



353 Fairmont Boulevard Rapid City, SD 57701 (605) 719-2300 FAX (605) 719-2310

August 16, 2013

U.S. Nuclear Regulatory Commission
ATTN: Anthony Gaines, Sr. Health Physicist
612 E. Lamar Blvd., Suite 400
Arlington, TX 76011-4125

Revised Prostate Seed Implant Procedures for Rapid City Regional Hospital LDR brachytherapy medical event, February 26, 2013

Licensee Name: Rapid City Regional Hospital

License Number: 40-00238-04

Medical Event Number: 48876

Dear Mr. Gaines,

Please find enclosed a copy of our updated prostate seed implant procedures. We have revised them to take into consideration our best estimate of what would best prevent another error like the one we made on February 26 and any others that may have occurred due to other weaknesses we have identified.

I would like to discuss in this letter few items that were listed on our action plan that are not directly addressed in our new procedures:

- 1.) As I explained in my email dated July 26, 2013 to Jason Razo, we are upgrading our HDR unit to a V3 Digital unit. We will be connecting the HDR to our MOSAIQ electronic medical record (EMR) at the same time. We would like to defer our revision of the HDR procedures (item 7 in the Action Plan) until that time so we can include this EMR connectivity in our revisions.
- 2.) Physics and dosimetry have completed our moves to our new office spaces. This has allowed us to settle in and create standard locations for our paper charts during our transition to the EMR. It has also allowed us to consolidate all of the relevant planning activities into one location.
- 3.) In Action Item 2, we indicated that we would create a checklist for the dosimetrist to use in the volume study phase of treatment planning. As we reviewed and revised our procedures, it was felt that this was a bit excessive. The dosimetrist did exactly as she was supposed to. The weakness lay in the configuration files in the planning

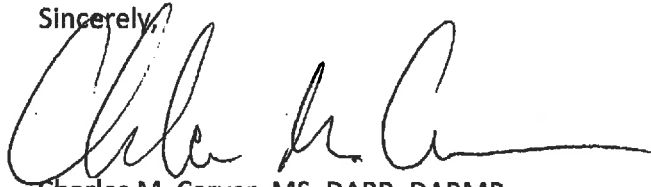
system. This has been fixed and the checklists used by physics in the planning process forces a second and third check. The physician check is essentially a fourth check.

- 4.) Items 6 and 9 of the Action Plan are essentially the same thing. We will be using the training we plan to give new employees for training the dosimetrists to be able to assist physics in the planning process. This will also give us the opportunity to refine the training before we need to use it on a new employee.

We would appreciate it if you would let us know of any omissions or weaknesses you might identify in your review. We would like this to be as strong and self-reinforcing program as we can possibly make it. I am confident that you will find it a vast improvement over our previous procedures, but it is by no means perfect. We will continue to make improvements as we move forward with the implementation phase.

Please contact me or James Mckee if you have any questions or require any additional information.

Sincerely,



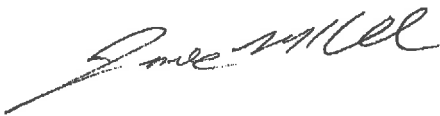
Charles M. Carver, MS, DABR, DABMP

Chief Physicist

John T Vucurevich Regional Cancer Care Institute

Rapid City Regional Hospital

Rapid City, SD



James McKee, MS

Medical Physicist / RSO

John T Vucurevich Regional Cancer Care Institute

Rapid City Regional Hospital

Rapid City, SD

GUIDELINES FOR VOLUME STUDY FOR PERMANENT SEED IMPLANTS

Volume Study:

