytherapy sources acquired for specific cases, e.g. Pd-103 or I-125 are placed in temporary storage room 1H-152. Source receipt transport to storage upon receipt, transport from storage for disposal, and disposal is performed by radiation safety. Source transport from storage to patient and back from patient to storage is performed either by Radiation Safety or by departmental personnel.
2. Radiation surveys
 - a. Surveys in the vicinity of the patients are performed by departmental personnel of radiation safety at the time of patient loading and again when sources have been removed from the patient. Survey meters are calibrated at least annually by radiation safety
3. Treatment Planning
 - a. No brachytherapy application is to be performed without a complete and unambiguous prescription, written in ink by radiation oncologist. This shall include type number and activity of sources, dose rate, total dose duration of implant signature and date. Any calculation of dose rate or application time including computer isodose plans shall be approved by the radiation oncologist by indicating the prescribed dose rate total dose duration of implant signature and date.
 - b. All brachytherapy dose calculations performed by a dosimetrist or physician must be checked by a physicist before the prescribed dose is

delivered. If the calculation is performed by a physicist, the calculation must be checked by second physicist or a dosimetrist before the prescribed dose is delivered.

4.0 Radiation Safety

- c. As part of the VAMC Radiation Safety program personnel involved in the brachytherapy use of radioactive materials which may include physicians, supervised residents, physicists and/or dosimetrists, will have had training appropriate for the handling and administering of the materials.
- d. Personnel are required to wear radiation exposure monitors (film badges, TLD rings) as per radiation safety policies
- e. Warning notices are posted on the patient's room door and in the patient's chart during brachytherapy implants.
- f. Radiation surveys source inventories and leak tests are performed as described above (or in 3B)

5.0 Criteria and Tolerances

1. Quality control procedures which provide a data base for monitoring established indicators have been described. The following criteria with their corresponding reported levels (tolerances) form the basis for assessing the effectiveness of the brachytherapy Quality Assessment plan. All of the following are to be reported to the QA Committee.
 - a. Any occurrence of a misplaced or lost radioactive source, for any period of time.
 - b. Failure to log source removal from storage or return to storage
 - c. Failure to perform surveys as required by applicable polices and procedures
 - d. Failure to wear appropriate exposure monitors as required by the radiation safety polices and procedures.
 - e. Any treatment delivered without an appropriately written and signed prescription.
 - f. Any treatment delivered without appropriate calculation checks.
 - g. Any calculation errors and/or source application errors found to result in delivered tumor (or critical structure) dose errors in excess of 2% over the complete course of the implant. In such cases the radiation oncologist will be notified as soon as possible.
 - h. Any calculation errors and/or source application errors found to result in delivered tumor (or critical structure) dose in excess of 10% over the complete course of the implant. IN such cases the radiation oncologist

will be notified as soon as possible who will in turn inform the department chairman and the QA committee. Appropriate steps will be taken to ensure that any relevant Stage Federal and/or institutional reporting requirements are followed.

- i. Changes in quality control procedures or frequencies.

6.0 Applicability of QA Standard

The quality assessment standards described in this document may be temporarily suspended under special circumstances by direct order of an attending Radiation .
Oncologist when such action is clearly in the patient's best interest. Such suspension must be reported as soon as possible to the department chairman and to the quality assessment committee as its next meeting.

7.0 Appendix

Appendix 7.1 : QA documents

Hunter Holmes McGuire V.A. Medical Center
 Department of Radiation Oncology
 Permanent Prostate Implant Seed Order Form

Patient Name:	New, sheet	RT Number:	00-0000
Order Date:	9/23/08	P.O. Number:	652-C50063
Radiation Oncologist:	Oncologist	Physicist/Dosimetrist:	Planner
Isotope:	Isotope	Plan Activity / Seed:	Unit
Reference Date:	1/0/1900	Reference Activity:	0.000 Unit
Number of Seeds:	10	Delivery Method:	Seed Method
Implant Date:	01/00/00	Delivery Date:	
Theragenics Phone Number: 1-877-444-7333			
Theragenics Fax Number: 1-800-458-4303			
For Pre-loaded needles: (Variseed needle loading report attached)			
<input type="checkbox"/> Use square hub needles			
<input type="checkbox"/> Load manual Retraction			
<input type="checkbox"/> Use trailing Spacers			
<input type="checkbox"/> Assay 100% of Seeds			
<input type="checkbox"/> Sterilization required			
<input type="checkbox"/> Fax order confirmation to 804-675-5287			
Ordered By:		Total Pages Faxed	

