# Hunter Holmes McGuire Veterans Medical Center

## Radiation Oncology Service

# Prostate Seed Implant Procedures and QA

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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 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 ± 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 $^{125}I$ and $^{103}Pd$ 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 ±**5%** with the vender 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.

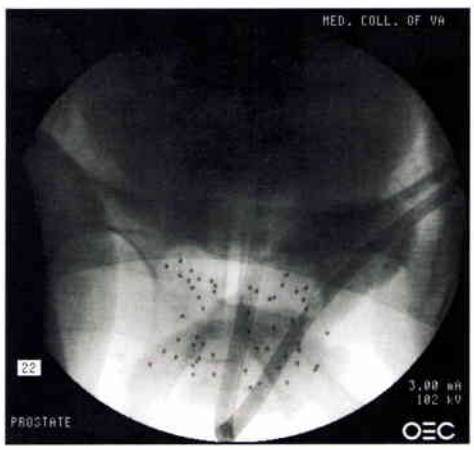
5. At the needle insertion stage, physicist scrubs in and hands the needles to the MD.
6. At the conclusion of the implant procedure, the exposure around the patient is measured using a calibrated survey meter. Readings are taken next to the patient's pelvis, 3 feet from the pelvis and at the OR door and recorded in the patient's chart (Form E).

**Post-implant phase**

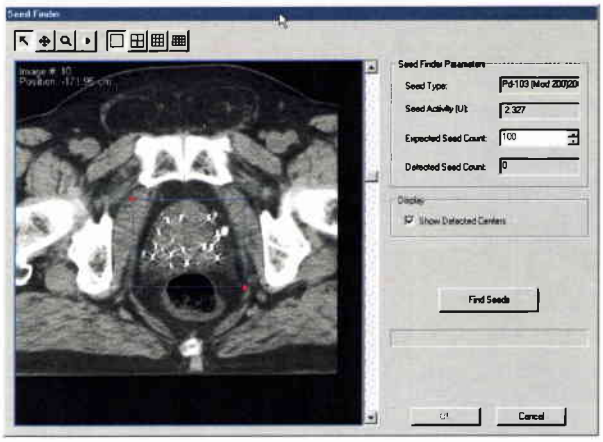
1. Complete the **Part II of the written directive** (Form D).
2. Fill in radiation warning label (Form G) and place on the nurse chart.
3. After patient leaves the OR, survey the operation room including trash and pitcher that holds the used needles.
4. Fill in the Patient Survey Form (Form E), make 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*™ seed finder module (shown in picture).




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

### *3.2.8BrachyTherapy 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 date 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
Grapes/grape juice
Carbonated beverages
Chilies/spicy foods
Citrus fruits and drinks
Tomatoes
Chocolate
Cranberries and juice
Coffee including decaf
Pineapple
Plums
Tea
Strawberries
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 ± 1mm)

| Vertical (Z) | Digital Reading (mm) | Digital Distance (mm) | Mechanical Reading (mm) | Mechanical Distance (mm) | Sat. | Unsat. |
|---|---|---|---|---|---|---|
| Initial position | | 0.0 | | 0.0 | | |
| Lowered 200 r | | | | | ☐ | ☐ |

| 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 | | | | | ☐ | ☐ |

2. Laser Digital Accuracy (tolerance ±1mm)

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 | | | | | ☐ | ☐ |

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 | | | | | ☐ | ☐ |

| Lateral (X) | Left (-125mm) | Center (0 mm) | Right (+125 mm) | Sat. | Unsat. |
|---|---|---|---|---|---|
| Alignment with Laser QA Device | | | | ☐ | ☐ |

3. Laser tracking (tolerance ±1mm)
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) |
|---|---|---|
| | | |

| | Sat. | Unsat. | Sat. | Unsat. | Sat. | Unsat. |
|---|---|---|---|---|---|---|
| **Wall Lasers** | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **Ceiling Lasers** | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**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 | ☐ | ☐ |
| 1.5 | | ± 0.5 mm | ☐ | ☐ |
| 3.0 | | ± 0.5 mm | ☐ | ☐ |

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 $mm^2$; Tolerance: CT # = 0 ± 4, Std Dev = 4.5 ± 0.5)

| **120 kVp** | **Center** | **3** | **6** | **9** | **12** | **Sat.** | **Unsat.** |
|---|---|---|---|---|---|---|---|
| CT # Std. Dev. | | | | | | ☐ | ☐ |

| 140 kVp | Center | 3 | 6 | 9 | 12 | Sat. | Unsat. |
|---|---|---|---|---|---|---|---|
| CT # Std. Dev. | | | | | | ☐ | ☐ |