- Ultrasound unit with rectal probe attached.
- Lidocaine gel.
- 60 cc syringe with ultrasound gel filled to 60cc – NO AIR.
- Condom covers rectal probe with some of gel from the syringe inside – NO AIR – secured in place by tape.
- Laptop computer from physics with Variseed software, power adapter, and mouse.
- Cable for video acquisition of ultrasound images – plug into back of ultrasound unit and computer before turning computer on.
- Digital level
 - Position stirrups on bed rail to allow enough room for stepper device clamps.
 - Position ultrasound unit on right side of bed as you look at it from the bottom.
 - Position computer on table to the right of the ultrasound unit.
 - Power on ultrasound unit and enter patient name, ID and birthdate under “New Patient Data”.
 - Power on computer and set up new patient folder for patient’s name, then new study name “Preplan Volume Study”, choose ultrasound video acquisition mode, enter a source activity of .394 mCi and “Volume Study” in the Structures box. Use all other defaults, including B&K template for the grid. Make sure that the same image that is on the ultrasound monitor appears on computer monitor.
 - The physician will position the patient, place the stirrups and put the stepper equipment together, including placing the holder on the rails.
 - When the physician is ready to acquire images, acquire them on the computer, axial cuts only. Pictures of the sagittal cuts will be printed for set up in the OR but are not used for the preplan.
 - After all of the images have been acquired, register the template, and move to the contour tab. The physician will complete the contouring of the prostate, the urethra and the pubic arch. SAVE.

Completing Paperwork and Charging:

- Have physician fill out the written directive before leaving Simulation.
- Scan the written directive form into MOSAIQ. Place in the “Documents” section under the heading “Brachy Written Dir”.
- Put ultrasound images inside photo holder and secure in chart.
- Document in chart that the volume study was performed with date and signature. Also document any other pertinent information relating to the volume study.
- Open up patient’s chart in MOSAIQ.

- Set up Rx and Treatment Field in D&I
- Go Tools, quality checklist, patient and then Append the “LDR BRACHYTHERAPY” checklist to the patient.
- Fill out the “Technical Charges for Permanent Seed Implant” form and enter the charges in MOSAIQ.

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GUIDELINES FOR PREPLANS FOR PERMANENT SEED IMPLANTS

Planning:

- Change Study Name to “PrePlan PSI”.
- Change structure set to dose indicated on Written Directive (145 Gy = Full Dose I125; 110 Gy = Boost Dose I125).
- Place sources to achieve optimum plan.
- Guidelines to follow for developing an adequate preplan, based on information derived at ABS meeting in June 2004
 - ◆ V100 >95%
 - ◆ V150 <50%
 - ◆ D90 110%-140%
 - ◆ V150(urethra) <15%
- Try to use 1 cm spacing as much as possible. Sometimes loading on the periphery requires .5 cm loading

- Second checks:
 - When an acceptable plan has been achieved, it is to be checked by a second person if possible.
 - ◆ Create a document in MOSAIQ in “Documents” under the heading “Brachy Checklist” using the template called “Brachy Plan Check Off Cover Sheet1”.
 - ◆ On the Encounter window, place your name in the “Dictated By” box. Leave the “Review Req By” and “Co-Sign Req By” boxes blank.
 - ◆ Give to second person.
 - The second person should complete the physics checks on the Brachy Checklist document.
 - ◆ After completing the physics checks, close the document.
 - Open up a new workbook for the patient from "G:\WGData\CCI\CCI Staff Reference\CCI Rad Onc\PHYSICS\Brachytherapy\Forms\PERM SEED PT WORKBOOK.xls" and immediately “Save As...” “Lastname_Firstname”, so as not to save over the blank template.
 - Enter patient name and ID on the first page of the workbook.
 - Go to tab marked “PREPLAN CHECK” and do a second check of the plan activity by filling in the information.
 - You may also export to RadCalc for a second check, however, you must put some calc points into the plan in Variseed before you export.
 - Send to physician for final check.
 - ◆ If the physician finds the plan acceptable, the physician should fill out the physician section of the Brachy Checklist document.