Hunter Holmes McGuire VA. Medical Center
 Department of Radiation Oncology
 Permanent Prostate Implant Seed Inventory Form

Seed Order (To Be Filled by Dosimetrist / Physicist)			
Patient Name:	New, sheet	RT Number:	00-0000
Social Security Num:	111-22-3344	Rad. Oncologist:	Oncologist
Dosimetrist/Physicist:	Planner	Isotope:	Isotope
Number of Seeds:	10	Plan Activity / Seed:	Unit
Reference Date:	1/0/1900	Reference Activity:	0.000 Unit
Delivery Method:	Seed Method	Total Ref. Activity:	0.0 Unit
Implant Date:	01/00/00	Delivery Date:	

Shipment Receipt (To Be Filled by RSO)	
Date Received: _____	Activity Received: _____
Mean Seed Activity: _____	Reference Date: _____
Seed Count: _____	Received By: _____

Secondary Calibration (To Be Filled by Dosimetrist / Physicist)	
Activity Measured: _____	Planned Activity: _____ Unit
Result (within 5%) <input type="checkbox"/> Pass <input type="checkbox"/> Fail	Performed by: _____
Seeds Loaded: _____	Seed Remaining: _____

Post Implant Inventory (To Be Filled by Dosimetrist / Physicist)	
Imp Num. of Seeds: _____	Implanted Activity: _____
Implant Date: _____	Implant Time: _____

Patient Discharge Survey (To Be Filled by RSO)	
Survey Date: _____	Survey Time: _____
Results: <input type="checkbox"/> Room Clear of Activity <input type="checkbox"/> Seeds Found	
Final Exposure Rate: _____	Surveyed By: _____

Hunter Holmes McGuire VA Medical Center
 Department of Radiation Oncology
 Seed Calibration Form

Patient Name	New, sheet
Implant Date	1/0/1900
Number of Seeds	0
Isotope	Isotope
Today's Date	
Days Till Implant	
Reading 1	
Reading 2	
Reading 3	
Reading 4	
Average Reading	
Today's Activity	
Implant Day Activity	
Planned Activity	Unit
Percent Difference	
Calibrated By:	

For I-125 Seeds: Today's Activity = Average Reading x 1.014 mCi
Decay factors for I-125: 1: 0.9886, 2: 0.9772, 3: 0.9661, 4: 0.9550

For Pd-103 seeds, Today's Activity = Average Reading x 2.532 U
Decay factors for Pd-103: 1: 0.9605, 2: 0.9226, 3: 0.8861, 4: 0.8511

Hunter Holmes McGuire VA Medical Center
Richmond, Virginia

Prostate Implant QA Checklist

Patient Name: New, sheet

Social Sec. Number: 111-22-3344

<u>ITEM</u>	<u>INITIAL</u>	<u>DATE</u>
<input type="checkbox"/> Script Signed by Attending		
<input type="checkbox"/> Pre-implant contours approved by Attending		
<input type="checkbox"/> Treatment Plan Approved by MD (Resident or Attending)		
<input type="checkbox"/> Dose Calculation Double Check Performed by Physics		
<input type="checkbox"/> CT images loaded into VariSeed		
<input type="checkbox"/> Post Implant CT contours approved by Attending		
<input type="checkbox"/> Post Implant CT analysis (D90) performed by physics		
<input type="checkbox"/> Post Implant CT plan printed, filed, morning conference		
<input type="checkbox"/> Patient backed up and deleted		

Appendix 7.2 : Seed strength verification:

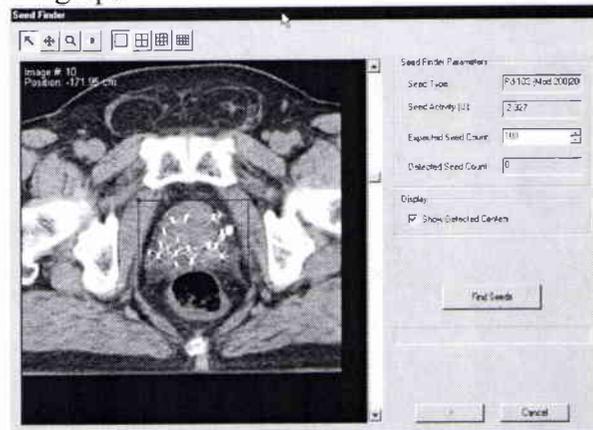
1. Dosimetry System:
 - Standard Imaging Well Counter, Model HDR1000 Plus S/N A981807
 - Standard Imaging Electrometer Model: CDX-2000A S/N B981531
2. The chamber and electrometer are calibrated every two years by an ADCL. (Copies of the recent calibration certificates from University of Wisconsin Accredited laboratory are attached.
3. Calibrated seeds of I-125 and Pd-103.
4. Chamber constancy check is performed every three months. If the discrepancy between venter supplied seed strength is differs by more than 5%, the chamber constancy is checked immediately
5. The method used is similar to the one discussed by Mellenberg and Kline (*Verification of manufacture-supplied ¹²⁵I and ¹⁰³Pd air kerma strengths, Medical Physics 22(9), Sep 1995*). Batch of 10 seeds assayed and the seed strength is calculated using an Excel® Spreadsheet (copies of the spreadsheet attached). The geometry/self-absorption factor is experimentally determined every year.
6. 30 seeds assayed for each patient. (3 batches of 10 seeds in each batch totaling 30 seeds for each patient)
7. Criterion for agreement is $\pm 5\%$ with the venter specified strength
8. The venter specified seed strength is used for planning in *Variseed™*

Appendix 7.3 : Source accounting

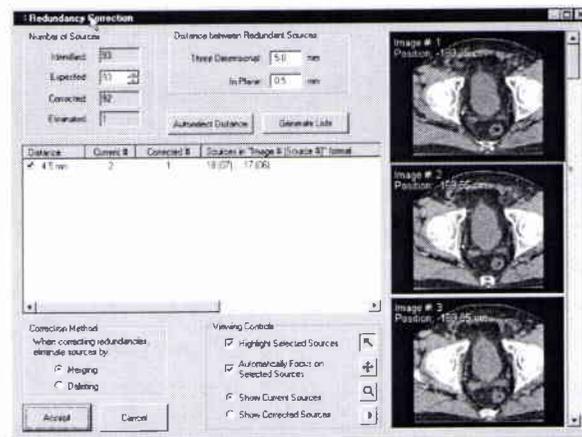
1. A Posterior to Anterior (PA) radiograph taken at the completion of the implant (shown is the picture)



2. A second physicist/dosimetrist keeps track of seed inventory of the implanted seeds and number of seeds remaining. If there is a discrepancy, seeds are counted from the Posterior to Anterior (PA) radiograph
3. Diagnostic quality Anterior to Posterior (AP) and Lateral radiograph used to count seeds, and then the found number of seeds is entered into *Variseed's*TM seed finder module (shown in picture).



4. The redundancy check is performed in *Variseed*TM by the redundancy module (shown in picture below). A manual slice-by-slice inspection performed by the planner after the *Variseed*TM redundancy check.

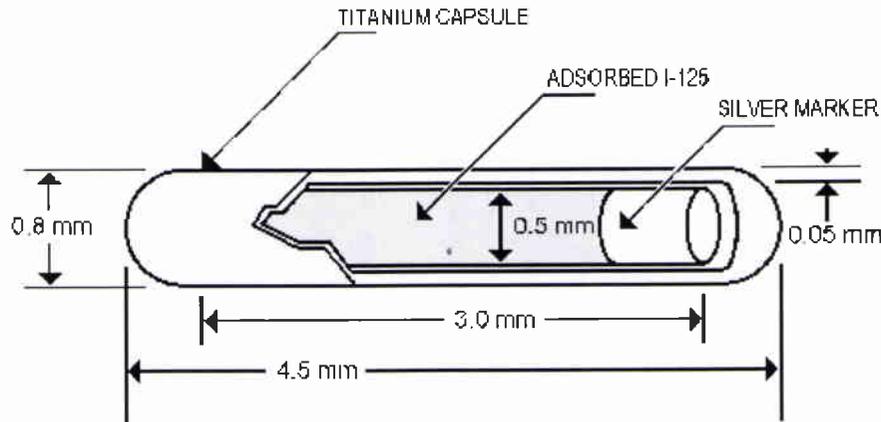


5. The discrepancy limit from the time the patient leaves the hospital to the time of the post implant is one seed. If more than one seed is missing from the implant to post implant study after multiple recounts of the radiographs, the patient is re-radiographed at different angles or stereo-shifted and seeds are counted again, if still there is more than one seed missing, the number of seeds missing is documented on the chart.