4. Resolution and CT Numbers ( Protocol : Head STD-QA protocol, ROI = 20 $mm^2$)

| Item | Measured | Tolerance | Sat. | Unsat. |
|---|---|---|---|---|
| Spatial Resolution | | Resolve all 7 rows | ☐ | ☐ |
| Contrast Resolution | | Resolve 5 of 6 pins | ☐ | ☐ |
| Aculon CT # | | +100 ± 15 | ☐ | ☐ |
| Polyethylene CT # | | -70 ± 15 | ☐ | ☐ |
| Teflon CT # | | +1016 ± 50 | ☐ | ☐ |
| Perspex CT # | | +140 ± 15 | ☐ | ☐ |
| Lexan CT # | | +116 ± 15 | ☐ | ☐ |
| Water CT # | | 0 ± 2 | ☐ | ☐ |
| Air CT # | | -1000 ± 50 | ☐ | ☐ |

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 | ☐ | ☐ |
| Left/right peg cross hair lateral distance | | 250 mm ± 2 mm | ☐ | ☐ |
| Left PEG crosshair | | | | |

| | | | | |
|---|---|---|---|---|
| (longitudinal position) | | 600 mm ± 2 mm | ☐ | ☐ |
| Center PEG crosshair (longitudinal position) | | 600 mm ± 2 mm | ☐ | ☐ |
| Right PEG crosshair (longitudinal position) | | 600 mm ± 2 mm | ☐ | ☐ |

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 | ☐ | ☐ |
| Right PEG cross hair distance | | | | | 125 mm ± 2 mm | ☐ | ☐ |

**C. RECOMMENDATIONS/ACTION TAKEN:**

1. _____
2. _____
3. _____

## *7.2 Ultrasound QA:*

***Complete QA procedure is available with the phantom manufacturer manual***

**McGuire Holmes VA Medical Center -** **Department of Radiation Oncology**

## 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)

- ☐ Use square hub needles
- ☐ Load manual Retraction
- ☐ Use trailing Spacers
- ☐ Send 5 extra loose seeds
- ☐ Assay 100% of Seeds
- ☐ Sterilization required
- ☐ Fax order confirmation to 804-675-5287

Ordered By: Total Pages Faxed

VA Prostate Implants Ver1 4
2/9/2009

## *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: | ☐I-125 ☐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: | ☐ Room clear of Activity | ☐ Seeds found | # _____ |
| | | Surveyed By: | |

## *Form C Seed Calibration*

Hunter Holmes McGuire VA Medical Center
**Department of Radiation Oncology**
Seed Calibraton 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 ©** |
| Seed1 | | 21.5 |
| Seed2 | | |
| Seed3 | | **Pressure (mm Hg)** |
| Seed4 | | 774 |
| Seed5 | | |
| Average Reading | #DIV/0! | Ctp |
| | | **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*m^2/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*m^2/hr/A**
**Decay factors for Pd-103: 1: 0.9605, 2: 0.9226, 3: 0.8861, 4: 0.8511**

## *Form D Implant Written Directives*

### Hunter Holmes McGuire VA. Medical Center

**Department of Radiation Oncology**

Permanent Prostate Implant Written Directive

| | | | |
|---|---|---|---|
| Patient Name: | **0** | SSN: | 000-00-0000 |
| RT Number: | 00-0000 | Procedure Date: | 1/0/00 |

- ☐ **Physics consult request for volume study, pre-plan and seed/needle preparation**
- ☐ **Physics consult request for post implant dose analysis**
- ☐ **Patient identified by two methods**

| **Written Directive Part I: Pre-implant** | | | |
|---|---|---|---|
| Modality: | Sole | Isotope: | Isotope |
| Number of Seeds: | 0 | Activity / Seed: | Unit |
| Total Activity: | 0.0 Unit | Dose: | 124 Gy |
| | | | |
| Authorized User | | | Date |

| **Written Directive Part II: Post-implant** | | | |
|---|---|---|---|
| | | Isotope: | Isotope |
| Planned Seeds: | | Total Dose: | 124 Gy |
| Extra Seeds: | | | |
| Total # of Seeds: | | Activity Implanted: | |
| | | | |
| Authorized User | | | Date |