- The second physics checker should then place the physician in the “Co-Sign Req By” box in the “Encounter” window of the Brachy Checklist document.
 - The second physics checker should then approve the Brachy Checklist document.
 - The physician should then Co-Sign the document.
- ◆ The physician should then sign the plan if a paper chart or approve the plan in MOSAIQ if kept electronically.
- **Printing the Plan:**
 - Print out the following reports to paper (while still using paper charts) or to MOSAIQ (for electronic charting):
 - Study Summary
 - Needle Loading
 - DVH
 - Therapy Visualization
 - 2D View
 - 3D View
 - Place the paper copy in the paper chart on the back of the first tab.
 - For printing to MOSAIQ:
 - ◆ Use the “doPDF v7” printer in the printer dialog.
 - ◆ When asked for a location to print to, select the “R: RadOncology” location.
 - ◆ In MOSAIQ, import the PDF into the “Documents” section under the heading “Brachy Plan”.

Completing Paperwork and Charging:

- Make two copies of the needle loading report so that they are ready to take to the OR and secure in chart somewhere, clearly marked copies for OR.
- Determine the date of the implant, complete steps for ordering seeds (see separate procedure) and place the order.
- If a paper chart, secure everything inside the chart. Place the chart in the physics work area on the shelf over the Variseed treatment planning computer.
- Fill out the “Technical Charges for Permanent Seed Implant” form and enter the charges in MOSAIQ.

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GUIDELINES FOR PROSTATE SEED IMPLANTS DAY OF SURGERY

Equipment to take to OR:

- Ultrasound unit with rectal probe – make sure the scissors and some tape are with the unit.
- Utility cart:
 - Stepper Device and tools.
 - Extra rectal probe in black case.
 - 60 cc syringe with ultrasound gel filled to 60 cc mark (make sure there is minimal or no air).
 - Ultrasound probe covers.
 - Treatment chart, with two copies of the needle loading report.
 - Survey meter(s) to survey for seeds in the OR and take readings of the patient after the implant –the survey meters are kept in the hot lab in the department.
 - Package of needles with sources.
 - Lead container that holds the 5 loose seeds used for assaying upon arrival.
 - Digital level to compare probe angle with volume study.

Preparations

- Open ultrasound probe cover and unroll it a bit and place ultrasound gel from the syringe that you filled up before inside the ultrasound probe cover. Roll the ultrasound probe cover onto the rectal probe, making sure that there is very little air in the gel – using a piece of tape that is about 1 cm wide, tightly secure the ultrasound probe cover on the probe by wrapping it around just below the probe tip, this can be done the prior evening or the morning of the procedure.
- Plug in and turn on the planning computer. Bring up US images from volume study and attach the computer to one of the overhead monitors.
 - Place the mouse pad and mouse on top of the US unit (Use tape on the string tied to the mouse so it can't fall off).
- Tape the grid pattern from the needle loading report to the side of the monitor so that the doctors can double check the needle numbers and retraction plane as you hand them the needles.
- OR staff will make sure C-arm is available.
- When the C-Arm arrives, the monitors go on the right side of the bed and the C-Arm goes on the left side, the ultrasound unit at the bottom of the bed on the left side.
- The scrub nurse will set up a separate table with a sterile drape, then you can hand him/her the sterile seed packages.
- The scrub nurse will supply you with a sterile marker and ruler.

- Verify the patient identity and document on the “Prostate Seed Brachytherapy Post Implant Written Directive Form”.
- When the radiation oncologist arrives a time out will be performed. The time out will include the dose to be delivered by the seed implant (110 Gy Boost or 145 Gy Full Dose)
- The radiation oncologist will reposition the patient, remove the end of the bed, and attach the stepper rails.
- After the radiation oncologist places the probe in the rectum he will ask for the level, and the probe angle. The probe angle should be measured during volume study and angle recorded on Rx page.
- Put on sterile gloves and prepare needles. The needle containers bend in the middle making a stand for the needles.
- Remove the rubber stoppers from the needles.
- Start loading with needle number 1, unless the radiation oncologist requests differently.
- Verify the needle number with the plan, then hand the radiation oncologist the needle and read off the needle coordinates.
 - Once the needles are in place the radiation oncologist will verify needle measurements and seed counts, before releasing seeds.
- After all the planned needles are inserted, the doctors will decide if they want to use the discretionary needles.
- Once the physicians are satisfied with the implant, the radiation oncologist will write the post plan written directive on the “Prostate Seed Brachytherapy Post Implant Written Directive Form”.
- After the probe is removed, capture 2 fluoroscopic images, one AP and one slightly oblique to document seed positions.
- Perform survey of patient.
- Perform surveys of all the trash, linen, and needle bucket before the patient is removed from the room and then again after he is taken out of the room.
- Return equipment to the Radiation Oncology workroom, the dosimetrist will clean the equipment.
- Place all unused sources in lead vial with the loose seeds, mark on cap the number, date and return them to the hot lab.