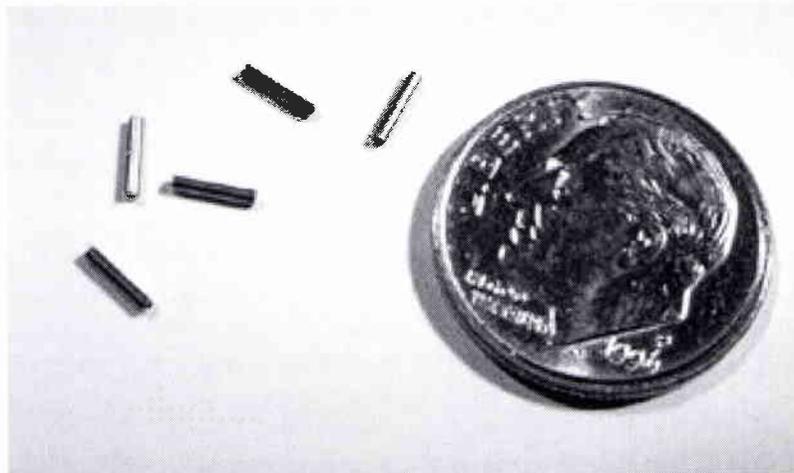
Appendix 7.4 : Discharge Instructions for Prostate Brachytherapy Patients

After the Procedure

Part of your treatment for prostate cancer, a small amount of radioactive was implanted in your prostate. Two isotopes are most commonly used in prostate brachytherapy: Iodine I-125 and Palladium Pd-103. More recently, another one, Cs-131 is being used, with virtually the same energy as Iodine but much faster decay. The 'seeds' are in fact welded titanium capsules containing the radioactive material, usually absorbed on silver (an example is shown below).



There size is about 4-5mm in length and 0.8mm in diameter, pretty much the size of a rice grain (seen below compared with a dime):



The Nuclear Regulatory Commission (NRC) has determined that no radiation precautions need to be taken for patients who undergo prostate seed implantation with I-125 or Pd-103 seeds. The NRC states that *these patients do not represent any risk to the people around them*, including young children and pregnant women. However, *we do ask patients to follow a few common sense guidelines*. They are:

1. Children and pets should not sit on the patient's lap for the first two months after the procedure
2. Pregnant (or possibly pregnant) women should avoid prolonged close contact with the patient for the first two months after the procedure (She can greet the patient briefly and then move to a distance of three feet or more away. At a six foot distance, there is no limit to the length of time she can be in the same room with the patient.)
3. Iodine and palladium are low energy radioactive materials. The emitted radiation is not deeply penetrating and loses energy at short distances. Your prostate will absorb most of the radiation. Objects that are touched or used by the patient ***do not become radioactive.***
4. Body wastes (urine and stool) or body fluids (saliva, tears, semen or blood) are ***not radioactive.***
5. You ***may resume sexual relations two weeks after the procedure. A condom should be used for the first two weeks.*** Your semen may be dark brown or black; this is normal and is related bleeding that may have occurred during the implant. After two months, condom use should return to normal public health recommendations.

After two (2) months, no further precautions are necessary. If you have any questions, please call the Radiation Oncology Department at (804) 675-5000 ext:5105

Special Instructions Related to the Seeds:

It is unlikely that you will pass an Iodine-125 seed in your urine. However, as a precaution, for the next week, urinate through the strainer that you received when you left the hospital. The seeds are silver in color and are about as large as a grain of rice. If you pass a seed, follow the directions in your discharge kit.

