



February 15, 2012

Tara Weidner
Health Physicist
Nuclear Regulatory Commission Region 1
475 Allendale Road
King of Prussia, PA 19406

RECEIVED
REGION 1
2012 FEB 16 AM 10:43

Dear Tara,

The following are replies to your inquiries as requested in an email sent to Daniel Berkley, Joshua Hayes and David McClure on February 3, 2012 in regards to the NRC Inspection for Camden Clark Medical Center. 47-09772-02; 030-03390

For HDR:

Typical dwell times range from 0.1s to a maximum of 90s.

LDR Prostate Implants

A) See attached. Quality Assurance in Brachytherapy.

B) The first steps are to ensure the proper nuclide was ordered. This is done via the vendor's source certificate and third party verification. Typically, preloaded needles are ordered and verified via autoradiograph. Implant is carried out by radiation oncologist and urologist. Patient returns (typically) to urologist for 30 day CT which is imported into Variseed software. The following questions must be answered.

- a. Can at least 90% of the seeds be accounted for?
- b. Does the target site receive at least 80% of dose? Doctor may consult on this as cancer may only be located in certain lobes of the prostate. Can variances be accounted for via seed drift?

Rec'd for processing
04/08/13

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RE: NRC Inspection for Camden Clark Medical Center

C) See attached packets, sorted by patient for i, ii, iii and iv

v)

Patient	Planned	Implanted*	Ratio
1	79	74	93.67%
2	58	58	100.00%
3	57	51	89.47%
4	57	55	96.49%
5	63	63	100.00%

*found on post plan.

Please contact us if further information or clarification is necessary.

Thank you.

Sincerely,



David K. McClure, FACHE
Vice President, Operations
Camden Clark Medical Center
Parkersburg, WV 26102

DKMc/jfe
Enclosures

CAMDEN-CLARK MEMORIAL HOSPITAL
COMMUNITY COMPREHENSIVE CANCER CENTER GUIDELINE

TITLE: Quality Assurance in Brachytherapy

WRITTEN BY: Venkat Kanumalla, Ph.D.

EFFECTIVE DATE: 7/1/97

PURPOSE: To provide quality assurance guidelines in the performance of brachytherapy procedure.

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GUIDELINES:

1. Brachytherapy procedures will be performed only after a Written Directive is completed by the supervising Radiation Oncologist. The completion of the Written Directive will be verified by the Radiological Physicist and/or a Medical Dosimetrist.
2. Implant instruments to be used in a brachytherapy procedure (e.g., tandems/colpostats) will be checked for structural integrity using established department procedure(s).
3. Informed consent will be obtained from the patient, or an individual legally empowered to do so, prior to all brachytherapy procedures.
4. Radioactive materials to be used in a brachytherapy procedure will be calibrated prior to the procedure to ensure the activity to be within plus/minus 5% of the prescribed activity. Radioactive materials that are special ordered from a manufacturer/supplier must be confirmed to be within plus/minus 5% of the activity ordered.
5. All dosimetry/computerized brachytherapy treatment planning will be reviewed and verified by the Radiological Physicist and/or Dosimetrist prior to the patient receiving 50% of the prescribed radiation dose.
6. A brachytherapy source inventory will be maintained for all radioactive materials used in brachytherapy. This inventory will be routinely verified/confirmed once each month and updated immediately before and after each brachytherapy procedure.
7. A radiation safety survey will be performed and documented on the appropriate form following all brachytherapy procedures in order to ensure that exposure levels do not exceed 2 mR/hr in all non-controlled areas.
8. Proper radiation safety (warning) signs will be posted on the front of the patient's hospital chart and on the patient's hospital room door.
9. Proper nursing instructions will be delivered to the nurse manager or his/her designee for signature. The Nursing Instruction Sheet will be placed and maintained as the first (1st) sheet on the patient's hospital

chart. A copy of the Nursing Instruction Sheet will be made for Department files.

10. A discrepancy of plus/minus 20% in the radiation dose delivered will be treated as a misadministration. Appropriate action will be taken to document and report such misadministrations. Appropriate follow-up action will be taken to correct and prevent future incidents, as per NRC 10-1-35.33.
11. A radiation safety survey of the patient and the patient's room/bathroom is mandatory following radioactive source removal and/or discharge from the hospital.
11. Staff education regarding brachytherapy procedures and related radiation safety issues will be conducted by the Radiation Safety Officer on an annual basis.

Formulated: 8/96
Reviewed: 7/1/97, 8/99, 9/02, 8/05, 2/11
Revised: 9/97, 3/10

CAMDEN - CLARK MEMORIAL HOSPITAL RADIATION ONCOLOGY DEPARTMENT

Prostate Implants: Q.A.

Patient : _____ I.D # _____ M.D: CS / SV Implant Date : _____
 Gleason Score : _____ Volume : _____ Stage : _____
 Implant type : Primary / Boost
 Isotope : I-125 / Pd-103 Dose(in cGy) : 14400 / 12500 10800 / 10000 .

1. Patient Identification verified by TWO methods : _____
2. M.D's authorization to order seeds(written directives) verified : _____
3. # of seeds ordered : _____ on : _____ & # Received : _____ on : _____
4. Inventory / LOG of Radio-Isotopes updated : _____
5. Seeds' Activity verified in Dose Calibrator : _____ Second check done : _____
6. # of needles needed & / Available for this Implant : _____
7. Spacers and bonewax availability checked : _____
8. Availability of atleast 5 lead aprons at O.R. checked : _____
9. Volume study done on : _____, preplan done on : _____
10. Seeds loading as per Dose Distribution Plan checked : _____
11. **SPECIAL NEEDLES loading written on operating room report** : _____
12. Needle placement in the Hot Box as per plan : _____
13. Needle placement in the Hot Box reconfirmed : _____
14. Needle placement in the Template read as per plan : _____
15. Needle placement in the Template verified : _____
16. Planned # of seeds for implant : _____
17. Actual # of seeds implanted : _____
18. # of seeds flushed / recovered : _____
19. Final # of seeds implanted in the patient's prostate : _____
20. Recovered # of seeds brought back by patient : _____
21. Total # of seeds stored for decay/return : _____
22. Surveymeter Model : _____ Serial # : _____ Calibrated on : _____
23. Post op survey done on : _____ by : _____ Exposure at 1m : _____ mR/hr.
24. Radiation safety label kept on the in-patient chart : _____
25. Written discharge instructions given to patient : _____
26. Isotope Inventory / LOG sheet updated : _____ Date : _____
27. Leftover seeds returned to Amersham/Theragenics or stored for decay on : _____
28. Post implant CT done on : _____
29. Post implant dose distribution plan done on : _____
30. M.D signed pre & post implant dose distribution plans : _____

Dosimetrist / Physicist

Physicist / R.S.O.