Community Comprehensive Cancer Center
CamdenClark
MEDICAL CENTER
MEMORIAL CAMPUS

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December 11, 2012

Tara Weidner
Health Physicist
Nuclear Regulatory Commission Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

Licensee: Camden-Clark Memorial Hospital Corporation (1)
License No.: 47-09772-02

Dear Ms. Weidner:

This response is to your email dated 11/27/2012 and subsequent phone call 12/03/12. In that call you requested we notify the NRC operation center and amend the Medical Event report (EN 47719). This was done on 12/3/12. The responses to your questions of 12/03/12 are listed below:

1. With regard to hot lab security, the Director of Radiology verbally counseled the Nuclear Medicine staff and followed with a written mandate.
2. Enclosed you will find the modified procedure for testing the HDR timer linearity. As you can see the procedure is extended out to 90 seconds.
3. The post implant surveys will be performed and documented according to the Prostate Brachytherapy procedure (F.1)(attached)
4. The Prostate Brachytherapy procedure (attached) added a new section (G. 1-7) which focuses on reviewing the post implant dosimetry to ensure it is in compliance with the original treatment parameters.
5. The Prostate Brachytherapy procedure (attached) added a new section (G. 8) which addresses the notification of the USNRC.

We hope this letter and subsequent attachments address the commission's concerns. If you have any questions or concerns, please contact our Radiation Safety Officer, Mr. Berkley at (724)4542371.

Sincerely,

David K. McClure

David McClure
Vice President, Operations
Camden Clark Medical Center

CamdenClark
MEDICAL CENTER

TITLE:	HDR Quarterly QA
DEPARTMENT:	Cancer Management
EFFECTIVE DATE:	12/6/2012

SCOPE: Camden Clark Medical Center

PURPOSE: To establish an HDR (High Dose Rate) quarterly quality assurance procedure.

POLICY: HDR QUARTERLY QA

PROCEDURE:

1. Activity of the Iridium 192 source must be verified with HDR 1000+ or equivalent chamber. Activity must be verified to be within 5% of manufacture's source certificate.

2. Timer linearity must be verified. Dwell times must cover the full capability of the HDR unit up to 90 seconds or longest clinical dwell time.

REFERENCES:

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TITLE:	Prostate Brachytherapy Procedure
DEPARTMENT:	Cancer Management
EFFECTIVE DATE:	12/6/12

SCOPE:	Camden Clark Medical Center

PURPOSE: To provide guidelines for prostate brachytherapy which include scheduling and steps taken before, during, and after the procedure to include education, safety, and coordination with other physicians and hospital departments.

PROCEDURE:

A. Prior to Scheduling Prostate Brachytherapy

1. The nurse receives order from Radiation Oncologist to schedule patient for procedure after Volume Study has been completed and data reviewed by Radiation Oncologist.

2. Radiation Oncology Nurse will ensure patient receives Prostate Brachytherapy Information Booklet and Pre-operative Instruction Sheet (see attached)

   Radiation Oncology Nurse will inquire when Radiation Oncologist prefers to schedule case, which urologist will be assisting him, and type of anesthesia preferred.

   Radiation Oncology Nurse will notify Radiation Oncology Coordinator via the flow sheet.

B. Scheduling Responsibilities

1. Radiation Oncology Nurse will notify urologist's office. Once the urologist's preferred date and time of surgery is established, the nurse will notify the Radiation Oncology Coordinator to schedule with surgery and admitting.

   If urologist is unavailable to perform procedure, the Radiation Oncologist and Radiation Physicist will be notified as soon as possible.

   Radiation Oncology Coordinator will notify appropriate staff via computer.

2. Radiation Oncology Coordinator will send the flow sheet information to the Dosimetrist to hold until completion of procedure.

   Radiation Oncology Coordinator will bill the radioactive seeds and write in amount billed on flow sheet upon completion of the brachytherapy procedure.

   Radiation Oncology Coordinator will file the completed flow sheet.

C. Patient Education

1. Radiation Oncology Nurse will send/give patient pre-op instruction information sheet, and prostate brachytherapy information booklet and verify patient has received and read information by contacting patient via telephone with documentation in nurses notes.

2. Per the instruction of the radiation oncology nurse, the unit clerk will schedule a follow up appointment for the patient two days prior to the scheduled procedure for radiation safety/discharge instructions and to ensure patient complies with surgical prep (clear liquids 18 hours prior and Fleets prep kit on hand to use - see form).

