

Jason Spaans, PhD  
Physicist for Siouxland Urology Center  
Dakota Dunes, SD

March 2, 2016

Mark R. Shaffer  
Director US NRC, Region IV  
1600 East Lamar Blvd.  
Arlington, Texas 76011  
817-200-1456

RE: Response to an Apparent Violation in NRC Inspection Report 030-36922/2015-001;  
EA-15-251  
Docket No.: 030-36922  
License No.: 40-34223-01

Dear Mr. Shaffer:

This letter concerns the apparent violation identified during an unannounced inspection by the NRC on June 15, 2015, at the Siouxland Urology Center located in Dakota Dunes, South Dakota. During this inspection, it was determined that there was a failure to ensure that written directives were dated and signed by an Authorized User before the administration of therapeutic doses of radiation from byproduct material.

In order to address this apparent violation, the following steps were taken:

1. Sections B and E of the Quality Management Program Record Form (QMPRF) were revised.
  - a. QMPRF attached
2. The Prostate Seed Implant procedure was revised to ensure the written directive was signed before administration of therapeutic doses of radiation.
  - a. Prostate Seed Implant procedure attached.
3. Annual radiation safety training meeting was conducted (detailed in next paragraph).

The annual radiation safety meeting was held on February 23, 2016. This meeting was led by the physicist, Jason Spaans, PhD, and attended by nursing and technician personnel associated with the brachytherapy program. A review of general radiation safety procedures was conducted. A review of the responsibilities and tasks associated with the radioactive material was discussed. This included a step-by-step discussion of seed storage and handling, before and after the implant. A walk-through of the activities on implant days was conducted. During this time the protocols were discussed and revised. The revised protocols will be submitted to the Radiation Safety Board for approval. Correct operation of the Ludlum GM survey meter was demonstrated. Finally, the apparent violation was addressed, and it was explained that Section B on the QMPRF needs to be signed by the Authorized User before the implant.

The physicist will be responsible for ensuring that the Authorized User has signed part B of the QMPRF before administration of therapeutic doses of radiation. The implant will only be allowed to occur if compliance with the written directive requirements are fulfilled.

Compliance was achieved in July of 2015.

Best Regards,

Jason Spaans, PhD  
Medical Physicist  
605-366-7471

# Prostate Seed Implant at Dakota Dunes

---

## Scheduling

- XXXXXXXXX

## Lock Codes

- Radiation room door – [REDACTED]
- Radiation cabinet – [REDACTED]
- Equipment room – [REDACTED]

## Before Implant

### Independent Assay – in Envelope

- Confirm seed number and activity
- Number of seeds surveyed should be 10% of total
- Average seed strength from survey should be within 3% of expected
- Max. and min. seed strength from survey should be within 5% of expected
- Only need two sheets and stickers
- From independent analysis, record mean seed activity on planning sheet and PIMRCR

### Package with Seeds

- Bag with seeds
  - Confirm seed number, activity, isotope, and U
- Radiation stickers – in plastic bag
  - Keep 1 for nurses
  - Deface radiation symbol and patient name/ID of remaining stickers and dispose
- Make sure lead patient container is present

### Paperwork

- Confirm seed number, activity, patient name, and current date on all paperwork
- Obtain patient stickers and place on documents (x3)
  - Seed placement worksheet
  - Physics Consult sheet
- Populate QMPRF and give to nurse
  - Rx is from the Physics Consult sheet which is generated by the dosimeterist
    - Normal Rx is 12,500cGy
    - If boost, Rx is 10,000cGy
      - The total activity required on the planning sheet is then 75% of the dose from the nomogram
  - Nurse will return to Physics
- Make copy of consent form
- Have the RO sign the QMPRF (written directive)

### Surgical Room Preparation

- Place radioactive source sign on door
- Check radiation detectors (GM and NaI)
  - Check battery and check source output
  - Survey implant room

## **During Implant**

### **Seed Bag**

- Sterilely transfer seed container to nurse upon request
- Deface radiation symbol and patient name of seed bag and dispose