More in-depth information:

Based on the current Nuclear Regulatory Commission (NRC) regulations, the time required to reach the annual limit (for general public) at the anterior skin surface would be 20 hours for I-125 and 59 hours for Pd-103 (Fig. 4). For exposure at the lateral skin surface the times would exceed 500 hours for either isotope, and would be even longer if decay during the exposure time was taken into account. At 1 meter, it would take a minimum 1429 hours to reach the annual limit from anterior exposure for I-125 and even longer for Pd-103. ***In practical terms, these data suggest that patients need not be concerned about being a radiation risk to the general public following their procedure.***

It appears that prostate brachytherapy patients present little exposure risk to the public, even at close contact. The only conceivable risk would be to a significant other who spent a large amount of time with the patient. Even then, considering that true skin-to-skin contact for times exceeding 1 hour would be unusual, the likelihood of receiving the maximum annual dose would be minuscule. The actual exposure to a spouse's oocytes

would be far lower than reported here because the ovaries would be shielded considerably by the overlying tissue of the spouse.

While it is unlikely that a family member or other member of the public would receive more than the NRC dose limit from exposure to a prostate brachytherapy patient, this should not preclude issuing guidelines to patients for maintaining doses as low as reasonably achievable (ALARA).

Specific recommendations for keeping radiation exposure to others ALARA will depend on the living situation of the patient. A patient living in a retirement community or nursing home, with no young children around, would have minimal restriction on activities as compared to a patient living in a household that includes infants and children.

Because of the significantly higher exposure rates at close anterior distances, prostate brachytherapy patients should be instructed to avoid extended close contact with others until after several radioactive half-lives have elapsed and contact dose rates are reduced to minimal. This includes not holding infants or young children in their lap. Also, radiation dose to a spouse would be reduced if the patient sleeps on his back rather than on his side. Patients should be encouraged to think of other ways to minimize radiation exposure to family members. Involving the patient in the process may increase the likelihood of his compliance with ALARA guidelines.

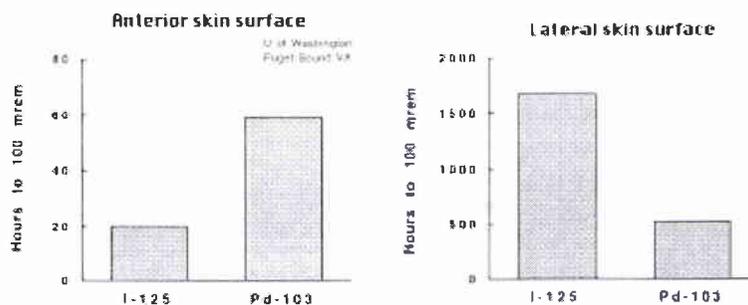


Fig. 4. Approximate exposure times at anterior and lateral skin surfaces needed to reach NRC annual limits for the general public (100 mrem). Calculation of the times needed to reach the NRC limit neglects decay during the exposure time, which would have minimal effect on the results.

Table 2. Lifetime effective dose equivalent predicted from radiation monitors

Isotope	Patient Waist dose (mSv)	Patient Collar dose (mSv)	Spouse dose (mSv)	Other family dose (mSv)	Any room dose (mSv)
Mean effective dose equivalent (entire study population)					
¹²⁵ I (n = 29)	6.47	1.10	0.10	0.07	0.05
¹⁰³ Pd (n = 15)	3.33	0.30	0.02	0.02	0.02
Mean effective dose equivalent (worst cases, >75%iles)					
¹²⁵ I	14.04	3.27	0.21	0.07	0.07
¹⁰³ Pd	6.39	0.80	0.03	0.02	0.02

In compliance with 10 CFR 35.75(a), the U.S. Nuclear Regulatory Commission (4) allows patient discharge to home if no more than 9 mCi (0.34 GBq) ¹²⁵I or 40 mCi (1.5GBq) ¹⁰³Pd was implanted. Not surprisingly, all the implants in this study exceeded this limit. However, because of internal absorption of radiation by the patient, very little radiation is emitted, and alternative regulations allow discharge if the exposure rate at 1 meter is at or below 0.01 mSv/h for ¹²⁵I and 0.03 mSv/h for ¹⁰³Pd. It is estimated that these dose rates keep exposure to an individual to less than 5 mSv total effective dose. Smathers *et al.* (10) reported that the exposure rates from patients with permanent brachytherapy implants are below these limits. Immediately after the brachytherapy procedure, exposures from patients treated at our institution are surveyed at 1 meter. In more than 300 consecutive prostate brachytherapy implants, we have never measured an exposure rate that exceeded the NRC guidelines.