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## *Form E: Nursing Instructions*

**Hunter Holmes McGuire VA Medical Center**
**Richmond, Virginia**
Radiation Safety Office

**Patient Survey Form**

| | | | |
|---|---|---|---|
| **Patient Name:** | 0 | | 000-00-0000 |
| **Patient Room:** | | **Isotope:** | Isotope |
| **Number of Seeds:** | | **Activity:** | mCi |

| **Radiation Exposure Rates - Patient Supine in Bed** | | | |
|---|---|---|---|
| Date of Survey: | 1/0/1900 | Time: | AM PM |
| Bedside Reading: | mR/hr | 3 feet from Bed: | mR/hr |
| Door Reading (Bkg): | mR/hr | Initials: | |

| **OR Survey Following Patient Departure** | | | |
|---|---|---|---|
| Survey for lost seeds: | ☐ Room clear of activity | ☐ _____ seeds found | |
| Survey for leakage: | ☐ Negative ☐ Positive | _____ | |

| **Nursing Instructions** |
|---|
| **No restrictions are placed on visitation or nursing care. Recovered seeds should be transferred to lead container and reported to Radiation Safety or Radiation Oncology personnel.** |

| **Patient Release Information** |
|---|
| **The patient may be released from the medical center and should follow safety instructions provided. Catheters urinals, surgical dressings and bed linen must not be removed from the room until a radiation survey of the room has been performed by the Radiation Safety Office. Patient Release limits: I-124 (1 mRem/hr), Pd-103 (3 mRem/hr). If patient exceeds limits, contact radiation safety** |

**John D. Wilson Ph.D.**
VA EXT 5115 & 4395,
VCU Office: 828-7225 and VCU Pager: 3253,
Home: 598-7682

**Frank D. Corwin, M.S.**
VA Ext: 5115 & 4395,
VCU Office: 828-3457 and VCU Pager: 7655
Home: 320-5913

## *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

| ITEM | | INITIAL | DATE |
|---|---|---|---|
| [ ] | Script Signed by Attending | | |
| [ ] | Pre-implant contours approved by Attending | | |
| [ ] | Treatment Plan Approved by MD (Resident or Attending) | | |
| [ ] | Dose Calculation Double Check Performed by Physics | | |
| [ ] | CT images loaded into VariSeed | | |
| [ ] | Post implant CT contours approved by Attending | | |
| [ ] | Post implant CT analysis (D90) performed by physics | | |
| [ ] | Post implant CT plan printed, filed, morning conference | | |
| [ ] | 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, the we paste the copied data on the "I-125 parameters" worksheet.

## *Form G: Radioactive Label*

## 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 anesthetists, 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 meet.

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 $cm^3$ 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 ≤ 10ng/ml and Gleason score ≤ 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 ≥T2b**
**or PSA ≥ 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: ≥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: ≥ 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 urethragram.
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 urethragram. 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 urethragram 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 urethragram.
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 ≤ 60cc, and with PSA ≤ 10ng/ml and Gleason score ≤ 6; patients meeting these criteria with the addition of Gl 7 (3+4) adenocarcinoma involving less than 10% of a single biopsy core.**

b. **T1-T2a, volume > 60cc with PSA ≤ 10ng/ml and Gleason score ≤ 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 ≤ 60cc with PSA >10ng/ml, but ≤ 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 ($D90_{CT}$) **as determined from CT images obtained at the time of the dose reconstruction.** The dose delivered will be deemed **satisfactory as planned** when the $D90_{CT}$ 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 $D90_{CT}$ falls below 80%. Implants delivering $D90_{CT} \leq$ 72% (i.e., $\leq$80% of $D90_{CT}$ =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 $\geq$ 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 $\leq$1.0ng/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 >1.0ng/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 $\geq$75Gy (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:

| Target | physical dose | bio-equivalent dose | # fractions/dose/fraction |
|---|---|---|---|
| $GTV_{HD}$ | 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):

| Structure | 50% criteria | 10% criteria | 2% criteria | # fractions |
|---|---|---|---|---|
| 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 foramena (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 $\geq$ 5 ng/ml for patients on finasteride therapy);
c. Adjuvant: Pre-irradiation PSA >20 ng/ml **and** T-stage $\geq$ T2C **and** Gleason score $\geq$ 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*