### **Determine number of needles and seeds per needle**

- Measurements from Rad. Onc.
  - Volume, circumference, and three longitudinal measurements of prostate
    - Confirm measurements on ultrasound printouts
- Use nomogram and volume measurement to determine activity needed (interpolate)
  - $A_p = A_L + (A_H - A_L)((V_p - V_L)/(V_H - V_L))$
- Determine number of seeds required in periphery (activity needed/seed activity\*0.75)
  - 75% of seeds in periphery and 25% in interior
    - In interior 10% of seeds in core
      - Example: if three seeds per needle then one seed will be in core, if four seeds then two will be in core
- Overall idea is to have the seeds 1 cm apart
- Want approximately as many needles as circumference measurement
  - Example: if circumference is 14.6 want 14 to 15 needles
  - Error on the side of too many needles
- Take average length of three longitudinal measurements, round and add one
  - Want number of seeds per needle to be approximately this number
  - Prefer 5 seeds per needle as Mick applicator handles 15 seeds at a time
- Interior
  - Number of needles = total number of seeds x 0.075
  - Number of seed per needle is almost always 3 to 4

### **Needle and Seed Insertion**

- Seed placement worksheet
  - Record number of needles and needle placement
  - Record number of extra seeds
  - Record seed placement
  - Confirm total number of seeds implanted with nurse

## **Post-Implant – Same Day**

### **Signatures**

- RO will sign QMPRF and PIMRCR

### **Survey Patient**

- With GM counter record reading in mR/hr (x10 w/o cap) at:
  - Surface
  - One meter
    - Palladium tolerance is 3 mR/hr at 1 meter
- When finished place GM counter in waiting room

### **Survey Room**

- With liquid scintillator detector (x1 w/ cap) look for any loose seeds in:
  - Mick applicator
  - Grid
  - Trash
  - Room in general

- Under tables
- US machine – BK medical

### **Post-Implant Documentation**

- Place Quality Management Program into binder
  - Do not need to copy
- Medical Physics Consultation Report
  - Make copy and place copy in binder
- Fill out Post Procedure Room Surveys and Seed Inventory and Tracking sheets
  - For Post Procedure Room Surveys, if needed record probe and survey meter used
- Copy both documents for independent assay (Theragenics)
  - Original goes in Physics office
- Document number of seed remaining in container (x2) and place container in radiation cabinet
- Place instruction to patient in front of room surveys
- Bring binder to waiting room
- Remove radioactive source sign
- Place NaI detector in equipment room

### **Implant Billing**

- xxxxxxxxx

### **Post Implant Plan Evaluation**

- Rectum <1.3 cc should get full dose
- Prostate D90>90
  - D90 – 120% of dose
- Urethra <150%

Siouxland Urology  
BRACHYTHERAPY  
QUALITY MANAGEMENT PROGRAM RECORD FORM

**Section A: Patient Data**

1. Patient: \_\_\_\_\_ 2. Address: \_\_\_\_\_  
3. Birthdate: \_\_\_\_\_ 4. ID#: \_\_\_\_\_  
5. SS#: \_\_\_\_\_ 6. Referring Physician: \_\_\_\_\_  
7. Diagnosis: Ca Prostate

**Section B: Written Directive by Authorized User (Licensed Physician)**

1. Written Directive: Prostate seed implant with Pd-103 I-125 (circle)  
2. Prescribed Dose: \_\_\_\_\_ cGy  
3. Route of Administration: Permanent Interstitial Implant with Mick applicator  
4. Authorized Physician Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Section C: Verification of activity by Physicist**

1. Verification of pharmaceutical: Yes No  
2. Verification of Activity: 3<sup>rd</sup> Party Activity Assay: # of Seeds \_\_\_\_\_ Within +- 5% \_\_\_\_\_  
3. Physicist Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Section D: Patient ID Verification by Staff**

1. Patient ID Verification

a. Must ask patient his/her name and confirm with written directive. (by OR Staff)  
b. Must confirm patient by comparison with corresponding information in patient's records.  
Check a minimum of one of the following:  
Birthdate Address SSN Name  
Name on Patient Medical Insurance Card  
Other, Specify: \_\_\_\_\_

2. Staff Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Section E: Review and Verification of Administered Dose**

1. Written Directive: Prostate seed implant with Pd-103 I-125 (circle)  
2. Administered Dose: \_\_\_\_\_ cGy  
3. Administered Activity: \_\_\_\_\_ # Seeds \_\_\_\_\_ mCi/seed \_\_\_\_\_ Total Activity  
3. Route of Administration: Permanent Interstitial Implant with Mick applicator  
4. No Exceptions Yes, Exceptions were made.  
Explanation: \_\_\_\_\_

2. Authorized Physician Signature: \_\_\_\_\_ Date: \_\_\_\_\_