Completing Paperwork

- In the I-125 Inventory file on the computer, sign the sources back in under seeds returned (including the loose ones).
- Complete the “Prostate Implant” sheet and also the wallet card. Print the wallet card, cut it out, and place inside a business card protector.
- Put it with the survey meter to be ready when recovery room calls for patient discharge.

- Complete the “Technical Charges for Permanent Seed Implant” form in the back of the patient’s chart for the Day of Procedure charges and enter into MOSAIQ.
- E-mail Mark Harder the seed and needle counts.
- Complete the treatment record and manually record a treatment on the treatment field in MOSAIQ.
- Scan the “Prostate Seed Brachytherapy Post Implant Written Directive Form” into MOSAIQ. Import it into the “Documents” section under the heading “Brachy Post WD”.
- Make sure all paper work is secured inside the treatment chart and is not loose if using a paper chart.
- Place the chart in the physics work area on the shelf over the Variseed treatment planning computer, to hold for the post-plan.

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GUIDELINES FOR POSTPLANS FOR PERMANENT SEED IMPLANTS

- The patient is scheduled for a CT about four weeks post implant.
- No prep is done.
- A foley catheter is inserted and contrast placed in the bladder.
- 3 mm slices are taken through the entire length of the prostate. We don't need many cuts as long as all the seeds are visible.
- A smaller window may be used.
- Send the images to the location Varisd. The Variseed computer in the physics work area must be connected to the network to receive the images.
- Check for images in DICOM Image file.
- Import images into patient's file under new study entitled "POSTPLAN"
- Insert correct source activity (from calibration data) for date of the implant and verify the correct Structure Set is used (Full dose or Boost).
- Identify seeds and check for redundancy.
- Contour the bladder, rectum and urethra.
- Notify the radiation oncologist that the plan is ready for PTV contouring.
- The radiation oncologist contours the prostate and approves the bladder, rectum and urethra volumes drawn by physics or dosimetry.
- Perform the calculations.
- Verify that the post implant V100 meets our Medical Event criteria. If it does not, notify the radiation oncologist immediately.

- Printing the Plan:
 - Print out the following reports to paper (while still using paper charts) or to MOSAIQ (for electronic charting):
 - Study Summary
 - Needle Loading
 - DVH
 - Therapy Visualization
 - 2D View
 - 3D View
 - Place the paper copy in the paper chart on the back of the first tab.
 - For printing to MOSAIQ:
 - ◆ Use the "doPDF v7" printer in the printer dialog.
 - ◆ When asked for a location to print to, select the "R: RadOncology" location.
 - ◆ In MOSAIQ, import the PDF into the "Documents" section under the heading "Brachy Plan".

- Second checks:

- Notify the radiation oncologist that the plan is ready for sign off in MOSAIQ or place the paper chart on his desk for his signature.

Completing Paperwork and Charging:

- Open up patient's workbook and fill out the Physics Consult report
- Complete items on the "Technical Charges for Permanent Seed Implants" form and enter the charges in MOSAIQ.

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Prostate Seed Brachytherapy Written Directive

Patient Name: _____

DOB: _____

MRN: _____

Treatment Site: Prostate

Isotope Used: I-125

Prescription: _____ Gy total decay

A Special Physics Consult is required.