D. Radiation Safety Precautions

1. Radiation Safety Officer will ensure on day of procedure radiation safety policies are complied with during the implant, in recovery room, SDC area, and on patient release. (See attached written policies for specific information)

E. Surgical Procedure

1. Radiation Oncology Nurse will assist Dosimetrist with instrument preparation for surgical case by sending to CSR Department all instruments needed for implant. In most cases, all instruments need to be sent to Central Supply 24 to 48 hours prior to each case and sent with the form "Radiation Oncology Instrument List."

2. During surgical procedure, the Medical Dosimetrist is present to assist Physicist and Radiation Oncologist as dosimetry map reader.

   a. Medical Dosimetrist uses "Prostate Seed Loading Pattern" for documenting total seeds used and seed activity at end of case.

   b. Template coordinates for placing needles are read top line to bottom line and read left to right.

   c. Call out alphabet letter, followed by numerical number. (Example: Baker Four and Charlie Six, etc.)

   d. Base number is given by physician at beginning of map reading (note: this can change during procedure). Base is 0.0 in the "retraction cm" column.

   e. One click is equivalent to 0.5 from base. (Example: One click is 0.5; Two clicks is 1.0; Three clicks is 1.5)

   f. Base beneath cradle has a line that coordinates with the 5mm increments on cradle.

      Example: Reader calls out to Radiation Oncologist, Charlie, three, four seeds, one click back. Oncologist then pulls loaded needle from seed box and hands loaded needle, keeping in horizontal position, to Urologist. Reader repeats, Charlie, three, four seeds, one click back. Urologist then inserts needle through template into perineum. The two physicians then agree on proper needle placement. Oncologist then unloads seeds into the prostate.

   g. Urologist will perform cystoscopy to look for and retrieve any loose seeds that may be in the bladder.

TITLE:	Prostate Brachytherapy Procedure
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F. Post-Operative

1. The Radiation Safety Officer will monitor all implant activities in the Operating Room and survey with a Geiger counter all patient and procedure related items before they are disposed of or removed from the suite, such as: bedding, catheters, and urine.

2. The Radiation Safety Officer will use a Geiger counter to measure and document the amount of radiation emitting from patient. Measurements should not exceed the following, as per NRC Guide 8.39:

   I-125 at 1 Meter = 1mrem/hr
   Pd-103 at 1 Meter = 3mrem/hr

3. Prostate seed implant patients will be transferred to the PACU after being cleared by the Radiation Safety Officer to leave the Operating Room. The Radiation Safety Officer is responsible for radiation safety and precautions education for PACU staff, patients, and patient family members/caregivers.

4. When patient is released or transferred from PACU, all urine, catheters, and bedding associated with the patient must be cleared by the Radiation Safety Officer before disposal.

5. A radiation sticker will be placed on the front of the patient's chart and on the door of the patient's room for the remainder of the patient's stay. Recommendations for persons near a patient with radioactive implants will be clearly explained to patient and family.

6. Once discharge is ordered by the admitting physician and the patient leaves the facility, all garbage, linen, bedding, and furniture must be Surveyed by the Radiation Safety Officer with Geiger counter and found to be free of radiation before the room can be released for housekeeping.

7. Before the patient is released, a discharge instruction information sheet will be provided by the nurse, under the direction of the admitting physician.

G. Post implant CT scan

1. The patient will be scheduled for a 25 slice CT scan of the prostate approximately 30 days after the implant.

2. Physics staff will import the CT images into the treatment planning computer. Physics staff will also input the activity and source type and identify all sources on the CT.

3. The Radiation Oncologist will identify and outline all relevant structures on CT (prostate, rectum, bladder, etc). The post plan, source locations, and DVH will be printed by physics staff for review and approval by the physician.

4. The senior physicist and the attending physician will sign off on the post plan.

5. The attending physician will determine if the implant meets minimum standards. If implant quality is inadequate, the attending physician will determine if additional treatment is required.

6. A second, independent, radiation oncologist will also review the post plan.

7. The post plan must be finalized within 30 days of post implant CT.

8. If it is determined that a medical event (as defined by the USNRC) has taken place, the Radiation Safety Officer will be notified immediately and the medical event will be filed in accordance with the USNRC reporting process within 24 hours of discovery.

REFERENCES:

CROSS REFERENCES:

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