

3/05/2012

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

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

Dear Ms Weidner,

This response is to your phone call dated 3/2/2012. In that call you requested we notify the NRC of a medical event on patient #5 of the requested material dated 2/3/2012. To this end we are notifying the NRC of a medical event related to patient number five. The authorized user was Gabor Altdorfer, M.D. (2) involved with this case. (3) In patient number five we assume we are reporting the fact that the prescribed isodose line is arguably in violation of 35.3045(a)(1)(i). However, the licensee feels that the patient was given a prescribed course of treatment that is not a medical event for the following reasons:

1. 75% of the drawn prostate volumes on the thirty day follow-up scan did receive a dose in excess of reportable events.
2. The area which contained tumor was covered by the 100% prescribed isodose line.
3. The patients PSA dropped as expected from an adequate treatment from 7.7 ng/ml to 1.76 ng/ml.
4. The isotopes were delivered by the appropriately credentialed physicians both Radiation Oncologist and Urologist.
5. The preplans in the OR were planned and delivered appropriately including, but not limited to the source, activity per seed, location of the source on ultrasound images and total number of seeds.
6. Preplanned images covered the prostate volumes with prescribed dosages.
7. Stranded seeds were used to minimize migration of the sources.

(4) The event occurred because seeds can migrate inside the patient during the implant process and after the procedure. The needles which contained the seeds were loaded according to the treatment plan which is the written directive. The needle positions were located by ultrasound guidance. After a certain amount of needles are in place the prostate gland can swell and move the position of the seeds. As the swelling goes down,

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seeds can change position although the stranded seeds can minimize this. It is possible the needle depths could have changed as the gland changed size. More seeds or higher initial volume coverage could make the 80% volume bigger thus making the implant fall less into the gray area.

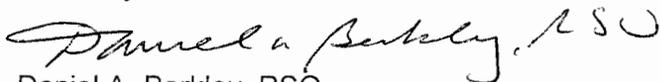
(5) The effect on the patient has been minimal as the desired response was achieved. The long term effect will be under constant follow-up.

(6) The entire implant process will be reviewed with special attention to real time seed placement and subsequent thirty day image evaluation with respect to NRC regulatory guidelines.

(7) Dr Altdorfer, based on medical judgment, felt that notifying the patient would be harmful. The patient is under the care of oncologic physicians and will be followed appropriately as per his disease type.

(g2) A copy of this letter will be sent to the referring physician.

Sincerely,



Daniel A. Berkley, RSO
Camden Clark Medical Center
800 Garfield Ave.
PO Box 718
Parkersburg, WV 26102