A Special Treatment Procedure is required.

Provider Name PRINTED: _____

Provider Signature: _____

Date: _____ Time: _____



John T. Vucurevich Cancer Care Institute
 Department of Radiation Oncology
Brachytherapy Treatment Plan

Patient Name: {Patient.NameLFM}
 Date of Birth: {Admin.Birth_Date}
 Unit Number: {Ident.IDB}

Check-Off Cover For:

Radiation Oncologist and Physicist

Attending Physician: Dr. {Admin.Attending_MD_ID*PnP.NameFL}

Physician Review

The Following items have been reviewed on the attached computerized treatment plan and are consistent with the treatment directive:

Treatment Site: Click here to enter text.

V100: Click here to enter text.

Isotope: Click here to enter text.

Viso: Click here to enter text.

RX: Click here to enter text.

Rectum D2cc: Click here to enter text.

Dose Volume Histogram: Click here to enter text.
 (If applicable)

Urethra D2cc: Click here to enter text.

Electronically Signed by Physician:

Dr. {Object.Sanct_ID2*PnP.NameFL}, {Object.Sanct_ID2*PnP.Suffix} {Object.Sanct_Date2}; {Object.Sanct_Time2}

Physics Checks:

Treatment Site

Nuclide

Doses to Critical Structures

Rx Dose Pt / Iso %

Dose to Volume Histogram (If applicable)

***** Second Independent check performed by RadCalc *****

Planning Physicist: Choose an item.

Electronically Signed by Reviewing Physicist:

{Object.Sanct_ID*PnP.NameFL}, {Object.Sanct_ID*PnP.Suffix} {Object.Sanct_Date}; {Object.Sanct_Time}

Prostate Seed Brachytherapy Post Implant Written Directive Form

Patient Name: _____

DOB: _____

MRN: _____

The following form must be completed/reviewed for all brachytherapy procedures.

I. REDUNDANT PATIENT IDENTIFICATION

Patient Name (ask and record the patient's name):

Redundant patient verification (obtain and verify from the patient's chart at least one of the following):

1. Patient birth date:
2. Patient Social Security Number:
3. Patient Address:
4. Patient Signature:
5. Name on patient I.D. bracelet:
6. Face photo:

Signature of person performing redundant patient ID:

Date and time of verification:

II. POST-TREATMENT VERIFICATION

Administered Treatment:

Isotope: I-125

Treatment Site: Prostate

Total Dose:

Total Activity:

of Sources:

Treatment Time:

Physician Signature:

Date/time:

PSI TRAINING CHECKLIST

Employee Name: _____

Department / Division: _____ Position: _____

Training Completion Date: _____

Primary Preceptor(s)/Validator(s): _____

Directions for the Preceptor/Validator: Once the skills or information have been validated, complete the last 3 columns using the codes for Method of Validation noted in the table.

Directions for Orientee: Beginning with page two, place an "X" in the appropriate column (Competent, Needs Assistance, or No Previous Experience) to indicate your comfort level with each of the skills listed. The initial assessment at the beginning of orientation should be completed by the orientee.

Training Overview

Demonstration and Discussion	<input type="checkbox"/> D	<input type="checkbox"/> S	<input type="checkbox"/> W	<input type="checkbox"/> R	<input type="checkbox"/> I
Policy and Procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Written Directive	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Checklists	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Brachytherapy Dosimetry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Variseed Treatment Planning Computer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Discuss "Standard" Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Demonstrate "Standard" Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Review Trainee's "Standard" Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Discuss Trainee's "Standard" Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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PSI TRAINING CHECKLIST

	Needs		No Previous	D	S	W	R	I		
	Competent	Assistance	Experience							
Policy and Procedures										
Written Directive										
Checklists										
Brachytherapy Dosimetry										
Variseed Treatment Planning Computer										

Comments

Key: D = Demonstrate by Orienteer S = Discussion with Orienteer W = Written Testing R = Reviews audio/visual or written material I = Inservice