The lifetime exposures calculated based on direct readings from our patients' household and family member dosimeters are well below the annual limit set by the NRC and other regulatory agencies. Even the highest exposures received by the patients' spouses are barely half the annual limit for members of the general public. The less intimate household readings of children, pets, and environment suggest that unusually high exposures are unlikely to be achieved through typical contact with the patient at home.

The average effective dose equivalent received from all sources by a member of the U.S. population is 3.6 mSv per year. In the year after a prostate brachytherapy implant, a spouse would add 0.20 mSv to her cumulative annual dose. In that year, a spouse would receive no more than 5% of her total annual radiation exposure from her husband's implant. Of course, patients receive only a single implant, and for all other years before and after the implant, the spouse would not be exposed to this source of radiation. To put the findings of this study into a perspective that patients and the general public may understand, the annual radiation exposure difference that a Denver citizen receives compared to a St. Louisan is nearly 5-fold greater than the lifetime exposure received by living with a man who had a radioactive ¹²⁵I implant.

The magnitude of radiation exposure to family members from patients undergoing prostate brachytherapy is no worse than that from events most people take for granted every day.

It is important to stress that there may be no "safe" thresholds for radiation exposure. The National Council on Radiation Protection and Measurement encourages the concept of "As Low As Reasonably Achievable" (12). The ALARA principle still applies in the context of the patient's home. Patients should do simple things to minimize exposure to family members, especially children and pregnant women, who may be more sensitive to radiation. Minimizing direct contact for prolonged periods of time, especially for the first few weeks or months after an implant, should be practiced. An implant patient can hold a child, but he should restrict activities such as allowing the child to sit in his lap for many hours on multiple occasions. Wearable lead shields that minimize radiation exposure seem entirely unnecessary.

In those uncommon situations where a patient is at home with a pregnant spouse or family member, the choice of ¹⁰³Pd will reduce the expected radiation exposure to the woman and fetus.

References:

**U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 8.39
Release of Patients Administered Radioactive Materials (April 1997)**

Radiation exposure to family and household members after prostate brachytherapy, *International Journal of Radiation Oncology*Biology*Physics, Volume 56, Issue 3, 1 July 2003, Pages 764-768,* Jeff Michalski, Sasa Mutic, John Eichling and S. Nisar Ahmed

Radiation safety parameters following prostate brachytherapy, *International Journal of Radiation Oncology*Biology*Physics, Volume 45, Issue 2, 1 September 1999, Pages 397-399,* Sesalie Smathers, Kent Wallner, Tammy Korssjoen, Carl Bergsagel, Rick H. Hudson, Steven Sutlief and John Blasko

Appendix 7.5 : Other QA procedures

1. The computer generated plan is checked against a hand calculation method based on AAPM TG-43 and TG-64 formalisms. The seed positions and dose calculation points are imported from *Variseed*TM. The spreadsheet compares point dose calculations for various points to those calculated by *Variseed*TM.
2. A review of the patient records is performed by a physicist to make sure that the patient meets the protocol criteria.
3. A radiograph of pre-loaded seeds is taken prior to the implant to confirm seed/spacer configurations.

From: Origin ID: LITA (501) 257-1571
Kelly Mayo
VHA National Health Physics Pr
2200 FORT ROOTS DR
B101 R208D
NORTH LITTLE ROCK, AR 72114



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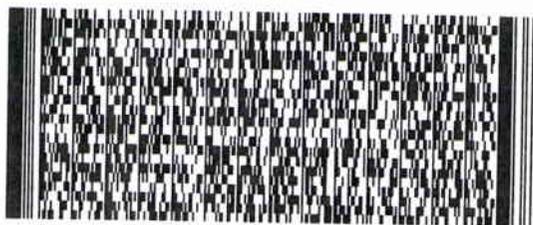
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Cassandra Frazier
Nuclear Regulatory Commission
2443 Warrenville Road
Suite 210
Lisle, IL 60532



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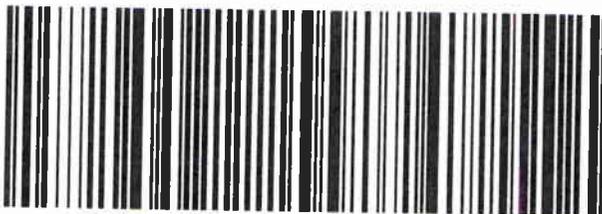
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3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

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