Siouxland Urology Associates P.C.

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March 8, 2016

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

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 is 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 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. Enclosed are copies of our policy and forms.

Compliance was achieved in July of 2015.
Best Regards,

Greg Haar
Administrator

455 Sioux Point Road · Dakota Dunes, SD 57049 · Phone: (605) 217-7000 · Fax: (605) 217-7015

Prostate Seed Implant at Siouxland Urology Center, Dakota Dunes, SD

July 2015

Ordering of Seeds

- The dosimetrist will populate section A of the QMPRF
- Authorized User (physician) will sign and date section B of the QMPRF
- Dosimetrist will order seeds based off of parameters determined by the volume study and the written directive

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
- Physicist will sign and date Section C of the QMPRF
- 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
    - QMPRF
- Nurse or staff will populate, sign, and date Section D of the QMPRF
    - Nurse will return to Physics
- Make copy of consent form

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

- Rx note:
  - 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
- Measurements from Authorized Physician
  - 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

- Authorized User (physician) will sign and date Section E of the QMPRF and the 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

Post Implant Plan Evaluation

- CT will be done approximately one month after implant
- Rectum <1.3 cc should get full dose
- Prostate D90>90
    - D90 – 120% of dose
- Urethera <150%
- Authorized User (physician) will sign off on treatment plan summary in electronic medical record

Siouxland Urology Center
BRACHYTHERAPY
QUALITY MANAGEMENT PROGRAM RECORD FORM

Section A: Patient Data

1. Patient: _____ 2. Birthdate: _____
3. JENCC ID#: _____ 4. Referring Physician: Dr. Naden
5. 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 User (physician) Signature: _____ Date: _____

Section C: Verification of activity by Physicist

1. Verification of pharmaceutical: ___ Yes ___ No
2. Verification of Activity: ___3rd 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
4. Route of Administration: Permanent Interstitial Implant with Mick applicator
5. ___ No Exceptions ___ Yes, Exceptions were made.
Explanation: _____

6. Authorized User (physician) Signature:_____ Date:_____